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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.

2. The relationship between the Federal Register and Code of Federal Regulations.

3. The important elements of typical Federal Register documents.

4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, September 11, 2007
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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To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

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[Docket No. 070809455–7478–01]

RIN 0694–AE12

Updated Statements of Legal Authority for the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule updates the Code of Federal Regulations legal authority citations for the Export Administration Regulations (EAR) to include the citation to the President's Notice of August 15, 2007—Continuation of Emergency Regarding Export Control Regulations.

DATES: This rule is effective September 5, 2007.

ADDRESSES: Comments concerning this rule should be sent to *publiccomments@bis.doc.gov,* fax (202) 482–3355, or to Regulatory Policy Division, Bureau of Industry and Security, Room H2705, U.S. Department of Commerce, Washington, DC 20230. Please refer to regulatory identification number (RIN) 0694–AE12 in all comments, and in the subject line of e-mail comments.

FOR FURTHER INFORMATION CONTACT: William Arvin, Regulatory Policy Division, Bureau of Industry and Security, Telephone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Background

Since the expiration of the Export Administration Act on August 20, 2001, the EAR have been continued in force pursuant to Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002) and the annual notices declaring the continuation of the international emergency noted in that Executive Order. This rule revises the citations of authority in the Code of Federal Regulations for all parts of the EAR to reflect the legal authorities in effect as a result to the President's notice of August 15, 2007—Continuation of Emergency Regarding Export Control Regulations (72 FR 46137, August 16, 2007).

Rulemaking Requirements

1. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule does not involve any collection of information.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. The Department finds that there is good cause under 5 U.S.C. 553(b)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment because they are unnecessary. This rule only updates legal authority citations. This rule does not alter any right, obligation or prohibition that applies to any person under the EAR. Because these revisions are not substantive changes, it is unnecessary to provide notice and opportunity for public comment. In addition, the 30-day delay in effectiveness required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule.

List of Subjects

15 CFR Part 730

Administrative practice and procedure, Advisory committees, Exports, Reporting and recordkeeping requirements, Strategic and critical materials.

15 CFR Parts 732, 740, 748, 750, 752 and 758

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 734

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15 CFR Part 744

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Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements.

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15 CFR Part 747

Administrative practice and procedure, Exports, Foreign trade, Reporting and recordkeeping requirements.

15 CFR Part 754

Agricultural commodities, Exports, Forests and forest products, Horses, Petroleum, Reporting and recordkeeping requirements.

15 CFR Part 756

Administrative practice and procedure, Exports, Penalties.

15 CFR Part 760

Boycotts, Exports, Reporting and recordkeeping requirements.

15 CFR Part 762

Administrative practice and procedure, Business and industry, Confidential business information,

Exports, Reporting and recordkeeping requirements.

15 CFR Part 764

Administrative practice and procedure, Exports, Law Enforcement, Penalties.

15 CFR Part 766

Administrative practice and procedure, Confidential business information, Exports, Law enforcement, Penalties.

15 CFR Part 768

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements, Science and technology.

■ Accordingly, parts 730, 732, 734, 736, 738, 740, 742, 743, 744, 745, 746, 747, 748, 750, 752, 754, 756, 758, 760, 762, 764, 766, 768, 770, 772 and 774 of the EAR (15 CFR parts 700–799) are amended as follows:

PART 730—[AMENDED]

■ 1. The authority citation for 15 CFR part 730 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note, Pub. L. 108–175; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p. 133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p. 256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 179; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 12981, 60 FR 62981, 3 CFR, 1995 Comp., p. 419; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp. p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; E.O. 13338, 69 FR 26751, May 13, 2004; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of October 27, 2006, 71 FR 64109 (October 31, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 732—[AMENDED]

■ 2. The authority citation for 15 CFR part 732 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 734—[AMENDED]

■ 3. The authority citation for 15 CFR part 734 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp. p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of October 27, 2006, 71 FR 64109 (October 31, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 736—[AMENDED]

■ 4. The authority citation for 15 CFR part 736 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 2151 (note), Pub. L. 108–175; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp. p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, May 13, 2004; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of October 27, 2006, 71 FR 64109 (October 31, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 738—[AMENDED]

■ 5. The authority citation for 15 CFR part 738 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 740—[AMENDED]

■ 6. The authority citation for 15 CFR part 740 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; Sec. 901–911, Pub. L. 106–387; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 742—[AMENDED]

■ 7. The authority citation for 15 CFR part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of October 27, 2006, 71 FR 64109 (October 31, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 743—[AMENDED]

■ 8. The authority citation for 15 CFR part 743 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. 106–508; 50 U.S.C. 1701 *et seq.*; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 744—[AMENDED]

■ 9. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of October 27, 2006, 71 FR 64109 (October 31, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 745—[AMENDED]

■ 10. The authority citation for 15 CFR part 745 is revised to read as follows:

Authority: 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of October 27, 2006, 71 FR 64109 (October 31, 2006).

PART 746—[AMENDED]

■ 11. The authority citation for 15 CFR part 746 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 287c; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; 22 U.S.C. 6004; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Presidential Determination 2007–7 of

December 7, 2006, 72 FR 1899 (January 16, 2007); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 747—[AMENDED]

■ 12. The authority citation for 15 CFR part 747 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 748—[AMENDED]

■ 13. The authority citation for 15 CFR part 748 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 750—[AMENDED]

■ 14. The authority citation for 15 CFR part 750 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 752—[AMENDED]

■ 15. The authority citation for 15 CFR part 752 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp. p. 219; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 754—[AMENDED]

■ 16. The authority citation for 15 CFR part 754 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 30 U.S.C. 185(s), 185(u); 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 756—[AMENDED]

■ 17. The authority citation for 15 CFR part 756 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 758—[AMENDED]

■ 18. The authority citation for 15 CFR part 758 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 760—[AMENDED]

■ 19. The authority citation for 15 CFR part 760 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 762—[AMENDED]

■ 20. The authority citation for 15 CFR part 762 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 764—[AMENDED]

■ 21. The authority citation for 15 CFR part 764 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 766—[AMENDED]

■ 22. The authority citation for 15 CFR part 766 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 768—[AMENDED]

■ 23. The authority citation for 15 CFR part 768 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 770—[AMENDED]

■ 24. The authority citation for 15 CFR part 770 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 772—[AMENDED]

■ 25. The authority citation for 15 CFR part 772 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

PART 774—[AMENDED]

■ 26. The authority citation for 15 CFR part 774 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*, 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of August 15, 2007, 72 FR 46137 (August 16, 2007).

Dated: August 29, 2007.

Christopher A. Padilla,

Assistant Secretary for Export Administration.

[FR Doc. E7–17532 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–33–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 416

[Docket No. SSA–2006–0103]

RIN 0960–AF99

Technical Updates to Applicability of the Supplemental Security Income (SSI) Reduced Benefit Rate for Individuals Residing in Medical Treatment Facilities

AGENCY: Social Security Administration (SSA).

ACTION: Final rules.

SUMMARY: We are revising our regulations to reflect two provisions of

the Balanced Budget Act of 1997 that affect the payment of benefits under title XVI of the Social Security Act (the Act). One of the provisions extended temporary institutionalization benefits to children receiving SSI benefits who enter private medical treatment facilities and who otherwise would be ineligible for temporary institutionalization benefits because of private insurance coverage. The other provision replaced obsolete terminology in the Act that referred to particular kinds of medical facilities and substituted a broader, more descriptive term.

DATES: These final rules are effective October 5, 2007.

FOR FURTHER INFORMATION CONTACT: Curt Dobbs, Social Insurance Specialist, Office of Income Security Programs, Social Security Administration, 252 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–7963, for information about this notice. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at *http://www.socialsecurity.gov*.

SUPPLEMENTARY INFORMATION:

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at *http://www.gpoaccess.gov/fr/index.html*.

Background

The basic purpose of the SSI program is to ensure a minimum level of income to individuals who are age 65 or older, or blind or disabled, and who have limited income and resources. The Balanced Budget Act of 1997 (Pub. L. 105–33), enacted August 5, 1997, contained two provisions that affected the payment of SSI benefits to certain SSI beneficiaries who are institutionalized. One of the provisions extended temporary institutionalization benefits to children who enter private medical treatment facilities and who otherwise would be subject to a reduced benefit because of private insurance coverage. The other provision removed obsolete terminology in the Act that referred to particular categories of inpatient medical facilities and substituted the broader, more descriptive term ''medical treatment facility.'' This change in terminology permits us to correct an unintended inequity in the amount of SSI benefits that were payable to certain children under the obsolete terminology.

Extending Temporary Institutionalization Benefits to Children Under Age 18 in Private Institutions

Residents of public institutions generally are ineligible to receive SSI payments. However, there are some exceptions to this general rule. One exception in section 1611(e)(1)(B) of the Act provides that residents of medical treatment facilities (which we define as a facility licensed or otherwise approved by a Federal, State, or local government to provide inpatient medical care and services) may be eligible for SSI if Medicaid pays a substantial part (more than 50 percent) of the cost of the beneficiary's care. In such cases, SSI payments to the resident of the medical treatment facility are limited to a maximum of $30 a month.

Another exception in section 1611(e)(1)(G) of the Act allows payment of full SSI benefits for up to 3 full months after entering a public facility if a physician certifies that the recipient's stay in the facility is likely not to exceed 3 months and we determine the recipient needs to continue to maintain and provide for the expenses of the home to which he or she may return. These benefits are referred to as ''temporary institutionalization benefits.''

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. 104–193), enacted August 22, 1996, amended section 1611(e)(1)(B) of the Act to allow children under age 18 who are in medical treatment facilities and who have private health insurance to receive the reduced SSI payment ($30). However, Public Law 104–193 did not amend the statutory provision on temporary institutionalization to extend such benefits to children with private health insurance. Consequently, children who were temporarily in private medical facilities could not be eligible for 3 months of full benefits if private health insurance, or a combination of Medicaid and private health insurance, paid more than 50 percent of the cost of their care. Payments to these children were limited to the reduced benefit amount of no more than $30 a month beginning with their first full month of institutionalization.

Section 5522(c) of Public Law 105–33 revised section 1611(e)(1)(G) of the Act to correct this omission. Prior to this revision, section 1611(e)(1)(G) specified that the recipient must be an inmate of either a public institution whose primary purpose is to provide medical or psychiatric care, or a hospital, extended care facility, nursing home, or intermediate care facility that receives payments under a State plan approved under title XIX. As a result of Public Law 105–33, and subject to SSI eligibility and benefit computation rules, those children in private medical facilities for whom private health insurance, or a combination of Medicaid and private health insurance was paying more than 50 percent of the cost of care, now can be eligible for continuation of their full SSI benefits for up to 3 months under section 1611(e)(1)(G) of the Act. For example, when a child who is receiving SSI while living at home goes into a medical treatment facility, and private insurance through the parent's employment pays for more than 50 percent of the cost of care, the child can continue to receive SSI benefits during a temporary institutionalization of up to 3 months. Providing SSI benefits during a temporary period of institutionalization is designed to enable SSI beneficiaries (adult or child) to provide for the expenses of the home where they live and to reduce the risk of losing their place of residence due to a sudden loss of SSI benefits during a temporary period of institutionalization.

Revised Terminology for Inpatient Providers

Section 5522(c) of Public Law 105–33 also replaced outdated terminology in section 1611(e)(1)(B) the Act. Prior to this statutory change, section 1611(e)(1)(B) specified certain categories of inpatient providers used in the Medicaid program. In the early years of the SSI program, the terminology ''hospital, extended care facility, nursing home, or intermediate care facility'' provided a comprehensive list of all possible inpatient settings as defined by the Medicaid program. However, as Medicaid dropped or renamed some of those coverage categories and added new categories, the list in section 1611(e)(1)(B) became obsolete and was no longer used. As a result, prior to Public Law 105–33, children in certain kinds of inpatient facilities were subject to the reduced benefit amount of no more than $30, while children in other kinds of Medicaid covered inpatient facilities could receive the full SSI benefit. For example, Medicaid created the new coverage category of Psychiatric Residential Treatment Facility (PRTF) for individuals under age 21. PRTFs can receive substantial Medicaid payments, including the room and board payment. Before Public Law 105–33 made this technical amendment, children residing in a PRTF received full SSI benefits because that kind of facility was not listed in section 1611(e)(1)(B) as a facility whose residents would be

subject to the $30 payment limit. For many PRTF residents, Medicaid was paying all of their expenses, and yet Public Law 104–193 required payment of the full SSI benefit rate. This situation created an inequity between those children and children in other kinds of Medicaid covered inpatient facilities. This change in terminology now allows for similarly situated children (i.e., children residing in medical treatment facilities where Medicaid is providing for more than 50 percent of the cost of their care) to be paid the same amount of SSI benefits.

Explanation of Changes

We are making the following changes to our rules to codify provisions of Public Law 105–33 that affect the payment of benefits under title XVI of the Act to individuals who are in institutions:

- We are revising § 416.212(b)(1) by adding ''or private'' to the introductory text to reflect the provision that gives full temporary institutionalization benefits to children who enter private medical treatment facilities when Medicaid pays more than 50 percent of the cost of their care.
- We are revising §§ 416.201 and 416.414(c) to remove the definition for ''medical care facility'' and replace it with a new definition for ''medical treatment facility.''
- We are amending §§ 416.201, 416.211(b) and (c)(5)(iv), 416.414(a), (b)(2) and (3)(i)–(ii), 416.571, 416.1149(a)(1) and (c)(1)(i)–(ii), 416.1165(g)(6) and (i)(1), 416.1167(a)(2), and 416.1202(b)(2)(i) by eliminating the obsolete terms ''medical facility'' and ''medical care facility'' and replacing them with the term ''medical treatment facility.''
- We are amending § 416.708(k) by eliminating the terms ''hospital,'' ''skilled nursing facility,'' and ''intermediate care facility'' and replacing them with the term ''medical treatment facility.''

On March 26, 2007, we published proposed rules in the **Federal Register** at 72 FR 14053 and provided a 60-day comment period. We did not receive any comments. Therefore, we are publishing the text of the proposed rules unchanged in these final rules.

Regulatory Procedures

Executive Order 12866

The Office of Management and Budget (OMB) determined that the proposed rules on which these final rules are based, published on March 26, 2007 at 72 FR 14053, met the criteria for a significant regulatory action under Executive Order 12866, as amended. Therefore, they were subject to OMB review. We received no public comments on the proposed rules and are publishing these final rules exactly as proposed. For this reason, OMB determined that it did not need to review the final rules. We have also determined that these final rules meet the plain language requirement of Executive Order 12866, as amended.

Regulatory Flexibility Act

We certify that these final rules will not have a significant economic impact on a substantial number of small entities as they affect individuals only. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

In order to codify two provisions of the Balanced Budget Act of 1997, we are revising our regulations that affect the payment of benefits under title XVI of the Act. One of the provisions extended temporary institutionalization benefits to children who enter private medical treatment facilities and who otherwise would be subject to a reduced benefit because of private insurance coverage. The other provision replaced obsolete terminology in the Act that referred to particular kinds of medical facilities and substituted a broader, more descriptive term.

As a result, we are amending the terminology in § 416.708 (k) by eliminating the terms ''hospital,'' ''skilled nursing facility,'' and ''intermediate care facility'' and replacing them with the term ''medical treatment facility.'' As outlined below, this section contains specific public reporting requirements that require clearance under the Paperwork Reduction Act of 1995. Respondents to this collection are SSI recipients who are admitted to, or discharged from, a medical treatment facility or other public or private institution.

Title/section & collection description	Annual number of respondents	Frequency of response	Average burden per response (minutes)	Estimated annual burden (hours)
What you must report § 416.708(k) Admission to or discharge from: (1) A medical treatment facility (2) A public institution, or (3) A private institution.	34,200	1	7	3,990

In the publication of the proposed rules on March 26, 2007, we solicited comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. We received no public comments in response to this solicitation.

On April 4, 2007, OMB filed comment in accordance with 5 CFR 1320.11(c), requiring us to review public comments in response to the proposed rules and address any such comments in the preamble of the final rules. As a result, we have submitted a new clearance package for OMB review and approval.

These information collection requirements will not become effective until approved by OMB. When OMB has approved these information collection requirements, we will publish a notice in the **Federal Register**.

To receive a copy of the OMB clearance package, you may call the SSA Reports Clearance Officer on 410–965–0454.

(Catalog of Federal Domestic Assistance Program No. 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Dated: August 28, 2007.

Michael J. Astrue,

Commissioner of Social Security.

■ For the reasons set out in the preamble, we are amending subparts B, D, E, G, K, and L of part 416 of chapter III of title 20 of the Code of Federal Regulations as follows:

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart B—[Amended]

■ 1. The authority citation for subpart B of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1110(b), 1602, 1611, 1614, 1619(a), 1631, and 1634 of the Social Security Act (42 U.S.C. 902(a)(5), 1310(b), 1381a, 1382, 1382c, 1382h(a), 1383, and 1383c); secs. 211 and 212, Pub. L. 93–66, 87 Stat. 154 and 155 (42 U.S.C. 1382 note); sec. 502(a), Pub. L. 94–241, 90 Stat. 268 (48 U.S.C. 1681 note); sec. 2, Pub. L. 99–643, 100 Stat. 3574 (42 U.S.C. 1382h note).

■ 2. Section 416.201 is amended by removing the definition of ''Medical care facility'' and adding a definition of ''Medical treatment facility'' in alphabetical order to read as follows:

§ 416.201 General definitions and terms used in this subpart.

* * * * *

Medical treatment facility means an institution or that part of an institution that is licensed or otherwise approved by a Federal, State, or local government to provide inpatient medical care and services.

* * * * *

§§ 416.201 and 416.211 [Amended]

■ 3. In 20 CFR part 416, subpart B, remove the words ''medical facility'' and ''medical care facility'' each time they appear and add in their place the words ''medical treatment facility'' in the following places:

■ a. Section 416.201 in the definitions of ''Medical care facility'' and ''Public emergency shelter for the homeless''; and

■ b. Section 416.211(b) and (c)(5)(iv).

■ 4. Section 416.212 is amended by revising the introductory text in paragraph (b)(1) to read as follows:

§ 416.212 Continuation of full benefits in certain cases of medical confinement.

* * * * *

(b) * * *

(1) Subject to eligibility and regular computation rules (see subparts B and D of this part), you are eligible for the benefits payable under section 1611(e)(1)(G) of the Social Security Act for up to 3 full months of medical confinement during which your benefits would otherwise be suspended because of residence in a public institution or reduced because of residence in a public or private institution where Medicaid pays a substantial part (more than 50 percent) of the cost of your care or, if you are a child under age 18, reduced because of residence in a public or private institution which receives payments under a health insurance policy issued by a private provider, or a combination of Medicaid and a health insurance policy issued by a private provider, pay a substantial part (more than 50 percent) of the cost of your care if—

* * * * *

Subpart D—[Amended]

■ 5. The authority citation for subpart D of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611(a), (b), (c), and (e), 1612, 1617, and 1631 of the Social Security Act (42 U.S.C. 902(a)(5), 1382(a), (b), (c), and (e), 1382a, 1382f, and 1383).

■ 6. Section 416.414 is amended by:

■ a. Revising the section heading;

■ b. Removing the words ''medical care facilities'' and adding ''medical treatment facilities'' in their place in paragraphs (a) and (b)(2);

■ c. Removing the words ''medical care facility'' and adding ''medical treatment facility'' in their place in paragraphs (b)(3)(i) and (ii); and

■ d. Revising paragraph (c).

The revisions read as follows:

§ 416.414 Amount of benefits; eligible individual or eligible couple in a medical treatment facility.

* * * * *

(c) *Definition.* For purposes of this section, a *medical treatment facility* means an institution or that part of an institution that is licensed or otherwise approved by a Federal, State, or local government to provide inpatient medical care and services.

Subpart E—[Amended]

■ 7–8. The authority citation for subpart E of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1147, 1601, 1602, 1611(c) and (e), and 1631(a)–(d) and (g) of the Social Security Act (42 U.S.C. 902(a)(5), 1320b–17, 1381, 1381a, 1382(c) and (e), and 1383(a)–(d) and (g)); 31 U.S.C. 3720A.

§ 416.571 [Amended]

■ 9. In § 416.571, remove the words ''medical facility'' in the last sentence and add in their place the words ''medical treatment facility''.

Subpart G—[Amended]

■ 10. The authority citation for subpart G of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611, 1612, 1613, 1614, and 1631 of the Social Security Act (42 U.S.C. 902(a)(5), 1382, 1382a, 1382b, 1382c, and 1383); sec. 211, Pub. L. 93–66, 87 Stat. 154 (42 U.S.C. 1382 note), sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 11. Section 416.708 is amended by revising paragraph (k) to read as follows:

§ 416.708 What you must report.

* * * * *

(k) *Admission to or discharge from a medical treatment facility, public institution, or private institution.* You must report to us your admission to or discharge from—

(1) A medical treatment facility; or

(2) A public institution (defined in § 416.201); or

(3) A private institution. *Private institution* means an institution as defined in § 416.201 which is not administered by or the responsibility of a governmental unit.

* * * * *

Subpart K—[Amended]

■ 12. The authority citation for subpart K of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1602, 1611, 1612, 1613, 1614(f), 1621, 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, 1383 and 1383b); sec. 211, Pub. L. 93–66, 87 Stat. 154 (42 U.S.C. 1382 note).

§ 416.1149 [Amended]

■ 13. In § 416.1149, remove the words ''medical care facility'' and add ''medical treatment facility'' in their place in paragraphs (a)(1) and (c)(1)(i) and (ii).

§ 416.1165 [Amended]

■ 14. In § 416.1165, remove the words ''medical care facility'' and add ''medical treatment facility'' in their place in paragraph (g)(6) and remove the words ''medical facility'' and add ''medical treatment facility'' in their place in paragraph (i)(1).

§ 416.1167 [Amended]

■ 15. In § 416.1167, remove the words ''medical care facility'' and add ''medical treatment facility'' in their place in paragraph (a)(2).

Subpart L—[Amended]

■ 16. The authority citation for subpart L of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1602, 1611, 1612, 1613, 1614(f), 1621, 1631 and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, 1383 and 1383b); sec. 211, Pub. L. 93–66, 87 Stat. 154 (42 U.S.C. 1382 note).

§ 416.1202 [Amended]

■ 17. In § 416.1202(b)(2)(i), remove the words ''medical facility'' and add in their place the words ''medical treatment facility''.

[FR Doc. E7–17403 Filed 9–4–07; 8:45 am]
BILLING CODE 4191–02–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG–2001–10881]

RIN 1625–AA36

Drawbridge Operation Regulations; Amendments

AGENCY: Coast Guard, DHS.

ACTION: Final rule; correction.

SUMMARY: The Coast Guard is correcting an oversight to the operating schedule of the Beach Channel railroad bridge across Jamaica Bay, mile 6.7, at Queens, New York, published on December 4, 2006 in the **Federal Register**. We are also correcting a paragraph designation in the operating schedule for the Woodrow Wilson Bridge across the Potomac River between Oxon Hill, Maryland and Alexandria, Virginia.

DATES: This Final rule is effective September 5, 2007.

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–2001–10881 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. Chris Jaufmann, Office of Bridge Administration, United States Coast Guard Headquarters, 202–372–1511. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, Department of Transportation, telephone 202–493–0402.

SUPPLEMENTARY INFORMATION:

Regulatory History

On December 4, 2006, the Coast Guard published a final rule that made technical, organizational, and conforming amendments throughout 33 CFR part 117 (71 FR 70305). This rule became effective on January 4, 2007. However, the January 4, 2007 effective date inadvertently changed the operating schedule of the Beach Channel railroad bridge across Jamaica Bay, mile 6.7, at Queens, New York (33 CFR 117.795) which was published on October 20, 2006 and became effective on November 20, 2006 (71 FR 61895). Also, the amendatory language for 33 CFR 117.255 Potomac River, in the December 4, 2006 final rule, incorrectly designated paragraph (c) as paragraph (d).

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this rule. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM for the present rule. An NPRM entitled ''Drawbridge Operation Regulations; Jamaica Bay and Connecting Waterways, New York'', was published in the **Federal Register**, on May 24, 2006, for the original change to the operating schedule (71 FR 29869). We are not making any changes to that final rule and are in fact correcting our error in reversing the changes made when that rule was finalized. Further notice and comment would be contrary to public interest and unnecessary.

For the same reason, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**.

Background and Purpose

Originally, the owner of the Beach Channel railroad bridge, New York City Transit, requested a change to the drawbridge operation regulations to help reduce commuter rail traffic delays during the morning and afternoon commuter hours. An NPRM was published on May 24, 2006 and a final rule on October 20, 2006 reflecting these changes (71 FR 29869, 71 FR 61895). On December 4, 2006 another final rule was published that mistakenly removed the operating schedule for the Beach Channel railroad bridge from the Code of Federal Regulations (71 FR 70305). This current final rule reestablishes the regulation published on October 20, 2006, which allows the Beach Channel Bridge to remain in the closed position during the morning and afternoon commuter rush hours from 6:45 a.m. to 8:20 a.m. and 5 p.m. to 6:45 p.m., Monday through Friday, except Federal holidays.

This rule will also make a minor technical edit by changing the paragraph (d) designation to paragraph (c) for 33 CFR 117.255 Potomac River, which was written incorrectly in the amendatory language for the final rule that published on December 4, 2006.

Regulatory Evaluation

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

We expect no economic impact of this rule so a full Regulatory Evaluation is unnecessary. This conclusion is based on the fact that vessel traffic would not be precluded from transiting through the Beach Channel railroad bridge each day, except for two closures of short duration, one in the morning, and one in the afternoon. Mariners would simply need to plan their daily transits in accordance with drawbridge operation schedule in order to help balance the needs of both rail and marine traffic.

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.

This rule could affect the following entities, some of which may be small entities, commercial barges and recreational vessels intending to transit the Beach Channel span. 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 for the reasons set forth in the Regulatory Evaluation section.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement

Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding the rule so that they can 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 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 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 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 (32)(e) of the Instruction, from further environmental documentation. Under figure 2–1, paragraph (32)(e), of the Instruction, an ''Environmental Analysis Check List'' and a ''Categorical Exclusion Determination'' are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

■ Accordingly, 33 CFR part 117 is corrected by making the following correcting amendments:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

§ 117.255 [Amended]

■ 2. In § 117.255 redesignate paragraph (d) as paragraph (c).

■ 3. In § 117.795 add paragraph (c) to read as follows:

§ 117.795 Jamaica Bay and Connecting Waterways.

* * * * *

(c) The draw of the Beach Channel railroad bridge shall open on signal; except that, the draw need not open for the passage of vessel traffic, 6:45 a.m. to 8:20 a.m. and 5 p.m. to 6:45 p.m., Monday through Friday, except Federal holidays.

Dated: August 29, 2007.

J.G. Lantz,

Acting, Assistant Commandant for Prevention.

[FR Doc. E7–17509 Filed 9–4–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2007–29153]

RIN 1625–AA87

Security Zone; Hawaii Super Ferry Arrival/Departure, Nawiliwili Harbor, Kauai, HI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; request for comments.

SUMMARY: The Coast Guard has created a security zone in the waters of Nawiliwili Harbor, Kauai, and on the land of the jetty south of Nawiliwili Park, including Waapa Road. This zone is intended to enable the Coast Guard and its law enforcement partners to better protect people, vessels, and facilities in and around Nawiliwili Harbor in the face of non-compliant protesters who have impeded passage of the Hawaii Super Ferry to its dock in the harbor. This rule complements, but does not replace or supersede, existing regulations that establish a moving 100-yard security zone around large passenger vessels like the Hawaii Super Ferry.

DATES: This rule is effective from September 1, 2007, through October 31, 2007. Comments and related material must reach the Coast Guard on or before September 26, 2007.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2007–29153 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Web site: http://dms.dot.gov.*

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

(3) *Fax:* 202–493–2251.

(4) *Delivery:* Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(5) *Federal eRulemaking Portal: http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Lieutenant (Junior Grade) Laura Springer, U.S. Coast Guard Sector Honolulu at (808) 842–2600.

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. Though operation of the Hawaii Super Ferry from Oahu to Kauai has been voluntarily suspended by the operating company, operations could resume at any time. Delay in implementing this rule would expose protesters in the water and ashore, and ferry passengers and crew to undue hazards due to protesters' tactics of entering the water from land and waterfront facilities adjacent to the harbor and using themselves as human barriers to the Hawaii Super Ferry's movement into Nawiliwili Harbor. For the same reason, under 5 U.S.C. 533(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Although the Coast Guard has good cause to issue this effective temporary rule without first publishing a proposed rule, you are invited to submit comments and related material regarding this rule on or before September 26, 2007. We may change the temporary final rule based upon your comments.

All comments received will be posted, without change, to *http://dms.dot.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. You may review the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov.*

Background and Purpose

On August 26 and 27, 2007, protesters impeded the passage of the Super Ferry Hawaii Super Ferry into and through Nawiliwili Harbor by entering the water from the land and waterfront facilities adjacent to the harbor, often with kayaks, surfboards, and other small vessels, and then swimming into and blocking the harbor's navigable channel. In addition, several hundred onlookers watched the unfolding events from land adjacent to the harbor. Most of these observers were on the jetty that is south of Nawiliwili Park, which is adjacent to the Madsen shipping facility in Nawiliwili Harbor (hereinafter referred to as ''Nawiliwili Jetty''). Some of these onlookers threw rocks and bottles at Coast Guard personnel who were conveying detained protesters to shore on August 26. Most of the protesters who entered the water were observed doing so from Nawiliwili Jetty.

The transit of the entrance into Nawiliwili harbor is difficult for large vessels in all but calm weather. The turn around the outer breakwater, then immediately turning in the opposite direction around the inner jetty is made more difficult by the combined effects of the winds and seas. Due to the difficulty of maneuvering in the small area of Nawiliwili, and in the interest of ensuring the safety of the protesters, the Hawaii Super Ferry's master chose not to enter the channel until the Coast Guard had cleared the channel of protesters. However, because the vessel remained outside the harbor, and because the protesters did not approach to within 100 yards of the vessel, the existing security zone (see 33 CFR 165.1410) did not provide the Coast Guard with the authority to control protestor entry into Nawiliwili Harbor or clear the channel of protesters before the Hawaii Super Ferry commenced its transit into the harbor. The resulting situation substantially complicated an already difficult transit and created a substantial risk of damage and injury.

The purpose of this regulation is several-fold. First, by designating most of the waters of Nawiliwili Harbor as a security zone upon the occurrence of triggering events discussed later, the regulation provides the Coast Guard and its law enforcement partners the authority to prevent persons and vessels from endangering themselves and the Hawaii Super Ferry's passengers and crew by attempting to impede the vessel's passage after it commences the difficult transit into the harbor. Extending the security zone to Nawiliwili Jetty and its access road provides law enforcement personnel with the authority necessary to control access into the water so the Hawaii Super Ferry may enter and depart the harbor safely and unimpeded by protestors. Additionally, in the case of mass protests, the security zone makes land adjacent to the harbor available for law enforcement purposes, such as an incident command post and a processing point for detained protesters.

Discussion of the Rule

This rule creates a security zone in most of the waters of Nawiliwili Harbor, and on Nawiliwili Jetty in Nawiliwili Harbor. The security zone will be activated for enforcement 60 minutes before the Hawaii Super Ferry's arrival into the zone, and will remain activated for 10 minutes after the Hawaii Super Ferry's departure from the zone. The activation of the zone for enforcement will be announced by marine

information broadcast and by a red flag, illuminated after sunset, displayed from the Pier One and the Harbor Facility Entrance on Jetty Road. During its period of activation and enforcement, entry into the land and water areas of the security zone is prohibited without the permission of the Captain of the Port, Honolulu, 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.

The Coast Guard expects the economic impact of this temporary rule to be so minimal that a full Regulatory Evaluation is unnecessary. This expectation is based on the short activation and enforcement duration of the security zone created by this temporary rule, as well as the limited geographic area affected the security zone.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule will 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. While we are aware that affected areas have small commercial entities, including canoe and boating clubs and small commercial businesses that provide recreational services, we anticipate that there will be little or no impact to these small entities due to the narrowly tailored scope of these changes, and to the fact that such entities can request permission from the Captain of the Port to enter the security zone when it is activated.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If the temporary rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Lieutenant (Junior Grade) Laura Springer, U.S. Coast Guard Sector Honolulu, (808) 842–2600. 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 temporary 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 temporary rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

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

Environment

We have analyzed this temporary rule under Commandant Instruction M16475.1D, 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, under figure 2–1, paragraph (34)(g) of the Commandant Instruction M16475.1D, this temporary rule is categorically excluded from further environmental documentation because this rule creates a security zone. An ''Environmental Analysis Check List'' and ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES.**

List of Subjects 33 CFR Part 165

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

■ For the reasons set out 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.

* * * * *

■ 1. Add temporary § 165.T14–160 to read as follows:

§ 165.T14–160 Security Zone; Nawiliwili Harbor, Kauai, HI.

(a) *Location.* The following land areas, and water areas from the surface of the water to the ocean floor, is a security zone that is activated as described in paragraph (b) of this section, and enforced subject to the provisions of paragraph (c) of this section: All waters of Nawiliwili Harbor, Kauai, shoreward of the Nawiliwili Harbor COLREGS DEMARCATION LINE (See 33 CFR 80.1450), excluding the waters west of a line running from the southeastern most point of the breakwater of Nawiliwili Small Boat Harbor due south to the south shore of the harbor, and excluding the waters from Kalapaki Beach south to a line extending from the western most point of Kukii Point due west to the Harbor Jetty. The land of the Jetty south of Nawiliwili Park including Waapa Road is included within the security zone.

(b) *Activation.* The zone described in paragraph (a) of this section will be activated for enforcement 60 minutes before the Hawaii Super Ferry's arrival into the zone and remain activated for 10 minutes after the Hawaii Super Ferry's departure from the zone. The activation of the zone for enforcement will be announced by marine information broadcast, and by a red flag, illuminated between sunset and sunrise, displayed from the Pier One and the Harbor Facility Entrance on Jetty Road.

(c) *Regulations.* (1) Under 33 CFR 165.33, entry by persons or vessels into the security zones created by this section and activated as described in paragraph (b) of this section is prohibited unless authorized by the Coast Guard Captain of the Port, Honolulu or his or her designated representatives. Operation of any type of vessel, including every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water, within the security zone is prohibited. Under authority of 50 U.S.C. 192, if a vessel is found to be operating within the security zone without permission of the Captain of the Port, Honolulu, and refuses to leave, the vessel is subject to seizure and forfeiture.

(2) All persons and vessels permitted in the security zone must comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene-patrol personnel. These personnel comprise commissioned, warrant, and petty officers of the Coast Guard and other persons permitted by law to enforce this regulation. Upon being hailed by an authorized vessel or law enforcement officer using siren, radio, flashing light, loudhailer, voice command, or other means, the operator of a vessel must proceed as directed.

(3) If authorized passage through the security zone, a vessel must operate at the minimum speed necessary to maintain a safe course and must proceed as directed by the Captain of the Port or his or her designated representatives. While underway with permission of the Captain of the Port or his or her designated representatives, no person or vessel is allowed within 100 yards of a the Hawaii Super Ferry when it is underway, moored, position-keeping, or at anchor, unless authorized by the Captain of the Port or his or her designated representatives.

(4) When conditions permit, the Captain of the Port, or his or her designated representatives, may permit vessels that are at anchor, restricted in their ability to maneuver, or constrained by draft to remain within the security zone in order to ensure navigational safety.

(d) *Enforcement.* Any Coast Guard commissioned, warrant, or petty officer, and any other person permitted by law, may enforce the regulations in this section.

Dated: August 31, 2007.

Sally Brice-O'Hara,

Rear Admiral, U.S. Coast Guard, Commander, Fourteenth Coast Guard District.

[FR Doc. 07–4357 Filed 8–31–07; 2:16 pm]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2005–NM–0006; FRL–8463–3]

Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Prevention of Significant Deterioration and New Source Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is approving revisions to the New Mexico State Implementation Plan (SIP) that were submitted to EPA on April 11, 2002, and December 29, 2005. The revisions modify New Mexico's Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) regulations in the SIP to address changes to the Federal PSD and NNSR regulations which were promulgated by EPA on December 31, 2002 and reconsidered with minor changes on November 7, 2003 (collectively, these two Federal actions are called the ''2002 New Source Review (NSR) Reform Rules''). The revisions include provisions for baseline emissions calculations, an actual-to-projected-actual methodology for calculating emissions changes, options for plantwide applicability limits (PALs), and recordkeeping and reporting requirements. EPA is approving these revisions pursuant to section 110, part C, and part D of the Federal Clean Air Act (Act).

DATES: This rule is effective on October 5, 2007.

ADDRESSES: The EPA has established a docket for this action under Docket ID Number EPA–R06–OAR–2005–NM–0006. 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, e.g., Confidential Business information or other information the disclosure of which 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 *www.regulations.gov* or in hard copy at the Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. The file will be made available by appointment for public inspection in the Region 6 Freedom of Information Act Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below to make an appointment. If possible, please make the appointment at least two working days in advance of your visit. There will be a 15 cent per page fee for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area at 1445 Ross Avenue, Suite 700, Dallas, Texas.

The State submittal is also available for public inspection during official business hours by appointment at the New Mexico Environment Department, Air Quality Bureau, 1190 St. Francis Drive, Santa Fe, New Mexico 87502.

FOR FURTHER INFORMATION CONTACT: Mr. Stanley M. Spruiell, Air Permits Section (6PD–R), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone (214) 665–7212; fax number (214) 665–7263; e-mail address *spruiell.stanley@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, any reference to ''we,'' ''us,'' or ''our'' shall mean EPA.

Outline

I. What Action Is EPA Taking?

The EPA is taking final action to approve the SIP revisions that the Governor of New Mexico submitted on December 29, 2005. This submittal consists of revisions to two regulations that are already part of the New Mexico SIP. The affected regulations are 20.2.74 New Mexico Administrative Code (NMAC) (Permits—Prevention of Significant Deterioration) and 20.2.79 NMAC (Permits—Nonattainment Areas). The revisions will update New Mexico's PSD and NNSR regulations to make them consistent with changes to the Federal NSR regulations published on December 31, 2002 (67 FR 80186) and November 7, 2003 (68 FR 63021). These EPA rulemakings are collectively referred to as the ''2002 NSR Reform Rules.'' EPA finds that the changes meet section 110, part C, and part D of the Act.

This SIP revision also includes other non-substantive changes to New Mexico's PSD and NNSR rules needed to update the regulatory citations, make clarifying revisions to the regulatory text, and correct typographical errors. Since the non-substantive changes do not change the regulatory requirements, EPA finds they meet section 110(l), part C and part D of the Act. Please see the Technical Support Document for further information.

The EPA is also approving portions of the SIP submittal dated April 11, 2002. This action only approves the following provisions of the April 11, 2002, SIP submittal:

- The removal of the definition of ''complete'' currently in Paragraph O of 20.2.74.7 NMAC; and
- Revisions to 20.2.74.400 NMAC and 20.2.79 NMAC which relate to the requirements for public notice and public participation for PSD and NNSR permits. Although the definition of ''complete'' is removed from New Mexico's rules, other provisions in the rules address the criteria that a permit application must include in order to be administratively complete. These provisions meet Federal requirements. While New Mexico's rules governing the procedures for determining administrative completeness and for public participation have been revised, these rules also meet Federal requirements. Therefore, the removal of the definition of ''complete'' and the revisions to administrative completeness and public participation for PSD and NNSR permits meet section 110(l), part C, and part D of the Act. The EPA will take appropriate action on the remaining provisions of the April 11, 2002, submittal in a separate action.

On June 20, 2007 (72 FR 33933), we published our proposed approval of this SIP revision. The proposal provided detailed information about the New Mexico SIP revision that we are approving today. The proposal also provided a detailed analysis of EPA's rationale for approving the New Mexico SIP revisions. In the proposal, we provided opportunity for public comment on the proposed action. The comment period for this proposed rulemaking ended July 20, 2007. We received no comments, adverse or otherwise, on the proposed rulemaking. We are therefore finalizing our proposed approval without changes. For more details on this submittal, please refer to the proposed rulemaking and to the Technical Support Document, which is in the docket for this action.

II. Statutory and Executive Order Reviews

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

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, the relationship between the Federal Government and Indian tribes, or 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, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. The EPA interprets Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks such that the analysis required under section 5–501 of

the Executive Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it would approve a State program. Executive Order 12898 (59 FR 7629 (February 16, 1994)) establishes Federal executive policy on environmental justice. Because this rule merely approves a State rule implementing a Federal standard, EPA lacks the discretionary authority to modify today's regulatory decision on the basis of environmental justice considerations.

In reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the 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 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 rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as 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. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 5, 2007. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: August 23, 2007.

Richard E. Greene,

Regional Administrator, Region 6.

■ 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 GG—New Mexico

■ 2. The first table in § 52.1620(c) entitled ''EPA Approved New Mexico Regulations'' is amended by revising the entries for part 74 and part 79 to read as follows:

§ 52.1620 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED NEW MEXICO REGULATIONS

State citation	Title/subject	State approval/ effective date	EPA approval date	Explanation
New Mexico Administrative Code (NMAC) Title 20—Environment Protection Chapter 2—Air Quality				
*	*	*	*	*
Part 74	Permits—Prevention of Significant Deterioration.	12/06/05	09/05/07 [Insert FR page number where document begins].	
*	*	*	*	*
Part 79	Permits—Nonattainment Areas	12/06/05	09/05/07 Insert FR page number where document begins].	
*	*	*	*	*

* * * * *

[FR Doc. E7–17514 Filed 9–4–07; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 3000, 3100, 3150, 3200, 3500, 3580, 3600, 3730, 3810, and 3830

[WO–610–4111–02–24 1A]

RIN 1004–AD95

Minerals Management: Adjustment of Cost Recovery Fees

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: This final rule amends the Bureau of Land Management (BLM) mineral resources regulations to update some fees that cover the BLM's cost of processing certain documents relating to its mineral programs and some filing fees for mineral-related documents. These updates include fees for actions such as lease applications, name changes, corporate mergers, lease consolidations, and lease reinstatements. The fee changes are the BLM's continued response to recommendations made by the Department of the Interior's Office of Inspector General in a 1988 report. This report was part of a 1980s Presidential initiative, which called for all Federal agencies to charge appropriate user fees for agency services, consistent with the law. This final rule also makes some editorial corrections to the rule.

DATES: This final rule is effective October 1, 2007.

FOR FURTHER INFORMATION CONTACT: Tim Spisak, Chief, Division of Fluid Minerals, 202–452–5061, or Cynthia Ellis, Regulatory Affairs Specialist, (202) 452–5012. Persons who use a telecommunications device for the deaf (TDD) may leave a message with the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, 7 days a week.

ADDRESSES: You may send inquiries or suggestions to Director (630), Bureau of Land Management, MS–LS 401, 1849 C Street, NW., Washington, DC 20240; Attention: RIN 1004–AD95.

SUPPLEMENTARY INFORMATION:

Background

The BLM has specific authority to charge fees for processing applications and other documents relating to public lands under Section 304 of the Federal Land Policy and Management Act of 1976 (FLPMA), 43 U.S.C. 1734. In 2005, the BLM published a final cost recovery rule (70 FR 58854) establishing or revising certain fees and service charges, and also establishing the method it would use to adjust those fees and service charges.

At 43 CFR 3000.12(a), the rule provides that the BLM will annually adjust fees established in Subchapter C according to changes in the Implicit Price Deflator for Gross Domestic Product (IPD–GDP), which is published quarterly by the U.S. Department of Commerce. (See also 43 CFR 3000.10.) Because the fee recalculations are simply based on a mathematical formula, we have changed the fees in a final rule without providing opportunity for notice and comment. This final rule will allow the BLM to update these fees and service charges by October 1 of this year, as required by the 2005 regulation. The public had opportunity to comment on this procedure during the comment period on the cost recovery rule, and this new rule simply administers the procedure set forth in those regulations. The Department of the Interior, therefore, for good cause finds under 5 U.S.C. 553(b)(B) and (d)(3) that notice and public comment procedures are unnecessary, and that the rule may be effective less than 30 days after publication.

Discussion of Final Rule

Because the 2005 cost recovery final rule did not become effective until November 7, 2005, there was not a full calendar year between the effective date and the October 1 deadline the following year for updating the fees. See 43 CFR 3000.12(a). The BLM therefore decided to issue this first fee update rule in 2007, to be effective on October 1, 2007. The fees in the 2005 rule reflect adjustments using the Implicit Price Deflator for 4th Quarter 2004. See 70 FR 58857. The fee updates that will be effective each October 1 will be based on the Implicit Price Deflator for the 4th Quarter of the preceding calendar year. This first fee update, based on the Implicit Price Deflator for 4th Quarter 2006, thus reflects inflation over eight calendar quarters. Future adjustments will reflect inflation over four calendar quarters.

While preparing this rule, we found that in compiling the fee table at 43 CFR 3000.12 for the 2005 final rule (70 FR 58854), we overlooked some already-existing filing fees. The following sections contain fees that should be reflected in the fee table: [1]

- In subpart 3150: sections 3152.1 (application for oil and gas geophysical exploration permit (Alaska)) [2] ($25) and 3152.3 (renewal of exploration permit (Alaska)) ($25)
- In subpart 3273: sections 3273.15 (site license application) ($50) and 3273.26 (assignment or transfer of site license) ($50)
- In part 3500: sections 3510.12(b) (lease modifications or fringe acreage leases) ($25); 3512.12, 3512.13(a)(6)(iii), 3512.16(b), and 3512.17(b) (assignments, subleases, or transfer of operating rights) ($25); 3512.19 (transfer of overriding royalty) ($25); and 3516.15 (use permits) ($25)
- In part 3580: sections 3583.3 (Shasta and Trinity hardrock leases) ($25) and 3586.2 (renewal of existing sand and gravel leases in Nevada) ($25)
- In Group 3700: section 3736.2(b) (notice of protest of placer mining operations) ($10)
- In Group 3800: sections 3816.2 (application to open lands to location) ($10) and 3830.21(h) (recording a notice of intent to locate mining claims on Stockraising Homestead Act lands) ($25)

In this final rule, we moved these fees to the fee table at 43 CFR 3000.12 and included a reference to the fee table in the relevant section of the rule text. This is an administrative revision for the convenience of the reader and has no substantive effect.

We also revised sections 3211.10(a) and 3504.10, which address fees in parts 3200 and 3500, respectively, to reflect the relocation of the fees to the table at 43 CFR 3000.12. In section 3211.10(a), we added to the list the filing fees noted above. In section 3504.10, instead of separate paragraphs for filing fees and processing fees, new paragraph (a)

[1] This rule will not include in the fee table at 43 CFR 3000.12 the $10 filing fee for requesting publication of notice of Leasing Act filing found at 43 CFR 3742.3–1(b)(4). The BLM is in the process of drafting a proposed rule that would, among other things, propose to remove this fee. The document to which this fee pertains relates to mining claims located in 1954 and earlier; no document of this type has been filed with the BLM in recent decades. If any such document were filed, the BLM would address it under a different part.

[2] Section 365 of the Energy Policy Act of 2005 (Pub. L. 109–58) directed in subsection (i) that ''the Secretary shall not implement a rulemaking that would enable an increase in fees to recover additional costs related to processing drilling-related permit applications and use authorizations.'' In the 2005 cost recovery rule, the BLM interpreted this prohibition to apply to geophysical exploration permits. 70 FR 58854–58855. However, the $25 fees for geophysical exploration permit applications for Alaska and renewals of exploration permits for Alaska pre-dated the 2005 cost recovery rule and were not affected by the Energy Policy Act prohibition.

Simply has the fee table, to which we added the filing fees and reordered the listed actions to put them in the same order as the corresponding sections in the rule text. The reference to exploration licenses that was in paragraph (a) was moved to new paragraph (b). These are also administrative revisions with no substantive effect.

Finally, we corrected minor errors in the existing rule. In section 3000.10(c), we changed the word ''annually'' to ''quarterly'' to correctly reflect the frequency of publication of the Implicit Price Deflator for Gross Domestic Product. In section 3103.1–2(a)(1), which addresses where fees should be submitted, we deleted the word ''filing'', as the fees referenced include processing fees. In section 3602.11(c), we changed ''as provided in section 3602.31(a)'' to ''as provided in section 3602.31(b)'', which is the correct cross-reference. We also changed the title of the fee table at 43 CFR 3000.12 to: ''FY [YEAR] Processing and Filing Fee Table.'' These are administrative revisions with no substantive effect.

The calculations that resulted in the new fees are included in the table below.

FIXED COST RECOVERY FEES FY08

Document/action	Existing fee [3]	IPD–GDP increase [4]	New value [5]	New fee [6]
Oil & Gas (parts 3100, 3110, 3120, 3130, 3150):				
Noncompetitive lease application	$335	$22.88	$357.88	$360
Competitive lease application	130	8.88	138.88	140
Assignment and transfer of record title or operating rights	75	5.12	80.12	80
Overriding royalty transfer, payment out of production	10	0.68	10.68	10
Name change, corporate merger or transfer to heir/devisee	175	11.95	186.95	185
Lease consolidation	370	25.27	395.27	395
Lease renewal or exchange	335	22.88	357.88	360
Lease reinstatement, Class I	65	4.44	69.44	70
Leasing under right-of-way	335	22.88	357.88	360
Geophysical exploration permit application—Alaska	25	.....	.....	[7] 25
Renewal of exploration permit—Alaska	25	.....	.....	[8] 25
Geothermal (part 3200):				
Noncompetitive lease application	335	22.88	357.88	360
Competitive lease application	130	8.88	138.88	140
Assignment and transfer of record title or operating right	75	5.12	80.12	80
Name change, corporate merger or transfer to heir/devisee	175	11.95	186.95	185
Lease consolidation	370	25.27	395.27	395
Lease reinstatement	65	4.44	69.44	70
Nomination of lands	$00 plus $0.10 per acre nominated	.....	.....	[9] $100 plus $0.10 per acre nominated
Site license application	50	3.42	53.42	55
Assignment or transfer of site license	50	3.42	53.42	55
Coal (parts 3400, 3470):				
License to mine application	10	0.68	10.68	10
Exploration license application	275	18.78	293.78	295
Lease or lease interest transfer	55	3.76	58.76	60
Leasing of Solid Minerals Other Than Coal and Oil Shale (parts 3500, 3580):				
Applications other than those listed below	30	2.05	32.05	30
Prospecting permit application amendment	55	3.76	58.76	60
Extension of prospecting permit	90	6.15	96.15	95
Lease modification or fringe acreage lease	25	1.71	26.71	25
Lease renewal	430	29.37	459.37	460
Assignment, sublease, or transfer of operating rights	25	1.71	26.71	25
Transfer of overriding royalty	25	1.71	26.71	25
Use permit	25	1.71	26.71	25
Shasta and Trinity hardrock mineral lease	25	1.71	26.71	25
Renewal of existing sand and gravel lease in Nevada	25	1.71	26.71	25
Multiple Use; Mining (Group 3700):				
Notice of protest of placer mining operations	10	0.68	10.68	10
Mining Law Administration (parts 3800, 3810, 3830, 3850, 3860, 3870)				
Application to open lands to location	10	0.68	10.68	10
Notice of location	15	1.02	16.02	15
Amendment of location	10	0.68	10.68	10
Transfer of mining claim/site	10	0.68	10.68	10
Recording an annual FLPMA filing	10	0.68	10.68	10
Deferment of assessment work	90	6.15	96.15	95
Recording a notice of intent to locate mining claims on Stockraising Homestead Act lands	25	1.71	26.71	25
Mineral patent adjudication	$2,520 (more than 10 claims)	172.12	2,692.12	2,690
	$1,260 (10 or fewer claims)	86.06	1,346.06	1,345
Adverse claim	90	6.15	96.15	95
Protest	55	3.76	58.76	60

[3] The Existing Fee was established by the 2005 cost recovery rulemaking, published October 7, 2005 (70 FR 58854), effective November 7, 2005.

[4] From 4th Quarter 2004 (109.426), to 4th Quarter 2006 (116.895) the IPD–GDP increased by 6.83%. The value in the IPD–GDP Increase column is 6.83% of the Existing Fee.
[5] The sum of the Existing Fee and IPD–GDP Increase is the New Value.
[6] The New Fee for 2008 is the New Value rounded to the nearest $5.00.
[7] As explained in footnote 1, above, the Energy Policy Act of 2005 (Pub. L. 109–58) prohibited certain fee increases that the BLM interpreted to apply to geophysical exploration permit applications. The $25 fee for geophysical exploration permit applications for Alaska pre-dated the 2005 cost recovery rule and was not affected by the Energy Policy Act prohibition. However, we interpret the provision quoted as prohibiting us from increasing this $25 fee.
[8] We interpret the Energy Policy Act prohibition discussed in footnotes 1 and 6, above, as prohibiting us from increasing this $25 fee, as well.
[9] The fee for nomination of lands under Part 3200 was added to the table by the final rule published on May 2, 2007 (72 FR 24400). Because the fee has been in effect for less than one year, we did not update it in this rulemaking.
Source for Implicit Price Deflator for Gross Domestic Product data: *http://www.bea.gov/national/nipaweb/TableView.asp#Mid*.

How Fees Are Adjusted

The figures in the ''New Value'' column in the table above, not those in the ''New Fee'' column, will be used in the future as the basis for calculating the annual adjustment to these fees. Because the new values are rounded to the nearest $5.00 in setting the new fees, future fees based on the figures in the ''New Fee'' column would become significantly over-or-under-valued over time. However, if the ''New Value'' column is blank because the fee was not updated in this rulemaking, future adjustments will be based on the figures in the ''New Fee'' column. Adjustments to future fees will be made by multiplying the annual change in the IPD–GDP by the reported New Value in the previous year's rulemaking. This calculation will define a new value for that year, which will then be rounded to the nearest $5.00 to establish the new adjusted fee.

Procedural Matters

Regulatory Planning and Review (Executive Order 12866). This document is not a significant rule and the Office of Management and Budget has not reviewed this rule under Executive Order 12866. We have made the assessments required by E.O. 12866 and the results are given below.

The BLM has determined that the rule will not have an annual effect on the economy of $100 million or more. It will not 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 governments or communities. This determination is based on the analysis that the BLM prepared in conjunction with the 2005 final rule. For instructions on how to view a copy of the analysis, please contact one of the persons listed in the **FOR FURTHER INFORMATION CONTACT** section, above.

This rule will not create inconsistencies or otherwise interfere with an action taken or planned by another agency. This rule does not change the relationships of the onshore minerals programs with other agencies' actions. These relationships are included in agreements and memoranda of understanding that would not change with this rule.

In addition, this final rule does not materially affect the budgetary impact of entitlements, grants, loan programs, or the rights and obligations of their recipients. This rule does apply an inflation factor that increases some existing user fees for processing documents associated with the onshore minerals programs. However, these fee increases are less than 7% and do not materially affect the budgetary impact of user fees.

Finally, this rule will not raise novel legal issues. As explained above, this rule simply implements a process to account for inflation that was proposed and explained in the 2005 cost recovery rule.

The Regulatory Flexibility Act. This final rule will not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). A Regulatory Flexibility Analysis is not required. Accordingly, a Small Entity Compliance Guide is not required. For the purposes of this section, a small entity is defined by the Small Business Administration (SBA) for mining (broadly inclusive of metal mining, coal mining, oil and gas extraction, and the mining and quarrying of nonmetallic minerals) as an individual, limited partnership, or small company considered to be at arm's length from the control of any parent companies, with fewer than 500 employees. The SBA defines a small entity differently, however, for leasing Federal land for coal mining. A coal lessee is a small entity if it employs not more than 250 people, including people working for its affiliates. The SBA would consider many, if not most, of the operators the BLM works with in the onshore minerals programs to be small entities. The BLM notes that this final rule does not affect service industries, for which the SBA has a different definition of ''small entity.''

The final rule will affect a large number of small entities since nearly all of them will face fee increases for activities on public lands. However, we have concluded that the effects will not be significant. The average increase in the fixed fees will be less than 7 percent as a result of this final rule. The adjustments result in no increase in the fee for processing of eight documents relating to the BLM's minerals programs. The highest adjustment is for mineral patent adjudications involving more than 10 mining claims, which will be increased by $170.00. For the 2005 final rule, the BLM completed a threshold analysis which is available for public review in the administrative record for that rule. (For instructions on how to view a copy of that analysis, please contact one of the persons listed in the **FOR FURTHER INFORMATION CONTACT** section, above.) The analysis for the 2005 rule concluded that the fees would not have a significant economic effect on a substantial number of small entities.

The Small Business Regulatory Enforcement Fairness Act. This final rule is not a ''major rule'' as defined at 5 U.S.C. 804(2). The final rule will not have an annual effect on the economy greater than $100 million; it will not result in major cost or price increases for consumers, industries, government agencies, or regions; and it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. For the 2005 final rule, which established the fee adjustment procedure that this rule implements, the BLM completed a threshold analysis, which is available for public review in the administrative record for that rule.

Executive Order 13132, Federalism. The proposed rule will not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. In accordance with Executive Order 13132, the final rule does not have significant Federalism effects. A Federalism assessment is not required.

The Paperwork Reduction Act of 1995. These regulations contain

information collection requirements. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we submitted a copy of the proposed information collection requirements to the Office of Management and Budget (OMB) for review. The OMB approved the information collection requirements under the following Control Numbers:

Oil and Gas

(1) 1004–0034 which expires April 30, 2009;

(2) 1004–0074 which expires December 31, 2009;

(3) 1004–0137 which expires July 31, 2010;

(4) 1004–0162 which expires February 28, 2009;

(5) 1004–0185 which expires July 31, 2009;

Geothermal

(6) 1004–0132 which expires July 31, 2010;

Coal

(7) 1004–0073 which expires March 31, 2010;

Mineral Materials

(8) 1004–0103 which expires March 31, 2008;

Mining Claims

(9) 1004–0025 which expires November 30, 2009;

(10) 1004–0114 which expires February 28, 2010; and

Leasing of Solid Minerals Other Than Oil Shale

(11) 1004–0121 which expires November 30, 2009.

Takings Implication Assessment (Executive Order 12630). As required by Executive Order 12630, the Department of the Interior has determined that this rule will not cause a taking of private property. No private property rights will be affected by a rule that merely reports changes in service fees. The Department therefore certifies that this final rule does not represent a governmental action capable of interference with constitutionally protected property rights.

Civil Justice Reform (Executive Order 12988). In accordance with Executive Order 12988, the BLM finds that this final rule will not unduly burden the judicial system and meets the requirements of Sections 3(a) and 3(b)(2) of the Executive Order.

The National Environmental Policy Act (NEPA). The BLM has determined that this final rule is administrative and involves only procedural changes addressing fee requirements. In promulgating this rule, the government is conducting routine and continuing government business of an administrative nature having limited context and intensity. Therefore, it is categorically excluded from environmental review under Section 102(2)(C) of NEPA, pursuant to 516 DM 2.3A and 516 DM 2, Appendix 1, Items 1.7 and 1.10. In addition, the final rule does not meet any of the 10 criteria for exceptions to categorical exclusions listed in 516 DM 2, Appendix 2.

Pursuant to Council on Environmental Quality regulations (40 CFR 1508.4) and the environmental policies and procedures of the Department of the Interior, the term ''categorical exclusions'' means categories of actions which do not individually or cumulatively have a significant effect on the human environment and which have been determined to have no such effect in procedures adopted by a Federal agency and therefore require neither an environmental assessment nor an environmental impact statement.

The Unfunded Mandates Reform Act of 1995. The BLM has determined that this proposed rule is not significant under the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, because it will not result in state, local, private sector, or tribal government expenditures of $100 million or more in any one year. This proposed rule will not significantly or uniquely affect small governments. Therefore, the BLM is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*).

Consultation and Coordination with Indian Tribal Governments (Executive Order 13175). In accordance with Executive Order 13175, the BLM has determined that this proposed rule does not include policies that have tribal implications. A key factor is whether the rule would have substantial direct effects on one or more Indian tribes. The BLM has not found any substantial direct effects. Consequently, the BLM did not utilize the consultation process set forth in section 5 of the Executive Order.

Data Quality Act. In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554).

Effects on the Nation's Energy Supply (Executive Order 13211). In accordance with Executive Order 13211, the BLM has determined that this proposed rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The distribution of or use of energy would not be unduly affected by this proposed rule.

Author

The principal authors of this rule are Stephen D. Salzman, Deputy Chief, Division of Fluid Minerals, assisted by the Division of Regulatory Affairs, Bureau of Land Management, and the Solicitor's Office.

List of Subjects:

43 CFR Part 3000

Public lands—mineral resources, Reporting and recordkeeping requirements.

43 CFR Part 3100

Government contracts, Mineral royalties, Oil and gas exploration, Public lands—mineral resources, Reporting and recordkeeping requirements, Surety bonds.

43 CFR Part 3150

Administrative practice and procedure, Alaska, Oil and gas exploration, Public lands—mineral resources, Reporting and recordkeeping requirements, Surety bonds.

43 CFR Part 3200

Geothermal energy, Government contracts, Mineral royalties, Public lands—mineral resources, Reporting and recordkeeping requirements, Surety bonds.

43 CFR Part 3500

Government contracts, Hydrocarbons, Mineral royalties, Mines, Phosphate, Potassium, Public lands—mineral resources, Reporting and recordkeeping requirements, Sodium, Sulfur, Surety bonds.

43 CFR Part 3580

Government contracts, Mineral royalties, Mines, Public lands—mineral resources, Recreation and recreation areas, Surety bonds.

43 CFR Part 3600

Public lands—mineral resources, Reporting and recordkeeping requirements.

43 CFR Part 3730

Administrative practice and procedure, Mines, Public lands—mineral resources, Reporting and recordkeeping requirements, Surety bonds.

43 CFR Part 3810

Mines, Public lands—mineral resources, Reporting and recordkeeping requirements.

43 CFR Part 3830

Mineral royalties, Mines, Public lands—mineral resources, Reporting and recordkeeping requirements.

C. Stephen Allred,

Assistant Secretary—Land and Minerals Management.

■ For reasons stated in the preamble, the Bureau of Land Management amends 43 CFR chapter II as follows:

PART 3000—MINERALS MANAGEMENT: GENERAL

■ 1. The authority citation for part 3000 continues to read as follows:

Authority: 16 U.S.C. 3101 *et seq.*; 30 U.S.C. 181 *et seq.*, 301–306, 351–359, and 601 *et seq.*; 31 U.S.C. 9701; 40 U.S.C. 471 *et seq.*; 42 U.S.C. 6508; 43 U.S.C. 1701 *et seq.*; and Pub. L. 97–35, 95 Stat. 357.

Subpart 3000—General

■ 2. Revise the first sentence of § 3000.10(c) to read as follows:

§ 3000.10 What do I need to know about fees in general?

* * * * *

(c) *Periodic adjustment.* We will periodically adjust fees established in this subchapter according to change in the Implicit Price Deflator for Gross Domestic Product, which is published quarterly by the U.S. Department of Commerce. * * *

* * * * *

■ 3. Revise § 3000.12(a) to read as follows:

§ 3000.12 What is the fee schedule for fixed fees?

(a) The table in this section shows the fixed fees that you must pay to BLM for the services listed for Fiscal Year 2008. These fees are nonrefundable and must be included with documents you file under this chapter. Fees will be adjusted annually according to the change in the Implicit Price Deflator for Gross Domestic Product (IPD–GDP) by way of publication of a final rule in the **Federal Register** and will subsequently be posted on the BLM Web site (*http://www.blm.gov*) before October 1 each year. Revised fees are effective each year on October 1.

FY 2008 PROCESSING AND FILING FEE TABLE

Document/action	Fee
(1) Oil and Gas (parts 3100, 3110, 3120, 3130, 3150):	
Noncompetitive lease application	$360
Competitive lease application	140
Assignment and transfer of record title or operating rights	80
Overriding royalty transfer, payment out of production	10
Name change, corporate merger, or transfer to heir/devisee	185
Lease consolidation	395
Lease renewal or exchange	360
Lease reinstatement, Class I	70
Leasing under right-of-way	360
Geophysical exploration permit application—Alaska	25
Renewal of exploration permit—Alaska	25
(2) Geothermal (part 3200):	
Noncompetitive lease application	360
Competitive lease application	140
Assignment and transfer of record title or operating rights	80
Name change, corporate merger or transfer to heir/devisee	185
Lease consolidation	395
Lease reinstatement	70
Nomination of lands	$100 plus $0.10 per acre of lands nominated.
Site license application	55
Assignment or transfer of site license	55
(3) Coal (parts 3400, 3470):	
License to mine application	10
Exploration license application	295
Lease or lease interest transfer	60
(4) Leasing of Solid Minerals Other Than Coal and Oil Shale (parts 3500, 3580):	
Applications other than those listed below	30
Prospecting permit application amendment	60
Extension of prospecting permit	95
Lease modification or fringe acreage lease	25
Lease renewal	460
Assignment, sublease, or transfer of operating rights	25
Transfer of overriding royalty	25
Use permit	25
Shasta and Trinity hardrock mineral lease	25
Renewal of existing sand and gravel lease in Nevada	25
(5) Multiple Use; Mining (part 3730):	
Notice of protest of placer mining operations	10
(6) Mining Law Administration (parts 3800, 3810, 3830, 3850, 3860, 3870):	
Application to open lands to location	10
Notice of location*	15
Amendment of location	10
Transfer of mining claim/site	10
Recording an annual FLPMA filing	10
Deferment of assessment work	95
Recording a notice of intent to locate mining claims on Stockraising Homestead Act lands	25

FY 2008 PROCESSING AND FILING FEE TABLE—Continued

Document/action	Fee
Mineral patent adjudication	2,690 (more than 10 claims). 1,345 (10 or fewer claims).
Adverse claim	95
Protest	60

*To record a mining claim or site location, you must pay this processing fee along with the initial maintenance fee and the one-time location fee required by statute. (43 CFR part 3833)

* * * * *

PART 3100—OIL AND GAS LEASING

■ 4. The authority citation for part 3100 continues to read as follows:

Authority: 30 U.S.C. 189 and 359; 43 U.S.C. 1732(b), 1733, and 1740; and the Energy Policy Act of 2005 (Pub. L. 109–58).

Subpart 3103—Fees, Rentals and Royalty

■ 5. Amend § 3103.1–2 by revising paragraph (a)(1), to read as follows:

§ 3103.1–2 Where submitted.

(a)(1) All fees for lease applications or offers or for requests for approval of a transfer and all first-year rentals and bonuses for leases issued under Group 3100 of this title shall be paid to the proper BLM office.

* * * * *

PART 3150—ONSHORE OIL AND GAS GEOPHYSICAL EXPLORATION

■ 6. The authority citation for part 3150 continues to read as follows:

Authority: 16 U.S.C. 3150(b) and 668dd; 30 U.S.C. 189 and 359; 42 U.S.C. 6508; 43 U.S.C. 1201, 1732(b), 1733, 1734, 1740.

Subpart 3152—Exploration in Alaska

■ 7. Revise the undesignated text at the end of § 3152.1 to read as follows:

§ 3152.1 Application for oil and gas geophysical exploration permit.

* * * * *

Note to § 3152.1: Submit your application along with the filing fee for geophysical exploration permit—Alaska, found in the fee schedule in § 3000.12 of this chapter (except where the exploration operations are to be conducted on a leasehold by or on behalf of the lessee), to the District Manager of the proper BLM office.

■ 8. Revise § 3152.3 to read as follows:

§ 3152.3 Renewal of exploration permit.

Upon application by the permittee and payment of the filing fee for renewal of exploration permit—Alaska, found in the fee schedule in section 3000.12 of this chapter (except where the exploration operations are to be conducted on a leasehold by or on behalf of the lessee), an exploration permit may be renewed for a period not to exceed one year.

PART 3200—GEOTHERMAL RESOURCE LEASING

■ 9. The authority citation for part 3200 continues to read as follows:

Authority: 30 U.S.C. 1001–1028; 43 U.S.C. 1701 *et seq.*; and Pub. L. 109–58.

Subpart 3211—Filing and Processing Fees, Rent, Direct Use Fees, and Royalties

■ 10. Amend § 3211.10 by removing the word ''and'' at the end of paragraph (a)(6), removing the period and adding a semicolon in its place at the end of paragraph (a)(7), and adding paragraphs (a)(8) and (9) to read as follows:

§ 3211.10 What are the processing and filing fees for leases?

(a) * * *

(8) Site license application; and

(9) Assignment or transfer of site license.

* * * * *

Subpart 3273—How to Apply for a Site License

■ 11. Amend § 3273.15 by revising paragraph (c) to read as follows:

§ 3273.15 What must I include in my site license application?

* * * * *

(c) The filing fee for a site license application found in the fee schedule in § 3000.12 of this chapter;

* * * * *

■ 12. Revise the second sentence of § 3273.26 to read as follows:

§ 3273.26 When may I assign or transfer my site license?

* * * Send BLM your completed and signed transfer application and the filing fee for assignment or transfer of site license found in the fee schedule in § 3000.12 of this chapter. * * *

PART 3500—LEASING OF SOLID MINERALS OTHER THAN COAL AND OIL SHALE

■ 13. The authority citation for part 3500 continues to read as follows:

Authority: 5 U.S.C. 552; 30 U.S.C. 189 and 192c; 43 U.S.C. 1701 *et seq.*; and sec. 402, Reorganization Plan No. 3 of 1946 (5 U.S.C. appendix).

Subpart 3504—Fees, Rental, Royalty and Bonds

■ 14. Revise § 3504.10 to read as follows:

§ 3504.10 What fees must I pay?

(a) The following table shows fees for various documents in this part.

Document	Processing fee
(1) Applications other than those listed below	As found in the fee schedule in § 3000.12 of this chapter.
(2) Prospecting permit application	Case-by-case basis as described in § 3000.11 of this chapter.
(3) Prospecting permit application amendment	As found in the fee schedule in § 3000.12 of this chapter.
(4) Prospecting permit extension	As found in the fee schedule in § 3000.12 of this chapter.
(5) Preference right lease application	Case-by-case basis as described in § 3000.11 of this chapter.
(6) Successful competitive lease application	Case-by-case basis as described in § 3000.11 of this chapter, and modified by §§ 3508.14 and 3508.21.
(7) Future or fractional interest lease application	Case-by-case basis as described in § 3000.11 of this chapter.
(8) Lease modification or fringe acreage lease	As found in the fee schedule in § 3000.12 of this chapter.

Document	Processing fee
(9) Lease renewal application	As found in the fee schedule in § 3000.12 of this chapter.
(10) Assignment, sublease, or transfer of operating rights	As found in the fee schedule in § 3000.12 of this chapter.
(11) Transfer of overriding royalty	As found in the fee schedule in § 3000.12 of this chapter.
(12) Application to waive, suspend, or reduce your rental, minimum royalty, or royalty rate.	Case-by-case basis as described in § 3000.11 of this chapter.
(13) Use permit	As found in the fee schedule in § 3000.12 of this chapter.

(b) Fees for exploration licenses are not administered under this section, but are administered under part 2920 of this chapter.

Subpart 3510—Noncompetitive Leasing: Fringe Acreage Leases and Lease Modifications

■ 15. Amend § 3510.12 by revising the first sentence of paragraph (b) to read as follows:

§ 3510.12 What must I do to obtain a lease modification or fringe acreage lease?

* * * * *

(b) Include the filing fee for lease modification or fringe acreage lease found in the fee schedule in section 3000.12 of this chapter. * * *

* * * * *

Subpart 3512—Assignments and Subleases

■ 16. Revise the first sentence of § 3512.12 to read as follows:

§ 3512.12 Is there a fee for requesting an assignment or sublease?

When you submit your instrument for assignment of record title or operating rights, or for transfer of overriding royalties, you must pay the filing fee for assignment, sublease, or transfer of operating rights found in the fee schedule in § 3000.12 of this chapter. * * *

■ 17. Amend § 3512.13 by revising paragraph (a)(6)(iii) to read as follows:

§ 3512.13 How do I assign my permit or lease?

* * * * *

(a) * * *

(6) * * *

(iii) The filing fee for assignment, sublease, or transfer of operating rights found in the fee schedule in § 3000.12 of this chapter.

* * * * *

■ 18. Amend § 3512.16 by revising paragraph (b) to read as follows:

§ 3512.16 How do I sublease my lease?

* * * * *

(b) The sublessee must also file a signed and dated request for approval and a statement of qualifications (see subpart 3502 of this part), and submit the filing fee for assignment, sublease, or transfer of operating rights found in the fee schedule in § 3000.12 of this chapter.

* * * * *

■ 19. Amend § 3512.17 by revising paragraph (b) to read as follows:

§ 3512.17 How do I transfer the operating rights in my permit or lease?

* * * * *

(b) The transferee must also file a signed and dated request for approval and a statement of qualifications (see subpart 3502 of this part), and submit the filing fee for assignment, sublease, or transfer of operating rights found in the fee schedule in § 3000.12 of this chapter.

* * * * *

■ 20. Revise the last sentence of § 3512.19 to read as follows:

§ 3512.19 Must I notify the BLM if I intend to transfer an overriding royalty to another party?

* * * Include the transferee's statement of qualifications required in subpart 3502 and the filing fee for transfer of overriding royalty found in the fee schedule in § 3000.12 of this chapter.

Subpart 3516—Use Permits

■ 21. Revise the third sentence of § 3516.15 to read as follows:

§ 3516.15 How do I apply for a use permit?

* * * Include the filing fee for a use permit found in the fee schedule in § 3000.12 of this chapter and the first year's rental. * * *

PART 3580—SPECIAL LEASING AREAS

■ 22. The authority citation for part 3580 continues to read as follows:

Authority: 16 U.S.C. 90c–1, 460n–5, 460q–5, 460dd–2, 460mm–4; 30 U.S.C. 189, 293, 359; 31 U.S.C. 9701; 43 U.S.C. 1201, 1732(b), 1733, 1740; 47 Stat. 1487.

Subpart 3583—Shasta and Trinity Units of the Whiskeytown-Shasta-Trinity National Recreation Area

■ 23. Revise the last sentence of § 3583.3 to read as follows:

§ 3583.3 Applications for hardrock mineral leases.

* * * Each application must be filed in triplicate in the proper BLM office and must be accompanied by the filing fee for Shasta and Trinity hardrock mineral leases found in the fee schedule in § 3000.12 of this chapter.

Subpart 3586—Sand and Gravel in Nevada

■ 24. Revise the second sentence of section 3586.2 to read as follows:

§ 3586.2 Existing leases.

* * * An application for renewal must be filed in triplicate in the proper BLM office within 90 days prior to the expiration of the lease term and be accompanied by the filing fee for renewal of existing sand and gravel leases in Nevada found in the fee schedule in § 3000.12 of this chapter. * * *

PART 3600—MINERAL MATERIALS DISPOSAL

■ 25. The authority citation for part 3600 continues to read as follows:

Authority: 30 U.S.C. 601 *et seq.*; 43 U.S.C. 1201, 1701 *et seq.*; Sec. 2, Act of September 28, 1962 (Pub. L. 87–713, 76 Stat. 652).

Subpart 3602—Mineral Materials Sales

■ 26. Amend § 3602.11 by revising the first sentence of paragraph (c) to read as follows:

§ 3602.11 How do I request a sale of mineral materials?

* * * * *

(c) You must pay a processing fee as provided in §§ 3602.31(b) and 3602.44(f). * * *

PART 3730—PUBLIC LAW 359; MINING IN POWERSITE WITHDRAWALS: GENERAL

■ 27. The authority citation for part 3730 continues to read as follows:

Authority: 30 U.S.C. 22 *et seq.*; 30 U.S.C. 28f–k; 30 U.S.C. 621–625; 43 U.S.C. 1201; 43 U.S.C. 1740; 43 U.S.C. 1744.

Subpart 3736—Mining Operations

■ 28. Amend § 3736.2 by revising the second sentence of paragraph (b) to read as follows:

§ 3736.2 Hearing; notice of protest.

* * * * *

(b) * * * Such notice, accompanied by the filing fee for notice of protest of placer mining operations found in the fee schedule in § 3000.12 of this chapter, must contain the party's name and address and a statement showing the nature of the party's interest in the use of the lands embraced within the mining claim. * * *

* * * * *

PART 3810—LANDS AND MINERALS SUBJECT TO LOCATION

■ 29. The authority citation for part 3810 continues to read as follows:

Authority: 30 U.S.C. 22 *et seq.*; 43 U.S.C. 1201 and 1740.

Subpart 3816—Mineral Locations in Reclamation Withdrawals

■ 30. Revise the last sentence of § 3816.2 to read as follows:

§ 3816.2 Application to open lands to location.

* * * Each application must be accompanied by the filing fee for application to open lands to location found in the fee schedule in § 3000.12 of this chapter.

PART 3830—LOCATING, RECORDING, AND MAINTAINING MINING CLAIMS OR SITES; GENERAL PROVISIONS

■ 31. The authority citation for part 3830 continues to read as follows:

Authority: 18 U.S.C. 1001, 3571; 30 U.S.C. 22 *et seq.*, 242, 611; 31 U.S.C. 9701; 43 U.S.C. 2, 1201, 1212, 1457, 1474, 1701 *et seq.* ; 44 U.S.C. 3501 *et seq.*; 115 Stat. 414.

Subpart D—BLM Service Charge and Fee Requirements

■ 32. Amend § 3830.21 by revising paragraph (h) to read as follows:

§ 3830.21 What are the different types of service charges and fees?

* * * * *

(h) Recording a notice of intent to locate mining claims on Stockraising Homestead Act Lands (part 3838).	The filing fee for recording a notice of intent to locate mining claims on Stockraising Homestead Act Lands found in the fee schedule in § 3000.12 of this chapter.	No.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 98

RIN 0970–AC29

Child Care and Development Fund Error Rate Reporting

AGENCY: Administration for Children and Families (ACF), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the Child Care and Development Fund (CCDF) regulations to provide for the reporting of error rates in the expenditure of CCDF grant funds by the fifty States, the District of Columbia and Puerto Rico. The error rate reports will serve to implement provisions of the *Improper Payments Information Act of 2002 (IPIA)* and the *President's Management Agenda (PMA)'s* goal of ''Eliminating Improper Payments.''

DATES: Effective October 1, 2007.

FOR FURTHER INFORMATION CONTACT: Cheryl Vincent, Child Care Program Specialist, Child Care Bureau, 1250 Maryland Ave., SW., 8th Floor, Washington, DC 20024, telephone (202) 205–0750, e-mail *cheryl.vincent@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background

This final rule adds a new subpart to the Child Care and Development Fund (CCDF) regulations that requires States, the District of Columbia and Puerto Rico to employ a case review process in calculating CCDF error rates in accordance with an error rate methodology established by the Secretary of Health and Human Services (the Secretary). This methodology is specified in this rule and associated information collection forms and instructions. The final rule requires States, the District of Columbia and Puerto Rico to report specified information regarding errors to the Department of Health and Human Services. A discussion of comments received in response to the publication of a Notice of Proposed Rulemaking (NPRM) on March 2, 2007 (72 FR 9491) may be found below in the preamble. This final rule is not substantively different from the NPRM; however, minor technical changes have been made to address concerns raised by some commenters.

A. Child Care and Development Fund (CCDF)

CCDF provides Federal funds to States, Territories, Indian Tribes and tribal organizations for the purpose of assisting low-income families, including families receiving or transitioning from the Temporary Assistance for Needy Families program (TANF), in the purchase of child care services, thereby allowing parents to work or attend job training or an educational program. States and Territories also must spend no less than four percent of their CCDF allotment on expenditures to improve the quality and availability of child care. CCDF is provided to States, Territories and Tribes—there is no provision for direct funding to individual families or providers.

Federal law establishes eligibility criteria for families receiving CCDF assistance; however, States and Territories administering CCDF funds may impose more restrictive eligibility standards. Regulations governing CCDF are codified in 45 CFR parts 98 and 99, and the Federal definition of a child's eligibility for child care services is set forth in 45 CFR 98.20. This description includes eligibility requirements related to a child's age, a child's special needs or protective services status, family

income and parent's work, training or educational activity. Lead Agencies of the CCDF Program, which are the State, territorial or tribal entities to which CCDF grants are awarded and that are accountable for the use of the funds provided, have established policies and procedures that vary considerably across and even within jurisdictions, including, but not limited to, stricter income limits, special eligibility or priority for families receiving TANF and eligibility that differs for a child with special needs. All clients seeking child care assistance supported by CCDF funds must undergo an eligibility determination process when they initially apply, and all Lead Agencies have defined a process for verifying information submitted in the application. Eligibility determination affects many other aspects of the program, including provider payment rates, authorized hours of care and a family's co-payment responsibility.

Section 658E of the Child Care and Development Block Grant (CCDBG) Act (42 U.S.C. 9858c) and 45 CFR 98.52 limit expenditures by States and Territories for the costs of administering the CCDF program to no more than five percent of the State's or Territory's aggregate expenditures from a fiscal year's allotment of CCDF funds. Various costs that are considered an integral part of service delivery are excluded from the five percent administrative cap, including eligibility determination and redetermination and the establishment and maintenance of computerized child care information systems.

B. Summary of the Statutory and Administrative Directives To Measure Improper Payments

The Improper Payments Information Act of 2002 (IPIA) (31 U.S.C. 3321 note) requires Federal agencies to identify programs that are vulnerable to improper payments and to estimate annually the amount of underpayments and overpayments made by these programs. An improper payment, as defined by the IPIA, is any payment that should not have been made or that was made in an incorrect amount under statutory, contractual, administrative or other legally applicable requirement. Incorrect amounts are overpayments and underpayments (including inappropriate denials of payment or service). An improper payment includes any payment that was made to an ineligible recipient or for an ineligible service. Improper payments also are duplicate payments, payments for services not received and payments that do not account for credit for applicable discounts.

According to the IPIA, Federal agencies must report on the actions they are taking to reduce improper payments if the estimated amount of improper payments for an activity or program exceeds $10 million and 2.5 percent of program payments. CCDF has been identified by the Office of Management and Budget (OMB) as a program susceptible to significant erroneous payments and for which improper payment information is required to be reported under the IPIA. This report must include a discussion of the causes of improper payments, what actions Federal agencies have taken to correct those causes and the results achieved. Federal agencies also must state whether they have the information systems and other infrastructure needed to reduce improper payments and, if not, what resources they have requested in their budget submissions. Finally, Federal agencies must report on what steps they have taken to hold managers accountable for reducing improper payments. The IPIA may be downloaded at: *http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR04878:TOM:/bss/d107query.html*.

The Executive Branch also has worked to address the improper payments issue. The President's Management Agenda (PMA)'s goal of ''Eliminating Improper Payments'' promises to establish a baseline of the extent of improper payments and to work with agencies to set goals to reduce improper payments for each program. The anticipated result of this effort is greater accuracy in benefit and assistance programs, which will enable programs to serve additional eligible recipients. The PMA may be downloaded at: *http://www.whitehouse.gov/omb/budget/fy2002/mgmt.pdf.*

The modifications in this final rule are designed to meet the requirements of the IPIA as well as to meet the PMA's goal of ''Eliminating Improper Payments.''

C. Error Rate Methodology

The methodology that is implemented in this final rule is based on a methodology the Child Care Bureau developed and field-tested in 2005 in partnership with four States that volunteered to participate in a pilot study (Arkansas, Colorado, Illinois and Ohio). This methodology focused on administrative error associated with client eligibility and improper authorizations for payment. At the conclusion of the pilot, it was determined that a version of the tested methodology would be an appropriate tool for calculating error rates related to client eligibility. A pilot study of additional States (Florida, Kansas, New Jersey, Oregon, and West Virginia) was completed in 2007. The final reports on the error rate methodology pilots may be downloaded electronically at: *http://www.acf.hhs.gov/programs/ccb/ccdf/ipi/ipi.htm.*

Although this final rule is broad enough to encompass reporting on all types of errors, the initial methodology and reporting requirements will focus on administrative errors associated with client eligibility and improper authorizations for payment, as described in more detail in the preamble and accompanying information collection forms and instructions associated with the rule (please refer to the section discussing the Paperwork Reduction Act below).

During the initial information collection, States, the District of Columbia, and Puerto Rico will evaluate both the frequency with which errors occurred and the amount of improper authorization for payment. ACF will use the improper authorization for payment error rates and amounts for each State, the District of Columbia, and Puerto Rico to compute a national improper authorizations for payment rate and amount that will be annually reported in the HHS' Performance and Accountability Report (PAR) beginning with the Fiscal Year 2008 PAR.

We will use a three-year rotational cycle to measure improper authorizations for payment in CCDF programs in the States, the District of Columbia, and Puerto Rico. Out of this group, we have selected 18 to measure in the first year of each cycle and 17 to measure in each of the remaining two years. The result is that each State, the District of Columbia, and Puerto Rico will be measured once, and only once, every three years. This rotation allows jurisdictions to plan for the reviews because they know in advance in which year they will be measured. States, the District of Columbia, and Puerto Rico have been randomly assigned using the following methodology. First, each entity was stratified by the 10 ACF regions, with the regions randomly ordered. Then within region each group was sorted by caseload, from the most cases to the least cases. Every third State (including the District of Columbia and Puerto Rico) on the list was selected, using a random start number between one and three the first year. After removing those selected for the first year from the frame, a second random start was drawn between one and two and every other State (including the District of Columbia and Puerto Rico, if they remained) was selected for the second

year. The third year includes those not selected in year one or year two. This sampling approach yielded a mix of county-administered and State-administered programs and programs serving both large and small numbers of children each year. A list of States (including the District of Columbia and Puerto Rico) assigned to each review year can be found in the information collection instructions.

D. Notice of Proposed Rulemaking

A Notice of Proposed Rulemaking (NPRM) was published in the **Federal Register** on Friday, March 2, 2007 (72 FR 9491) with a 60-day public comment period. As discussed later in this preamble, we received comments from 19 entities, including State child care administrators, national child care advocacy groups, and other organizations.

II. Statutory Authority

This regulation is being issued under the authority granted to the Secretary by Section 658I of the CCDBG Act (42 U.S.C. 9858g) and in accordance with the IPIA (31 U.S.C. 3321 note).

III. Summary of the Existing Regulations

Under CCDF regulations, ACF employs several methods to gather the information from States, the District of Columbia, and Territories needed to comply with the statutory requirements of the CCDBG Act and to efficiently oversee the administration of the CCDF program. States and Territories must submit plans every two years detailing their intentions for implementing programs under 45 CFR 98.17. Pursuant to 45 CFR 98.70, States and Territories also must collect monthly case-level reports (which may be submitted monthly or quarterly) and submit annual aggregated reports on services provided through all CCDF grant funds. Finally, States and Territories are required to submit quarterly reports on estimates and expenditures in conjunction with 45 CFR 98.65.

45 CFR 98.65(a) requires Lead Agencies to have an audit conducted after the close of each program period in accordance with OMB Circular A–133 and the Single Audit Act Amendments of 1996 and 45 CFR 98.67(c) requires Lead Agencies to have fiscal control and accounting procedures sufficient to establish that funds have been expended appropriately. Further, the regulations at 45 CFR 98.66 provide that ''[a]ny expenditures not made in accordance with the Act, the implementing regulations, or the approved Plan, will be subject to disallowance.'' However, prior to this final rule statute and regulations governing CCDF did not require States and Territories to systematically measure or report on errors committed in the administration of CCDF funds.

IV. Provisions of Final Rule

While retaining the provisions governing CCDF Lead Agency audits, financial reporting requirements, and fiscal requirements (located in 45 CFR 98.65 and 45 CFR 98.67), this final rule adds a new Subpart K—Error Rate Reporting to require CCDF Lead Agencies of the fifty States, the District of Columbia and Puerto Rico to measure, calculate and report error rates to the Department of Health and Human Services. This reporting must be in accordance with an error rate methodology established by the Secretary, as summarized in this final rule and detailed in the associated information collection forms and instructions. States, the District of Columbia and Puerto Rico are required to report specified information regarding errors every three years and to report on strategies for reducing the error rate. The rule also requires States, the District of Columbia and Puerto Rico to set target error rates for the next cycle. The first cohort of States (including Puerto Rico) subject to the final regulations will need to complete their reviews and submit their data to ACF on or before June 30, 2008.

Requirements under Subpart K apply only to the fifty States, the District of Columbia and Puerto Rico. American Samoa, the U.S. Virgin Islands, the Commonwealth of the Northern Mariana Islands, Guam and the Tribes are exempted from the requirements of this rule. We do not believe that the benefits of the error rate data obtained from these exempted Territories and Tribes justify the costs of compliance with the regulation, which would require a much greater portion of child care resources relative to the States, the District of Columbia and Puerto Rico. However, we encourage exempted Territories and Tribes to comply voluntarily with the requirements of the rule or to create their own methods and strategies for identifying and reducing improper payments. Additionally, should funding and provision of services change in these exempted Tribes and Territories, we will consider removing the exemption through the notice and comment rulemaking process.

Under Section 98.100(b) in the final rule, States, the District of Columbia and Puerto Rico are required to prepare a report calculating ''error rates.'' At this time—and consistent with our initial focus on client eligibility errors—we are operationalizing these requirements by asking States, the District of Columbia, and Puerto Rico to measure only administrative errors in eligibility determination and improper authorizations for payments to subsidy recipients rather than improper payments made to subsidy recipients.

As stated in the proposed rule and detailed in the associated information collection forms and instructions, the initial error rate methodology includes: (1) *Sample Selection:* A sample of 271 (or 276) cases will be selected by each State using a sampling frame based on the child population served by eligibility offices for each month of the designated Federal Fiscal Year to achieve a 90% confidence level +/− 5%; (2) *Record Review Worksheet:* A template of a record review worksheet will be customized by each State so its worksheet conforms to the specifics of State policies and procedures. The worksheet captures the detail for each element of eligibility, the benefit calculation as documented by the agency, the amount of the subsidy authorized, and any resulting errors; (3) *Case Review:* State reviewers will conduct case record reviews and collect key pieces of information, including administrative errors occurring during the review month, cause of improper authorization for payment, total amount of improper authorizations for payment during the review month, and total amount of authorizations during the review month; (4) *Error Measures Calculation:* States, the District of Columbia, and Puerto Rico will prepare a report calculating percentage of cases with an error, percentage of cases with an improper authorization for payment (expressed as the total number of cases with an improper authorization for payment as compared to the total number of cases), percentage of improper authorizations for payment (expressed as the total amount of improper authorizations for payment compared to the total dollar amount of authorizations made), average amount of improper authorization for payment, and the estimated annual amount of improper authorizations for payment; (5) *Federal Oversight and Monitoring, and Ongoing Technical Assistance:* The Child Care Bureau will provide ongoing oversight, monitoring, and technical assistance.

Under CCDF regulations at 45 CFR 98.52, Lead Agencies are prohibited from spending more than five percent of the aggregate CCDF funds expended by the Lead Agency from each fiscal year's allotment for administrative activities. Section 658E(c)(3)(C) of the CCDBG Act

(42 U.S.C. 9858c(c)(3)(C)) and the accompanying Conference Report (H.R. Conf. Rep. 104–725) specify that the costs of providing direct services are to be excluded from any definition of administrative costs. The Conference Report specifically identified eligibility determination and redetermination, reviews and supervision of child care placements and establishment and maintenance of computerized child care information systems as ''integral part[s] of service delivery'' that ''should not be considered administrative costs.'' Therefore, provided the focus of the error rate calculations and reports continue to focus on client eligibility, costs to Lead Agencies of conducting case reviews and preparing error rate reports shall be considered a part of service delivery and excluded from administrative costs subject to the five percent administrative cap. Further, any costs incurred by a Lead Agency in complying with this regulation that are directed toward establishing or improving child care information systems also shall be excluded from administrative costs subject to the five percent administrative cap.

Should an improper payment related to specific cases that were included in the sample during the case review process be identified, these funds are subject to existing disallowance procedures for misspent funds as set forth at 45 CFR 98.66 of CCDF regulations. Extrapolations of estimated improper payments derived from random sampling of total cases are not subject to disallowance.

Pursuant to CCDF regulations at 45 CFR 98.60(i), a Lead Agency is required to recover child care payments that are the result of fraud. The Lead Agency has discretion as to whether to recover misspent funds that were not the result of fraud, such as in cases of administrative error. Improperly spent funds are subject to disallowance regardless of whether the State pursues recovery.

In the event that improper payments identified through the case review process are recovered, 45 CFR 98.60(g) provides that such payments shall (1) If received by the Lead Agency during the applicable obligation period (described in 45 CFR 98.60(d) & (e)), be used for activities specified in the Lead Agency's approved plan and must be obligated by the end of the obligation period; or (2) if received after the end of the applicable obligation period, be returned to the Federal government.

Section 658F(a) of the CCDBG Act (42 U.S.C. 9858d(a)) makes clear that CCDF funding is not an entitlement to any child care provider or recipient of child care services. As a result, detection of an underpayment in any specific case during the error rate review process does not create an entitlement to that individual to a particular service or benefit. Nothing in this final rule should be construed to create a right requiring the States, the District of Columbia or Puerto Rico to remedy any individual, even if a payment error in the form of an underpayment has been made.

A. Consultation With States, Territories and Other Organizations

The Child Care Bureau has consulted with States, the District of Columbia and Territories since 2003 on different approaches to addressing improper payments and has field tested an error rate methodology in nine volunteer pilot States. Through quarterly conference calls, workshops at annual State Administrators Meetings and an Improper Payments survey, the Child Care Bureau has engaged States and Territories in conversations about strategies to identify, measure, prevent, reduce and collect improper payments. The Child Care Bureau also has been in contact with national organizations such as the American Public Human Services Association, the National Association for Program Information and Performance Measurement and the United Council on Welfare Fraud through conferences, meetings and conference calls regarding strategies to address improper payments.

B. Discussion of Comments

In response to the proposed rule, comments were received from 19 State child care administrators, national child care advocacy groups, and other organizations as follows.

National Error Rate Does Not Reflect Block Grant Flexibility

Comment: Several commenters questioned the practical application of a uniform national error rate to a block grant program, given the differences in programmatic activity that result from the flexibility inherent in CCDF. Commenters felt it would not be appropriate to establish a national error rate, since CCDF eligibility requirements vary greatly across States meaning that the difficulty of achieving accuracy in determining client eligibility varies from State to State. Commenters recommended that the final rule be limited to review of Federal requirements to reflect a true national error rate.

Response: We acknowledge concerns about establishing a national error measure for the CCDF program, and understand that States differ greatly in their eligibility requirements which may lead to a wide range of error rates. A principle goal of CCDF set forth in Section 658A of the Child Care and Development Block Grant (CCDBG) Act of 1990, as amended (42 U.S.C. 9858, *et seq.*), is to ''Allow each State maximum flexibility in developing child care programs and policies that best suit the needs of children and parents within such State.'' As a result, there is significant variation in how CCDF is implemented across the country.

However, the methodology focuses on administrative error associated with client eligibility and improper authorizations for payment. A principal reason for focusing on client eligibility is that, while the methods used to determine initial and ongoing client eligibility are not uniform across States, Territories and Tribes, all States, Territories and Tribes must have procedures in place for parents to apply for child care services and some system to initially determine and periodically re-determine eligibility. Also, determining client eligibility is the first step in the child care subsidy process and therefore affects the administration of the entire program.

The primary purpose of this final rule is to improve State administration of the CCDF program. We believe that the State error measures will be useful for improving overall program integrity and that it will help inform program administrators about which quality control or other initiatives will be most effective in reducing error rates and improper authorizations for payment in their own programs. At the same time, the Improper Payments Information Act (IPIA) requires a national-level measure of improper payments, which will provide a broader perspective of the CCDF program as it is administered across States.

Finally, we do not believe limiting the rule to only Federal requirements would be useful for the purpose of identifying and reducing improper payments. Federal law establishes broad eligibility criteria for families receiving CCDF assistance; however, States, Territories, and Tribes administering CCDF funds may impose more restrictive eligibility standards. States must describe the basis for determining family eligibility in their CCDF Plan and are responsible for ensuring that the program complies with the approved Plan and all Federal requirements. States are accountable for properly implementing the eligibility policies and procedures they have in place.

Short Implementation Timeframe

Comment: A number of commenters expressed concerns about the short implementation timeframe for the proposed rule. Commenters felt that States included in the first cycle of the review process would not have adequate lead time to secure funding from their State legislatures, hire and train staff, prepare and enhance their automated systems, and ensure access to archived records.

Response: The Improper Payments Information Act (IPIA) requires Federal agencies to submit estimates of improper payments to Congress in accordance with guidance prescribed by the Office of Management and Budget (OMB). The timeframe included in the rule is based on the requirement that HHS report a national improper authorizations for payment rate and amount for the CCDF program in the HHS Performance and Accountability Report (PAR) beginning with the Fiscal Year 2008 PAR. We recognize that the timeframe is expedited and will present challenges for some States. The Child Care Bureau intends to assist States by providing significant technical assistance and training to help them implement the error rate review process within the prescribed timeline.

Comment: Three commenters noted that under the proposed timeframe some States will be participating simultaneously in Medicaid's Payment Error Rate Measurement Project (PERM) and the CCDF error rate reporting cycle. Commenters felt that concurrent operation of these projects would create an extraordinary work burden, and asked that States not be subject to error rate reporting by multiple Federal agencies within the same year.

Response: States were randomly selected to participate in a three-year rotational cycle to arrive at a valid nationally representative improper authorizations for payment rate and amount for child care. The sampling approach yielded a mix of county-administered and State-administered programs and programs serving both large and small numbers of children each year. Selectively excluding States would undermine this methodology. The rotational cycle also allows jurisdictions to plan for future reviews because they know in advance in which year they will be measured.

Negative Fiscal Impact on States

Comment: Several commenters argued that the proposed rule would have a wide range of negative fiscal and operational impacts on States and that the additional costs of conducting the proposed activities would compromise the amount of funding available for program services.

Response: This final rule aims to identify and reduce errors and improper payments in the administration of CCDF funds, thus ensuring that the program is operated as efficiently and fairly as possible. Because States, Territories, and Tribes receive a fixed allotment of CCDF funds regardless of the number of children served, fewer improper payments translates into more funds for use in assisting eligible low-income families in purchasing child care services, providing comprehensive consumer education to parents and the public and improving the quality and availability of child care. In addition, we have tried to minimize the fiscal impact of conducting reviews by limiting the frequency of reporting to every three years and by allowing for sampling of cases as part of the review of case records.

Comment: Several commenters felt that the annual burden estimate included in the proposed rule did not reflect the full implementation cost of conducting the error rate review. Commenter's cited additional travel and mailing costs, staff hiring and training, updating automated computer systems, and costs associated with accessing hard copy records for the review process. Commenters found the estimated cost in the NPRM of approximately $150,000 for a single jurisdiction to conduct its case reviews and prepare the required reports to be insufficient. One commenter cited that travel costs alone would exceed the federally estimated cost. Commenters estimated the full implementation cost as ranging from 40 percent higher to as much as four times the proposed $150,000.

Response: We agreed with these comments and have revised the annual burden estimates for conducting the error rate case review and preparing the three required reports in compliance with the final rule. The cost estimate analysis was increased to reflect comments that costs of preparation, training, programming automated systems, and other support activities associated with the information collection forms were underestimated in the proposed rule. States vary greatly in their systems and personnel capacity and the burden of implementing the final rule may disproportionately impact some States more than others. The revised annual burden estimates account for these differences among States and reflect average burden. However, as States implement this methodology, we encourage all States to keep track of the burden associated with these reporting requirements—in terms of both time and monetary cost—and to provide us comments through the Paperwork Reduction Act information collection process so that we can update our estimates if necessary.

Distinction Between Improper Payments and Improper Authorizations for Payment

Comment: Several commenters questioned the inconsistency between the information collection forms and instructions and the regulatory language in the proposed rule, which distinguished between improper authorizations for payment and an actual improper payment. Commenters noted that the forms and instructions require States to report on the ''improper authorizations for payment,'' while the definition of ''improper payment'' given in Section 98.100(d) of the rule defines improper payment as an actual payment. Commenters noted that the broad language of the proposed rule would allow for the imposition of more extensive review and reporting requirements than discussed in the preamble and included in the information collection forms and instructions. Commenters recommended that we amend the rule to define ''improper payment'' consistently with the forms and instructions.

Response: This deviation between the rule and information collection forms and instructions is intentional. The terms ''error'' and ''improper payment'' have purposefully been defined broadly enough in the final rule to encompass reporting on all possible types of errors and improper payments, and are consistent with the definitions used in the Improper Payments Information Act (IPIA). Section 98.100 paragraph (c) defines the term ''error'' and paragraph (d) defines the term ''improper payment.'' The important distinction between the two terms is that every improper payment is the result of an error however, not every error results in an improper payment. Error is defined as any violation or misapplication of statutory, contractual, administrative, or other legally applicable requirements governing the administration of CCDF grant funds, regardless of whether such violations result in an improper payment. An improper payment is defined to mean any payment of CCDF grant funds that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative or other legally applicable requirements governing the administration of CCDF grant funds, including any payment of

CCDF grant funds to an ineligible recipient, any payment of CCDF grant funds for an ineligible service, any duplicate payment of CCDF grants funds and payments of CCDF grant funds for services not received.

At this time, we are implementing this rule narrowly, collecting data from States on improper authorizations for payment due to administrative error in client eligibility determination because we believe that improper authorizations for payment are closely related to improper payments. The forms and instructions related to the regulation deal only with these errors. (**Note:** More information on the forms and instructions that accompany this regulation can be found in the Regulatory Impact Analysis—Paperwork Reduction Act section of this rule.)

Eligibility determination and payment authorization are the first steps in the child care subsidy process and errors made at this stage are likely to affect the administration of the entire program. However, the regulatory language in the final rule provides flexibility to allow for changing or expanding the error rate methodology if future circumstances warrant doing so. Should we decide to revise or broaden the examination of ''error'' and ''improper payment'' we would provide advance notice and an opportunity for public comment through the information collection process.

Comment: Several commenters asked that we clearly differentiate between administrative errors and errors involving the independent verification of eligibility and authorization data elements. Commenters recommended that we amend the language in the proposed rule limiting improper authorizations for payment— ''based on an administrative misapplication of statutory or other legally applicable requirements.''

Response: We believe that the review of administrative errors in eligibility determination should be based on policies States have in place. If a State has established an eligibility verification policy that requires caseworkers to independently verify eligibility through a phone call or otherwise, then this should be documented and supported in the case record. The error rate record review process itself does not require reviewers to independently verify eligibility or other authorization data elements.

Comment: A few commenters were concerned that the initial error rate methodology's focus on eligibility determination and authorization for payment does not mirror administrative procedures for many States in which clients are deemed eligible for CCDF and authorized for a range of services and a subsidy rate, but then choose a particular service from that range and receive actual payment based on the appropriate applied subsidy.

Response: We acknowledge that State policies regarding eligibility determination and subsidy payment vary in the extent to which they are interrelated. As long as the client's eligibility and authorization for payment is correctly determined there is no error. If the authorized payment range properly reflects the client's eligibility status and need for care there is no improper authorization for payment. The initial error rate methodology is focused on client eligibility, and authorization to receive a subsidy is indicative of whether the eligibility determination process was properly conducted. Further, we received comments from a number of States indicating that their administrative procedures do align with the error rate methodology. These commenters said that there was not a distinction between an authorization for payment and actual payment in their processing of claims for service, and thus there would be little additional value to expanding the measurement of improper payments beyond improper authorizations for payment.

Multiple and Combined Funding Sources for Child Care

Comment: Several commenters requested that the proposed rule apply only to those cases reported on the ACF–801 reporting form to define the sample population as only those cases paid for with CCDF and pooled funds. Commenters were concerned that purely State-funded child care services also would be accountable to the proposed rule.

Response: This final rule applies to all child care cases served with CCDF grant funds, including Federal Discretionary Funds (which includes any funds transferred from the Temporary Assistance for Needy Families Block Grant), Mandatory and Matching Funds and State Matching and Maintenance-of-Effort (MOE) Funds. In States that cannot separately report on cases served with CCDF funds only, the rule applies to cases served by all child care funds pooled with CCDF. For many States, this will correspond to those cases reported on the ACF–801 reporting form.

Comment: One commenter suggested that we allow States that pool CCDF and non-CCDF funds to use the percentage of total CCDF expenditures to calculate an estimated amount of CCDF funds used to provide child care subsidies impacted in the sample.

Response: We recognize that many States do not serve children exclusively with CCDF funds. Many States combine CCDF and non-CCDF funds to serve the child care needs of their State—referred to as ''pooling'' funds—and may be unable to isolate those cases served only by CCDF funds. We have modified the information collection forms and instructions to allow States that pool child care funds (and correspondingly draw their sample for the error rate review from the universe of cases served by these combined funds) to multiply the total pooled child care funds by a percentage that reflects the proportion of these funds that are CCDF funds (also referred to as a ''pooling factor'') when calculating the total estimated amount of annual improper authorizations for payment. This will more accurately reflect the amount of improperly spent CCDF funds in those States that combine CCDF with non-CCDF funds to provide child care services.

Anticipated Problems With Sampling Methodology and Record Review

Comment: Some commenters thought that the proposed sampling frame would be a burden for States with smaller caseloads and suggested the sample size be determined based on the universe of cases in a particular State.

Response: Under § 98.101, Case Review Methodology, the error reports required by this final rule must be based on comprehensive reviews of case records conducted in accordance with the methodology detailed in this final rule and associated information collection forms and instructions. In determining which case records to review, States, the District of Columbia, and Puerto Rico must select a random sample of 271 (or 276) child records to achieve the calculation of an estimated annual amount of improper authorizations for payment with a 90 percent confidence interval of +/− 5.0 percent. We believe this sampling frame will achieve statistically valid data with the desired confidence levels. Sampling the same number of cases, regardless of caseload size, standardizes the methodology across States and reflects accepted practice for achieving the required precision.

Comment: Several commenters opposed the requirement to draw the sample of cases from 12 monthly sampling frames and suggested that States be allowed to choose a particular month from which to draw the sample for the error rate review.

Response: We believe the sampling methodology included in the rule

reduces the risk of bias in annual estimates associated with selection of the sample in particular months and accounts for variation that may occur throughout the year. If States were to review less than twelve months for the sampling frame, the resulting error rate would not be representative of the entire year.

Comment: A few commenters pointed out that some States do not have statewide data systems, particularly States that are county-administered, or do not have a system advanced enough to support the sampling methodology in the proposed rule. Commenters recommended that States be given flexibility to define the case review process based on the availability of data and case file information systems that exist in each State.

Response: A standard sampling methodology is necessary to ensure integrity and promote uniformity across States—particularly since State results will be used to calculate a national measure for improper payments. We understand automated systems capacity varies across States and that some States may have more difficulty in obtaining their sample and associated case records. For this reason we have increased the burden estimate associated with the information collection forms to reflect additional costs faced by States to implement the sampling methodology.

Comment: A number of commenters thought that accessing hard copy case records to conduct the record review process would require State staff to travel long distances in order to pick-up and/or review records or would require the case records to be mailed to the review location and require substantial postal costs. Commenters felt that there should be consideration in the proposed rule allowing for incomplete reviews due to inability to locate case records.

Response: We recognize that States have different recordkeeping procedures and may face additional costs to locate records for the review. As previously stated, we have tried to build these costs into the revised annual burden estimate in the final rule. The sampling process requires States to select at least three alternate replacement cases that can be used in the event a case cannot be reviewed for some valid reason.

Comment: Several commenters were unclear about the unit of measurement for drawing the sample. Section 98.101(a) of the proposed rule refers to both ''case records'' and ''child records.'' Commenters recommended the rule and information collection forms and instructions allow States flexibility to define the term ''case'' to be a child or a family.

Response: For initial implementation of the error rate methodology we intend for the error rate review to apply to child records and this is stated in the information collection forms and instructions. States do not have the flexibility to determine whether the case record should be based on the child or the family. However, consistent with the broader intent of the final rule, the regulatory language at 98.101(a) continues to use the more inclusive term ''case record'' to allow for future adjustments of the error rate methodology. The reference to ''child record'' also included at 98.101(a) has been changed to ''case record'' to eliminate any confusion.

Disallowance and Recovery of Funds

Comment: Many commenters did not understand the reference to disallowed funds in the proposed rule, given that the preamble and the information collection forms and instructions clearly stated the focus of the review to be on improper authorizations for payment. Commenters were further concerned that interest would be owed to the Federal government on disallowances. Commenters thought that as long as the case review is limited to improper authorizations for payment it would be incorrect to assume that an improper payment in the amount of the authorization resulted, meaning States would be unjustifiably penalized.

Response: In order for child care subsidies to be received by eligible recipients, States need to accurately authorize payment for child care services. It is our assumption that an improper authorization for payment will result in an improper payment which will be subject to a disallowance. However, if a State can demonstrate that an authorized improper payment was not actually made, that dollar amount would not be disallowed. Any actual improper payments related to specific cases in the sample are subject to disallowance in accordance with procedures set forth in 45 CFR 98.66 of the CCDF regulations. Section 98.66(3)(j) states that disallowances are subject to interest from the date of notification of the disallowance. When an improper authorization for payment is identified during the case record review process, the ACF regional office will work with the State to determine if an improper payment was made and the amount of the disallowance, if appropriate, using its customary procedures.

Comment: A few commenters pointed out that if the proposed error rate reporting cycle concludes after the grant year for which an obligation is paid to a recipient, States that recover payments may be acting after the obligation period, and thus must return the money to the Federal government. Commenters recommended that any payments recouped through the proposed rule be committed to program reinvestment and error rate reduction efforts.

Response: Pursuant to CCDF regulations at 45 CFR 98.60(i), a Lead Agency is required to recover child care payments that are the result of fraud. The Lead Agency has discretion as to whether to recover misspent funds that were not the result of fraud, such as in cases of administrative error. Improperly spent funds are subject to disallowance regardless of whether the State pursues recovery.

In the event that improper payments identified through the case review process are recovered, 45 CFR 98.60(g) provides that such payments shall (1) If received by the Lead Agency during the applicable obligation period (described in 45 CFR 98.60(d) & (e)), be used for activities specified in the Lead Agency's approved plan and must be obligated by the end of the obligation period; or (2) if received after the end of the applicable obligation period, be returned to the Federal government.

States may act to recover improper payments as soon as they are identified and need not wait until the end of the Federal error rate reporting cycle.

We do not have statutory authority to waive requirements related to funds that are recovered by Lead Agencies or mandated obligation and liquidation periods.

Penalties or Incentives Associated With Error Rates

Comment: Two commenters asked whether a State would be penalized if a certain error rate is found or if incentives would be offered for high performing States.

Response: While States are subject to disallowances for any identified improper payments (as they would be for any expenditures not made in accordance with CCDF regulations or the approved Plan identified outside of the error rate review process), there will not be penalties or incentives based on State error rates. We view the State error rate to be primarily useful for the States to inform quality control initiatives and improve program integrity. An incentive for States to decrease error rates and improper authorizations for payment is the increased availability of funds to serve CCDF eligible families.

Rule Undermines Existing State Efforts

Comment: Two commenters believed the focus in the proposed rule on client eligibility determination would be counterproductive for States that have existing strategies with proven results in reducing improper payments. Commenters felt the proposed rule might decrease focus in some States on errors in CCDF provider payments.

Response: We support existing State efforts to reduce improper payments and improve program integrity. States should continue to look at all aspects and areas in which there is risk for an improper payment to be made. We recognize that States are at different places in terms of approaches and initiatives to address program integrity. A section in the CCDF State Plan Pre-Print gives States an opportunity to provide descriptions and information related to these initiatives. We look forward to working with States to ensure that this final rule will complement, not supersede or complicate, existing State efforts.

Comment: A number of commenters thought that establishing a State baseline error rate and setting future target rates does not recognize the present actions of States to limit their exposure to incorrect eligibility authorizations. Commenters thought that States with more stringent standards for reducing administrative errors in client eligibility determination may be given an incentive to reduce their current efforts in order to establish more feasible future target rates.

Response: Section 98.102 of the final rule, Content of Error Rate Reports, addresses submission of baseline reports and standard reports. Under paragraph (a), in the initial cycle, States, the District of Columbia and Puerto Rico are required to submit a baseline report listing baseline error rate information and targets for the next cycle, as well as information about causes of, and strategies to address, error and information about their information technology systems. Under proposed paragraph (b), in subsequent cycles, States, the District of Columbia and Puerto Rico must submit a standard report that, in addition to updating the information provided in the baseline report, enables States, the District of Columbia and Puerto Rico to examine their ability to meet previously submitted targets, set future targets, and describe strategies to reduce their error rates.

Establishing a baseline error rate and setting future target rates is essential for measuring progress and improvement over time. Each State will have the ability to set its future targets based on their specific circumstances, including prior efforts to control improper payments. Additionally, the reported State error and improper authorizations for payment rates are not tied to any penalties. The State baseline and target setting should be used to inform existing prevention efforts and improve or validate their effectiveness.

We have deleted the parenthetical language at Section 98.102(a)(6) stating that targets for errors and improper payments must be lower than the most recent estimated error rates. We made this change recognizing that it is possible for a State to achieve a zero error rate thereby making the requirement obsolete.

We continue to expect States to set ambitious targets for reducing improper payments for each reporting cycle. As is described in the accompanying forms and instructions, State targets should anticipate continuous improvement. We intend this rule to be written broadly to accommodate any future efforts to revise or change the error rate reporting methodology. We believe it is more practical to add guidance on setting future target rates to the information collection forms and instructions rather than include it in the regulatory language.

Combining Overauthorizations and Underauthorizations

Comment: One commenter noted that the proposed rule requires States to report a combined ''improper authorizations'' figure that sums overauthorizations and underauthorizations together. The commenter thought that reporting only a combined figure could be misleading and mask the underlying source of the error. The commenter recommended that we require States to report separate figures for overauthorizations and underauthorizations along with a combined figure, and clarify in the instructions what amount of actual improper payments States are to base an anticipated recovery amount on.

Response: We agree with the comment and have changed the information collection forms and instructions to require States to separately report overauthorizations, underauthorizations, and the total combined figure. We also have clarified that States should base their expected recovery amounts on overauthorization amounts only.

Allowing a Threshold for Improper Authorizations

Comment: One commenter argued that factors affecting authorized payment levels could fluctuate from month to month, and States have discretion to determine the magnitude of changes that must be reported and applied in calculating CCDF benefits. The commenter felt that, similarly, small fluctuations in a clients' financial status should not be considered in the calculation of the number and percentage of cases with an improper authorization for payment. The commenter recommended clarifying the regulation to stipulate that changes in circumstances that do not need to be reported by clients will not be counted against the States as administrative errors.

Response: The initial methodology for the error rate review process is developed according to State-established policies and procedures in place to determine client eligibility for CCDF and to authorize payments. The process examines administrative error based on information in the case record that is available to the State. If a State does not require a client to report small changes in financial status this would not violate State policy and it would not be considered an error or improper authorization for payment, provided that the small change in financial status did not result in a violation of Federal income requirements, which cannot be waived.

C. Changes Made in Final Rule

As discussed above, three technical changes are made to the final rule in response to public comment. First, the annual burden estimate associated with the accompanying information collection forms and instructions has been increased to reflect public comments regarding additional costs of the error rate reporting review associated with staff, travel, accessing records, and automated systems. Secondly, the word ''child''after Sec. 98.101(a) has been replaced with the word ''case''to provide consistency in the terms used to refer to ''record''in the regulation. Lastly, we have deleted the parenthetical language at Section 98.102(a)(6) stating that targets for errors and improper payments must be lower then the most recent estimated error rates. We intend this rule to be written broadly and believe it is more practical to add guidance on setting future target rates to the information collection forms and instructions rather than include it in the rule itself.

V. Regulatory Impact Analyses

A. Executive Order 12866

Executive Order 12866 requires that regulations be drafted to ensure that

they are consistent with the priorities and principles set forth in Executive Order 12866. The Department has determined that this final rule is consistent with these priorities and principles.

Executive Order 12866 encourages agencies, as appropriate, to provide the public with meaningful participation in the regulatory process. As described earlier, the Child Care Bureau has consulted with States, the District of Columbia, and Territories on numerous occasions since 2003 concerning different approaches to addressing improper payments and has field tested an error rate methodology in nine volunteer pilot States. Specifically, through quarterly conference calls, workshops at annual State Administrators Meetings and an Improper Payments survey, the Child Care Bureau has engaged States and Territories in conversations about strategies to identify, measure, prevent, reduce and collect improper payments. The Child Care Bureau also has been in contact with national organizations such as the American Public Human Services Association, the National Association for Program Information and Performance Measurement and the United Council on Welfare Fraud through conferences, meetings and conference calls regarding strategies to address improper payments. In addition, we have provided a 60-day public comment period and have responded to comments in this final rule.

This rule is considered a ''significant regulatory action'' as defined under Executive Order 12866 and therefore has been reviewed by the Office of Management and Budget. Specifically, the rule raises ''novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.''

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) (5 U.S.C. Ch. 6) requires the Federal government to anticipate and reduce the impact of rules and paperwork requirements on small businesses and other small entities. Small entities are defined in the RFA to include small businesses, small non-profit organizations and small governmental entities. This rule will affect only the 50 States, the District of Columbia and Puerto Rico. Therefore, the Secretary certifies that this rule will not have a significant impact on small entities.

C. Assessment of the Impact on Family Well-Being

We certify that we have made an assessment of this final rule's impact on the well-being of families, as required under Section 654 of the Treasury and General Appropriations Act of 1999. This final rule aims to identify and reduce errors in the administration of CCDF funds, thus ensuring that the program is operated as efficiently and fairly as possible. Because States receive a fixed allotment of CCDF funds regardless of the number of children served, fewer improper payments translates into more funds for use in assisting low-income families in purchasing child care services, providing comprehensive consumer education to parents and the public and improving the quality and availability of child care.

D. Paperwork Reduction Act

The final rule requires States, the District of Columbia and Puerto Rico to compile information regarding errors made in the administration of CCDF funds using an error rate methodology established by the Secretary and detailed in this rule and information collection forms and instructions. Towards this end, this rule will require States, the District of Columbia and Puerto Rico to submit reports to the Department on their findings.

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR 1320) requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

The information collections in this rule, described below, are being reviewed by OMB and will not be effective until they have received OMB approval. Once they have received OMB approval, ACF will publish a notice in the **Federal Register** and make them available on the Child Care Bureau's Web page on Addressing Improper Payments at: *http://www.acf.hhs.gov/programs/ccb/ccdf/ipi/ipi.htm.*

Title: Child Care and Development Fund: Error Rate Report for States, the District of Columbia and Puerto Rico.

Description: States, the District of Columbia and Puerto Rico must prepare and submit to the Department reports of errors occurring in the administration of CCDF grant funds. They will be required to report the percentage of cases with an error; the percentage of cases with an improper authorization for payment; the percentage of improper authorizations for payment; the average improper authorization for payment amount; and the estimated annual amount of improper authorizations for payment. The report also will provide strategies for reducing the error rates and allow States, the District of Columbia and Puerto Rico to set target error rates for the next cycle.

Respondents: The fifty States, the District of Columbia and Puerto Rico.

Changes in Estimate of Burden

The annual burden in the proposed rule was estimated to be $150,000 per respondent. This estimate included the cost of drawing the sample of cases from 12 monthly sampling frames, training staff, conducting record reviews, compiling data, calculating error rates and preparing the final report. In estimating burden, we used information based on the error rate pilots and an estimation of the amount of time and cost required to complete various tasks associated with each of the three reporting forms: (1) The Record Review Worksheet, (2) the Data Entry Form, and (3) the State Improper Authorizations for Payment Report. In response to public comments, we have recalculated the burden estimate associated with each of these forms. The final rule increases the total cost estimate for case reviews and preparing the required reports to approximately $180,000 per respondent.

In the proposed rule the total burden hours associated with the Record Review Worksheet included sampling, preparation and training, and record review. We have increased the burden associated with the preparation and training component of this estimate to account for additional costs of mailing hard copy records, traveling to sites where records are maintained, or costs to enhance automated systems to access case records. Additionally, we have increased the burden associated with the record review component for completion of the Record Review Worksheet. Based on public comment we felt the original estimate did not adequately reflect the burden of implementing quality control activities associated with completion of this form.

In the proposed rule, the burden hours associated with the Data Entry Form primarily included the costs of consolidating information. The burden estimate associated with this form has been increased to account for public comment regarding costs of writing computer programs and making enhancements to automated systems to consolidate large quantities of data,

which were not considered in the original estimate.

Finally, in the proposed rule the burden hours associated with the State Improper Authorizations for Payment Report included the calculation of the findings and discussion of findings and report preparation. The burden estimate for completion of these two tasks associated with this form was not changed. However, we have added an additional component necessary for completion of this report, which was not previously considered. This component is the calculation of the total amount of authorizations for payment during the review period needed to compute the final error measure. The burden hours associated with completion of this report increased with the addition of this task.

The original burden estimate in the proposed rule did not account for States in which aggregate information on total amount of authorized payments was not readily available. Obtaining aggregate authorizations for payment information increases burden for States in which normal reporting requirements involve aggregate payments or total expenditures, not authorizations for payment. These States will experience increased burden for completion of this report if they are to generate the total for calculation of the required error measure. While it is important to account for the additional burden associated with this task, we continue to believe that reviewing authorizations for payment, rather than actual payments, is less burdensome for States when reviewing individual case records. We believe the benefits of focusing the individual record reviews on authorizations for payments outweighs any additional costs we have added here for completing the aggregated State Improper Authorizations for Payment Report. However, we encourage all States to keep track of the burden associated with these reporting requirements—in terms of both time and monetary cost—and to provide us comments through the Paperwork Reduction Act information collection process so that we can accurately account for the burden and more precisely determine the benefits and costs of these requirements.

RECALCULATED ANNUAL BURDEN ESTIMATES FOR FINAL RULE

Instrument or requirement	Number of respondents*	Yearly submittals	Average burden hours per submittal		Total burden hours	
			NPRM	Final rule	NPRM	Final rule
Record Review Worksheet	17.33	**271	13.74	15.43	64,562	72,478
Data Entry Form	17.33	**271	.14	.17	652	815
State Improper Payments Report	17.33	1	367	627	6360	10,864
Estimated Total Annual Burden Hours	.....	.....	.....	.....	71,574	84,157

* States, the District of Columbia and Puerto Rico will compile and submit error rate reports in staggered three-year cycles.
** These burden estimates are based on a review of 271 cases, which is estimated to be the amount needed to meet the sampling requirements of the rule.

E. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that a covered agency prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year.

The total annual cost burden of having 17.33 respondents, the average number required in any year, to conduct error rate case reviews and prepare the required reports would be approximately $3.1 million. Thus, this final rule will not result in the expenditure by State, territorial, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year.

F. Congressional Review

This final rule is not a major rule as defined in 5 U.S.C. 804.

G. Executive Order 13132

Executive Order 13132 guarantees ''the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution, to ensure that the principles of federalism established by the Framers guide the executive departments and agencies in the formulation and implementation of policies, and to further the policies of the Unfunded Mandates Reform Act.''

The Secretary certifies that this final rule does not have a substantial direct effect on States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. This final rule does not preempt State law and does not impose unfunded mandates.

This final rule does not contain regulatory policies with federalism implications that would require specific consultations with State or local elected officials.

List of Subjects in 45 Part 98

Administrative practice and procedure, Day care, Grant programs, Reporting and recordkeeping requirements.

(Catalogue of Federal Domestic Assistance Programs: 93.575, Child Care and Development Block Grant; 93.596, Child Care Mandatory and Matching Funds)

Dated: June 22, 2007.

Daniel C. Schneider,

Acting Assistant Secretary for Children and Families.

Approved: July 19, 2007.

Michael O. Leavitt,

Secretary, Department of Health and Human Services.

■ For the reasons set forth in the preamble, the Administration for Children and Families amends part 98 of title 45 of the Code of Federal Regulations as follows:

PART 98—CHILD CARE AND DEVELOPMENT FUND

■ 1. The authority for part 98 continues to read:

Authority: 42 U.S.C. 618, 9858.

■ 2. Amend 45 CFR part 98 to add Subpart K to read as follows:

Subpart K—Error Rate Reporting

Sec.

Subpart K—Error Rate Reporting

§ 98.100 Error Rate Report.

(a) *Applicability*—The requirements of this subpart apply to the fifty States, the District of Columbia and Puerto Rico.

(b) *Generally*—States, the District of Columbia and Puerto Rico shall calculate, prepare and submit to the Department, a report of errors occurring in the administration of CCDF grant funds, at times and in a manner specified by the Secretary in instructions. States, the District of Columbia and Puerto Rico must use this report to calculate their error rates, which is defined as the percentage of cases with an error (expressed as the total number of cases with an error compared to the total number of cases); the percentage of cases with an improper payment (expressed as the total number of cases with an improper payment compared to the total number of cases); the percentage of improper payments (expressed as the total amount of improper payments in the sample compared to the total dollar amount of payments made in the sample); the average amount of improper payment; and the estimated annual amount of improper payments. The report also will provide strategies for reducing their error rates and allow States, the District of Columbia and Puerto Rico to set target error rates for the next cycle.

(c) *Error Defined*—For purposes of this subpart, an ''error'' shall mean any violation or misapplication of statutory, contractual, administrative, or other legally applicable requirements governing the administration of CCDF grant funds, regardless of whether such violation results in an improper payment.

(d) *Improper Payment Defined*—For purposes of this subpart, ''improper payment.''

(1) Means any payment of CCDF grant funds that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements governing the administration of CCDF grant funds; and

(2) Includes any payment of CCDF grant funds to an ineligible recipient, any payment of CCDF grant funds for an ineligible service, any duplicate payment of CCDF grant funds and payments of CCDF grant funds for services not received.

(e) *Costs of Preparing the Error Rate Report*—Provided the error rate calculations and reports focus on client eligibility, expenses incurred by the States, the District of Columbia and Puerto Rico in complying with this rule, including preparation of required reports, shall be considered a cost of direct service related to eligibility determination and therefore is not subject to the five percent limitation on CCDF administrative costs pursuant to Section 98.52(a).

§ 98.101 Case Review Methodology.

(a) *Case Reviews and Sampling*—In preparing the error reports required by this subpart, States, the District of Columbia and Puerto Rico shall conduct comprehensive reviews of case records using a methodology established by the Secretary. For purposes of the case reviews, States, the District of Columbia and Puerto Rico shall select a random sample of case records which is estimated to achieve the calculation of an estimated annual amount of improper payments with a 90 percent confidence interval of +/−5.0 percent.

(b) *Methodology and Forms*—States, the District of Columbia and Puerto Rico must prepare and submit forms issued by the Secretary, following the accompanying instructions setting forth the methodology to be used in conducting case reviews and calculating the error rates.

(c) *Reporting Frequency and Cycle*—States, the District of Columbia and Puerto Rico shall conduct case reviews and submit error rate reports to the Department according to a staggered three-year cycle established by the Secretary such that each State, the District of Columbia, and Puerto Rico will be selected once, and only once, in every three years.

(d) *Access to Federal Staff*—States, the District of Columbia and Puerto Rico must provide access to Federal staff to participate and provide oversight in case reviews and error rate calculations, including access to forms related to determining error rates.

(e) *Record Retention*—Records pertinent to the case reviews and submission of error rate reports shall be retained for a period of five years from the date of submission of the applicable error rate report or, if the error rate report was revised, from the date of submission of the revision. Records must be made available to Federal staff upon request.

§ 98.102 Content of Error Rate Reports.

(a) *Baseline Submission Report*—At a minimum, States, the District of Columbia and Puerto Rico shall submit an initial error rate report to the Department, as required in § 98.100, which includes the following information on errors and resulting improper payments occurring in the administration of CCDF grant funds, including Federal Discretionary Funds (which includes any funds transferred from the TANF Block Grant), Mandatory and Matching Funds and State Matching and Maintenance-of-Effort (MOE Funds):

(1) Percentage of cases with an error (regardless of whether such error resulted in an over or under payment), expressed as the total number of cases in the sample with an error compared to the total number of cases in the sample;

(2) Percentage of cases with an improper payment (both over and under payments), expressed as the total number of cases in the sample with an improper payment compared to the total number of cases in the sample;

(3) Percentage of improper payments (both over and under payments), expressed as the total dollar amount of improper payments in the sample compared to the total dollar amount of payments made in the sample;

(4) Average amount of improper payments (gross over and under payments, divided by the total number of cases in the sample that had an improper payment (both over and under payments));

(5) Estimated annual amount of improper payments (which is a projection of the results from the sample to the universe of cases statewide during the 12-month review period) calculated by multiplying the percentage of improper payments by the total dollar amount of child care payments that the State, the District of Columbia or Puerto Rico paid during the 12-month review period

(6) For each category of data listed above, targets for errors and improper payments in the next reporting cycle;

(7) Summary of methodology used to arrive at estimate, including fieldwork preparation, sample generation, record review and error rate computation processes;

(8) Discussion of the causes of improper payments identified and actions that will be taken to correct those causes in order to reduce the error rates;

(9) Description of the information systems and other infrastructure that assist the State, the District of Columbia and Puerto Rico in identifying and reducing improper payments, or if the State, the District of Columbia or Puerto Rico does not have these tools, a description of actions that will be taken to acquire the necessary information systems and other infrastructure; and

(10) Such other information as specified by the Secretary.

(b) *Standard Report*—At a minimum, the State, the District of Columbia and Puerto Rico shall submit an error rate report to the Department, as required in § 98.100, made subsequent to the baseline submission report as set forth in § 98.102(a) which includes the following information on errors and resulting improper payments occurring in the administration of CCDF grant funds, including Federal Discretionary Funds (which includes any funds transferred from the TANF Block Grant), Mandatory and Matching Funds and State Matching and Maintenance-of-Effort (MOE Funds):

(1) All the information reported in the baseline submission, as set forth in § 98.102(a), updated for the current cycle;

(2) For each category of data listed in § 98.102(a)(1) through (5), States, the District of Columbia and Puerto Rico must include data and targets from the prior cycle in addition to data from the current cycle and targets for the next cycle;

(3) Description of whether the State, the District of Columbia or Puerto Rico met error rate targets set in the prior cycle and, if not, an explanation of why not;

(4) Discussion of the causes of improper payments identified in the prior cycle and actions that were taken to correct those causes, in addition to a discussion on the causes of improper payments identified in the current cycle and actions that will be taken to correct those causes in order to reduce the error rates; and

(5) Such other information as specified by the Secretary.

[FR Doc. 07–4308 Filed 8–29–07; 3:01 pm]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA 2007–29131]

RIN 2127–AI93

Federal Motor Vehicle Safety Standards; Occupant Protection in Interior Impact

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: Our safety standard on occupant protection in interior impact requires, in part, that light vehicles provide head protection when an occupant's head strikes upper interior components, such as pillars, side rails, headers, and the roof during a crash. While these requirements already apply to most vehicles, the compliance date for altered vehicles and vehicles built in two or more stages is September 1, 2007. In April 2006, we responded to two petitions for rulemaking by proposing certain amendments to the head protection requirements as they apply to these vehicles. We also proposed to delay the compliance date of the requirements for these vehicles. In this document, after carefully considering both the safety benefits of the upper interior protection requirements and practicability concerns relating to vehicles built in two or more stages and certain altered vehicles, we are amending the standard to limit these requirements to only the front seating positions of those vehicles. In addition, we are excluding from the requirements a narrow group of multi-stage vehicles delivered to the final stage manufacturer without an occupant compartment. Finally, we have decided to delay the compliance date of the head impact protection requirements as they apply to final stage manufacturers and alterers until September 1, 2009.

DATES: The amendments made by this final rule are effective September 1, 2007. The compliance date for the head impact protection requirements for altered vehicles and vehicles built in two or more stages is September 1, 2009.

Petitions for reconsideration: Petitions for reconsideration of this final rule must be received not later than October 22, 2007.

ADDRESSES: Petitions for reconsideration should refer to the docket number above and be submitted to: Administrator, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., West Building, 4th Floor, Washington, DC 20590.

See the **SUPPLEMENTARY INFORMATION** portion of this document (Section V; Rulemaking Analyses and Notices) for DOT's Privacy Act Statement regarding documents submitted to the agency's dockets.

FOR FURTHER INFORMATION CONTACT: The following persons at the National Highway Traffic Safety Administration, 1200 New Jersey Ave., SE., Washington, DC 20590:

For technical and policy issues: David Sutula, Office of Crashworthiness Standards, telephone: (202) 366–3273, facsimile: (202) 366–7002, E-mail: *David.Sutula@dot.gov.*

For legal issues: Ari Scott, Office of the Chief Counsel, telephone: (202) 366–2992, facsimile: (202) 366–3820, E-mail: *Ari.Scott@dot.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background

a. Previous History of Head Protection Requirements of FMVSS No. 201

On August 18, 1995, the National Highway Traffic Safety Administration (NHTSA) issued a final rule (August 1995) amending Federal Motor Vehicle Safety Standard (FMVSS) No. 201, ''Occupant Protection in Interior Impact,'' to provide enhanced head impact protection.[1] The August 1995 final rule required passenger cars, and trucks, buses and multipurpose passenger vehicles (MPVs) with a gross vehicle weight rating (GVWR) of 4,536 kilograms (10,000 pounds) or less, to provide protection when an occupant's head strikes upper interior components, including pillars, side rails, headers, and the roof, during a crash. The final rule set minimum performance requirements for upper interior components by establishing target areas that must be padded or otherwise have energy absorbing properties to minimize head injury in the event of a crash. The final rule added procedures for a new in-vehicle component test in which a free-motion head form (FMH) is fired at certain target locations on the upper interior of a vehicle at an impact speed of 24 km/h (15 mph). Targets that are

[1] See 60 FR 43031, Aug. 18, 1995; Docket No. NHTSA–1996–1762–1.

located on or within 50 mm (2 inches) of dynamically deployable upper interior head protection systems (air bags systems) can, at the option of the manufacturer, be impacted at the reduced speed of 19 km/h (12 mph). Data collected from a FMH impact are translated into a Head Injury Criterion (HIC(d)) score. The resultant HIC(d) must not exceed 1000.

The 1995 final rule provided manufacturers with three alternate phase-in schedules for complying with the FMH impact requirements. At this time, all vehicles except altered vehicles and vehicles manufactured in two or more stages are required to comply with the FMH impact requirements. The compliance date for altered vehicles and vehicles manufactured in two or more stages to comply with these requirements has been delayed several times, and is presently September 1, 2007.[2]

b. Petitions for Rulemaking and Agency Response

This rulemaking was initiated in response to petitions for rulemaking submitted by the Recreation Vehicle Industry Association (RVIA) and the National Truck Equipment Association (NTEA). The member companies of RVIA and NTEA are generally considered final stage manufacturers and alterers. That is, they purchase incomplete vehicles from major manufacturers to serve as the basis for specialty vehicles (manufactured in two or more stages) for certain uses and markets, or alter completed vehicles prior to first retail sale. As such, the petitioners' members face a variety of challenges in certifying that their vehicles meet applicable safety standards. We note that with respect to vehicles manufactured in two or more stages, some multi-stage vehicles are built from chassis-cabs with a completed occupant compartment. Others are built from less complete vehicles, sometimes necessitating the addition by the final stage manufacturer of its own occupant compartment. The final stage manufacturer is responsible for certification of the completed vehicle, although certification can often ''pass-through'' from the incomplete vehicle manufacturer.

RVIA and NTEA petitioned the agency to permanently exclude certain types of altered vehicles and vehicles manufactured in two or more stages from these requirements. On April 24, 2006, the agency published in the **Federal Register** (71 FR 20932) a response to petitions for rulemaking; notice of proposed rulemaking (NPRM)[3] in response to those petitions. NHTSA granted the petitions in part and denied them in part, and proposed certain amendments to the standard.

II. Summary of the Notice of Proposed Rulemaking

As indicated above, the agency published its April 2006 NPRM in response to the RVIA and NTEA petitions. The NPRM proposed to limit the occupant compartment area subject to the FMH impact requirements in ambulances, motor homes, and other vehicles manufactured in two or more stages, as well as altered vehicles. Furthermore, the NPRM proposed to exclude from the requirements a narrow group of multi-stage vehicles delivered to the final stage manufacturer without an occupant compartment. Finally, the NPRM proposed to delay the effective date of the requirements to September 1, 2008.

a. Proposal To Limit the Area Subject to the FMH Impacts in Certain Vehicles

In ambulances and motor homes, the current standard excludes the occupant compartment area located more than 600 mm (24 inches) behind the seating reference point of the driver's seating position from the FMH impact requirements. For all other vehicles, the occupant compartment area located more than 600 mm (24 inches) behind the seating reference point of the rearmost designated seating position is similarly excluded from the FMH impact requirements.

For altered vehicles and vehicles manufactured in two or more stages, including motor homes and ambulances, we proposed to limit the area subject to the FMH impact requirements to not more than 300 mm (12 inches) behind the seating reference point of the driver's seating position. We stated that this would have the effect of limiting the FMH impact requirements to the front seating positions for these vehicles. We stated our belief that the distance reduction to 300 mm (12 inches) is more representative of the distance between the seating reference point and the upper seat back/head restraint location where the occupant's head is located. We also stated that because of the front head restraint height requirements, we believe it is unlikely that the head of a seated occupant would come in contact with bulkheads, partitions, or overhead cabinets and storage shelves located further than 300 mm (12 inches) behind the seating reference point (SgRP) of the driver's seating position.

We stated that in developing this proposal, we had carefully considered both the safety benefits of the FMH requirements and practicability concerns relating to multistage vehicles. Based on previous estimates of the benefits of the FMVSS No. 201 final rule, and estimates from the National Automotive Sampling System, Crashworthiness Data System of the percent of injuries occurring to light truck occupants in multi-stage vehicles, the agency derived the following estimate of safety benefits. Requiring all multi-stage manufactured vehicles to meet FMVSS No. 201 would have annual benefits in the front seat of 16–22 fewer fatalities and 19–22 fewer AIS 2–5 injuries. However, in the rear seats, the benefits were estimated to be less than 1 fatality (which would round down to 0) and 1 AIS 2–5 injury. Thus, based on this analysis, excluding multi-stage vehicles from targets that could not be struck by the front row occupants would have a very small impact on safety.

Given the small safety benefits associated with the FMH impact requirements for rear seating positions and practicability concerns, we tentatively concluded that the FMH impact requirements should be limited to the front seating positions for these vehicles.

We noted that, as indicated in its petition, many commercial vehicles manufactured by NTEA members feature bulkheads or partitions located less than 600 mm (24 inches) behind the rearmost designated seating position. Bulkheads or partitions are used in a variety of work vehicles that haul odd-shaped objects that cannot be readily secured in the cargo area. These structures protect the driver and passenger from loose or shifting cargo or work equipment. NTEA had argued that the installation of bulkheads or partitions would likely require relocation of target areas originally certified by the incomplete vehicle manufacturer, thus significantly adding to the compliance burden.

We also noted that RVIA had argued that most conversion vans (CVs) and motor homes feature unique interior designs. Specifically, these vehicles include overhead cabinets, side valances, raised roof structures, and other unusual interior components. Among other things, RVIA stated that cooperative testing, suggested by NHTSA as a way to lessen compliance costs associated with FMH requirements, is not practicable because each RVIA member manufactures

[2] See 71 FR 51121, August 29, 2006.

[3] Docket No. NHTSA–2006–24497.

unique vehicles, each substantially different from its competitors. RVIA argued that cooperative testing would eliminate interior customization, which would in turn result in a loss of market for CVs and motor homes.

We stated that we believed our proposal to effectively limit the FMH impact requirements to the front seating positions for these vehicles would provide appropriate relief to the industries represented by NTEA and RVIA, while continuing to meet the need for safety.

We noted that NTEA and RVIA members can ordinarily purchase incomplete vehicles that are already designed to meet the FMH impact requirements for the front seating positions. Under our proposal, final stage manufacturers would ordinarily be able to take advantage of pass-through certification by not changing the upper interior portions of the front of the vehicle.

We also stated that we believe the requirements are justified by safety. As indicated above, we estimate that requiring all multi-stage manufactured vehicles to meet FMVSS No. 201 would have annual benefits in the front seat of 16–22 fewer fatalities and 19–22 fewer AIS 2–5 injuries. We stated that given the safety significance of these requirements, we believed, in situations where final stage manufacturers use incomplete vehicles that have occupant compartments that either are designed to meet the FMH impact requirements for the front seating positions or can be purchased in a configuration that is designed to meet those requirements, it would be inconsistent with the need for safety to generally exclude the vehicles from these head impact protection requirements. We also noted that while final stage manufacturers will be able to submit petitions under subpart B of part 555, it is unlikely in this type of situation that the agency would find it in the public interest to exclude final stage manufacturers from the front seat head impact protection requirements of FMVSS No. 201 to facilitate customization of the upper interior portions of the front of the vehicle.

We noted that the proposal would, however, facilitate customization of the rear of vehicles, including conversion vans, where there would be no significant impact on safety. We also stated that we continue to believe that final stage manufacturers can use cooperative testing to determine the types of changes that can be made while enabling vehicles to continue to comply with the FMH requirements, including ones related to use of overhead cabinets, raised roof structures, and so forth. We stated that while customization of the front portion of occupant compartments will be more difficult and may be more limited, it will by no means be eliminated.

b. Proposal To Exclude Vehicles Without a Finished Occupant Compartment From the FMH Impact Requirements

We tentatively concluded that a narrow group of multi-stage vehicles contains physical attributes that make compliance with the FMH impact requirements impracticable. These are vehicles built on a ''stripped'' chassis; i.e., an incomplete vehicle without an occupant compartment. The manufacturers of these vehicles would not be able to rely on pass-through certification. This is because these vehicles are highly customized and produced in quantities that would make compliance prohibitively expensive. Further, these vehicles are often equipped with partitions and bulkheads that present a further impediment to the compliance efforts. We noted that for vehicles manufactured from stripped chassis, the cost of meeting the FMH impact requirements could be substantial because alternative means of compliance such as pass-through certification are not available.

We stated that in the context of serving niche markets demanding specialized work vehicles that are not delivered to the final stage manufacturers with an intact occupant compartment (unlike for example, chassis cabs and cutaway vans), we believed that the physical limitations of these vehicles can adversely affect the ability of multi-stage manufacturers to design safety performance into their completed vehicles. Accordingly, we believed it appropriate to exclude this narrow group of vehicles from FMH impact testing.

c. Question Regarding Multi-Stage Vehicles With Raised Roofs

The NPRM also raised the issue of offering a manufacturer alternative for vehicles with raised roofs. This would allow the final stage manufacturer to certify that the vehicle meets the FMH impact requirements in either the original or altered configuration. The reasoning behind this was that while some test points have been altered due to the raised roof, those points are very unlikely to be impacted by a seated occupant.

d. Change of Effective Date

The NPRM proposed to delay the effective date of the FMH impact requirements as they apply to final stage manufacturers and alterers until September 1, 2008.

III. Public Comments

Both NTEA and RVIA submitted comments generally supportive of the NPRM. Both entities supported the proposal to delay the effective date for compliance with the requirements to September 1, 2008. In addition, NTEA suggested that the date be extended further if the delay is not published by January 2007. The proposal to limit the area that is subject to the FMH impact requirements was also supported by both commenters. Finally, both parties were generally supportive of the proposal to exclude vehicles delivered to a final stage manufacturer without an occupant compartment from the FMH requirements.

While generally supportive of the NPRM, both entities suggested expanding the scope of vehicles excluded from the FMH impact requirements beyond that which was proposed by NHTSA. Citing the small size and economic difficulties of the recreational vehicle industry, RVIA stated that NHTSA should consider excluding CVs and motor homes from the FMH impact requirements. It argued that given the numerous interior layouts for these vehicles, a large number of tests would need to be performed, burdening the industry disproportionately. RVIA also reiterated its original cost estimates presented in its petition, stating that interior designs and layouts can change every year, thus making the industry unable to amortize testing costs over a number of years.

NTEA also supported expanding the scope of the FMH impact requirement exclusion to additional vehicles. In addition to vehicles delivered without an occupant compartment, NTEA suggested that multi-stage vehicles built from ''chassis cutaways,'' i.e., incomplete vehicles delivered with an occupant compartment but without the rear part of the chassis, should be excluded as well. NTEA stated that the occupant compartment in these vehicles is not delivered ''intact,'' because there is no rear wall. NTEA also requested clarification regarding which vehicles would be excluded.

Finally, NTEA provided comments concerning the testing of vehicles with bulkheads and partitions in relation to the FMH impact requirements. Specifically, it expressed concern that partition, bulkheads, and B-pillars on the majority of vehicles used commercially with a GVWR of 10,000 lbs. or less would fall within the proposed testing area. This, NTEA stated, would lead to high testing and

compliance costs for small manufacturers. In addition, NTEA asked for clarification on whether secondary headform hits would count towards the overall HIC(d) value, suggesting that they should not. NTEA also suggested that areas located less than 300 mm (12 inches) from the forward seating position, but behind bulkheads or partitions, should not be tested under the impact requirements.

IV. The Final Rule and Response to Public Comments

a. Limitation of the Areas Subject to FMVSS No. 201

The agency is adopting its proposal to limit, for multi-stage vehicles, the FMH impact requirements to the front of vehicles, i.e., we are excluding targets more than 300 mm (12 inches) behind the driver's SgRP. This change will maintain the vast majority of the safety benefits for multi-stage vehicles, while facilitating customization of the rear of vehicles.

As the cited safety data indicate, the vast majority of the safety benefits of the FMH impact accrue mainly in the front portions of the vehicle. Because of the front head restraint height requirements, we believe it is unlikely that the head of a seated occupant would come in contact with bulkheads, partitions, or overhead cabinets and storage shelves located further than 300 mm (12 inches) behind the seating reference point of the driver's seating position. Therefore, we believe that this final rule preserves the vast majority of the safety benefits provided by the FMH impact requirements for multistage vehicles.

We note that NTEA and RVIA members can ordinarily purchase incomplete vehicles that are already designed to meet the FMH impact requirements for the front seating positions. Thus, under our proposal, final stage manufacturers would ordinarily be able to take advantage of pass-through certification by not changing the upper interior portions of the front of the vehicle.

NTEA expressed concern about the installation of partitions and bulkheads behind the occupant seating compartment. It was concerned that the 300 mm (12 inches) distance from the driver's SgRP could include the B-pillar of the majority vehicles used commercially with a GVWR of 10,000 lbs. or less. It indicated that partitions and bulkheads could fall within the detailed area, and themselves become subject to testing.

NHTSA notes, as a general matter, that while partitions are not necessarily targeted by the FMH requirements, secondary impacts [4] on partitions are permitted as well as relocation of a targeted area in accordance with S10(b). In these cases, any secondary impacts would be incorporated into the total HIC(d) value, and any target areas that are relocated may fall upon a bulkhead or partition provided that the contact area is not specifically excluded from the test.

As indicated above, the purpose of excluding targets more than 300 mm (12 inches) behind the driver's SgRP is to address the special circumstances of final stage manufacturers, while maintaining the vast majority of the benefits from the FMH requirements. To the extent that bulkheads, partitions or other items located more than 300 mm (12 inches) behind the driver's SgRP could contribute to the HIC(d) value, final stage manufacturers could potentially need to add countermeasures to comply with FMVSS No. 201, as well as engage in testing, engineering analysis, or other means to have a basis for certifying compliance.

To ensure that the change we are making provides the intended accommodation for final stage manufacturers, we are providing that tests for altered vehicles and vehicles built in two or more stages do not include, within the time period for measuring HIC(d), any FMH contact with components rearward of the plane 300 mm (12 inches) behind the driver's SgRP. Of course, if it is possible to strike an intended target within the range of permissible approach angles without FMH contact with components rearward of that plane, the agency will test the target in that fashion. We note that the position we are taking on this specific issue should not be viewed as an indication of how we might address the issue of secondary impacts for other portions of FMVSS No. 201.

In order to take full advantage of this accommodation, a final stage manufacturer or alterer adding a partition or bulkhead needs to ensure that it is rearward of the plane 300 mm (12 inches) behind the driver's SgRP. NHTSA notes that it has surveyed several vehicles with partitions,[5] and the closest partition was approximately 380 mm behind the driver's SgRP. We believe that partitions are ordinarily located more than 300 mm (12 inches) behind the driver's SgRP in order to permit the seat to recline. Therefore, we believe the change we are adopting provides appropriate accommodation for final stage manufacturers and alterers.

We note, however, that if a final stage manufacturer or alterer wishes to add a partition or bulkhead closer than 300 mm (12 inches) behind the driver's SgRP, it can add any needed countermeasures (e.g., padding) to comply with FMVSS No. 201, and conduct testing, engineering analysis, or other means to have a basis for certifying compliance. It could do this on its own, in conjunction with the partition manufacturer, or as part of cooperative testing.

b. Areas Behind the Partition

In its comments, NTEA asserted that it is not practical to include targets that are behind the forward surface of a partition or bulkhead. NTEA argued that these targets could not possibly be contacted by the head of an occupant seated forward of the partition. The agency believes, for reasons discussed earlier, that partitions are ordinarily located more than 300 mm (12 inches) behind the driver's SgRP. Therefore, this issue would affect few vehicles. In any event, barring a particularly rare series of events (which would be unlikely to be alleviated by the installation of additional interior padding), the agency concurs that these areas are unlikely to be impacted by a person in the front occupant compartment, and it is therefore not appropriate to test areas behind such partitions or bulkheads. NHTSA is adjusting the rule to exclude these areas from the FMH impact requirements as well.

c. Conversion Vans and Recreational Vehicles

RVIA expressed concern that, given the small size of the manufacturers of these products, as well as the declining size of the market, meeting the FMH impact requirements is impractical. It requested that CVs and motor homes be completely excluded from the FMH impact requirements. While NHTSA recognizes that most manufacturers represented by RVIA meet the Small Business Administration (SBA) definition for small businesses, we do not believe that this should preclude these manufacturers from being required to meet the FMH impact requirements for the front seats.

We believe that the safety benefits of FMVSS No. 201 can be maintained without substantial burdens being imposed on multi-stage manufacturers. Much like other vehicles, CVs and

[4] Secondary impacts occur when part of the FMH (usually the chin) strikes in the vicinity of the intended target at or near the time that the forehead impact zone contacts that target, more specifically, within the HIC(d) calculation time period specified in S7.

[5] We are placing in the docket a memorandum that discusses that survey.

motor homes in this category are typically manufactured from an Original Equipment Manufacturer (OEM) chassis product that has a completed front passenger compartment. Most of these have Incomplete Vehicle Documents (IVDs), so that the final stage manufacturer has the option of purchasing an OEM incomplete vehicle that is pre-certified to meet the FMH impact requirements.[6]

While the RVIA states that small motor home and CV manufacturers expect to have to conduct substantial compliance testing at high costs, we do not believe that this is necessarily the case. Under our rule, as long as the final stage manufacturers preserve the OEM specifications in the forward area subject to the FMH impact requirements, they can customize the rear portion of the interior. By not changing the upper interior portions of the vehicle, they will be able to take advantage of pass-through certification. We continue to believe that these requirements are justified by the safety benefits cited above and discussed in the NPRM.

Moreover, as discussed in the NPRM, final stage manufacturers can use cooperative testing to determine the types of changes that can be made while enabling vehicles to continue to comply with the FMH requirements, including ones related to use of overhead cabinets, raised roof structures, and so forth. Thus, while customization of the front portion of occupant compartments will be more difficult and may be more limited, it is by no means eliminated.

d. Multi-Stage Vehicles Completed From a Cutaway Chassis

As part of the final rule, we have decided to adopt our proposal to exclude from the FMH requirements a narrow group of multi-stage vehicles delivered to the final stage manufacturer without an occupant compartment. However, we are not extending that exclusion to vehicles completed from a ''chassis cutaway.'' A chassis cutaway consists of part of a chassis, which is delivered to a final stage manufacturer without a back wall. In its comments, NTEA suggested that a chassis cutaway is not ''intact,'' and therefore should be excluded from the FMH impact requirements. NTEA stated that it would not be able to certify a vehicle built from a chassis cutaway using pass-through certification because the OEM provides no guidelines for maintaining ''vital spatial clearance.'' This lack of guidelines, NTEA claims, prohibit the use of reasonable engineering analysis for pass-through compliance with FMVSS No. 201.

NHTSA does not accept NTEA's argument in this area for several reasons. First, provided no changes have been made to the portion of the occupant compartment forward of the rearmost part of the B-pillar (and if located 300 mm rearward of the driver's SgRP), it is reasonable for a manufacturer to assume that all ''vital spatial clearances'' will have been maintained. Therefore, in these situations, the final stage manufacturer can take advantage of the available pass-through certification.

Second, we are aware of the availability of some cutaway chassis vehicles that can be used in this manner by final stage manufacturers. NHTSA is aware of cutaway vehicles manufactured by Ford and Daimler-Chrysler that are provided with IVDs certifying that the vehicle will meet the FMH impact requirements of FMVSS No. 201 forward of the cut point in the forward occupant compartment.[7] This includes compliance with all applicable spatial clearance requirements. Because these vehicles are available to second stage manufacturers, we do not believe that compliance will be overly burdensome, and cutaway vehicles do not merit additional compliance relief.

e. Delay of Compliance Date

Both commenters supported NHTSA's proposal to delay the implementation date of the FMH impact requirements. NTEA further requested that NHTSA delay the implementation date until September 1, 2009 if the final rule is not published prior to January 2007. NHTSA agrees with the commenters that the extension is necessary to provide manufacturers of altered vehicles sufficient time to comply with the FMH impact requirements. Considering the timing of this final rule, we are delaying the implementation until September 1, 2009.

f. Miscellaneous Issues

NHTSA makes note of two additional issues that were addressed in the NPRM. First, in the NPRM, we requested comments on an issue related to multistage vehicles with raised roofs. We stated that we were considering permitting manufacturers to meet requirements for either the target locations as calculated for the original configuration or changed configuration. We did not receive comments on this issue, and have decided not to adopt such a provision.

Second, we proposed to extend the scope of the agency's new more streamlined temporary exemption procedures such that multistage manufacturers would be able to petition NHTSA for an exemption from the FMH impact requirements. See 71 FR at 20936. The new procedures streamline the temporary exemption process by allowing an association or another party representing the interests of multiple manufacturers to bundle exemption petitions for a specific vehicle design, thus permitting a single explanation of the potential safety impact and good faith attempts to comply with the standards. We noted, however, that the same issue was also before the agency in another proceeding. In a final rule published in the **Federal Register** (71 FR 28179) on May 15, 2006, this procedure was extended to final stage manufacturers in relation to the FMH requirements of FMVSS No. 201. Therefore, this final rule does not specifically address that issue. We also note that the May 2006 final rule addressed a number of other relevant issues relating to final stage manufacturers and alterers.

g. Effective Date

We find good cause for making this rule effective in less than 30 days, i.e., September 1, 2007. As discussed above, we have concluded that certain amendments should be made that will provide relief to final stage manufacturers and alterers, and also that the compliance date of the relevant requirements should be delayed to September 1, 2009. If the September 1, 2007 compliance date were not changed, it is likely that some final stage manufacturers and alterers would need to immediately stop producing or altering some of the specialty vehicles they provide.

V. Regulatory Analyses and Notices

a. Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), provides for making determinations whether a regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and to the requirements of the Executive Order. The Order defines a ''significant

[6] We also note that the agency has created a temporary exemption process for multi-stage vehicles by which intermediate and final stage manufacturers and alterers can obtain temporary exemptions from dynamic performance requirements based on financial hardship. The agency also allows associations or multiple manufacturers to ''bundle'' temporary exemption petitions for specific vehicle designs. *See* 70 FR 7414.

[7] We are placing in the docket a memorandum that discusses some of these vehicles.

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 governments 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; or

(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.

This final rule was not reviewed under Executive Order 12866. It is not significant within the meaning of the DOT Regulatory Policies and Procedures. It does not impose any new burdens on manufacturers of vehicles built in two or more stages or vehicle alterers. Further, this rule limits certain existing requirements as they apply to multi-stage vehicles, and excludes a narrow group of multi-stage vehicles manufactured from chassis without occupant compartments from the same requirements. The agency believes that this impact is so minimal as to not warrant the preparation of a full regulatory evaluation.

b. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must either prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions) [8] or certify that the rule will not have a significant economic impact on a substantial number of small entities. In order to make such a certification, the agency must conduct a threshold analysis. The results of that analysis must be included in a statement that accompanies the certification and provides the factual basis for making it. I hereby certify that this final rule will not have a significant economic impact on a substantial number of small entities.

NHTSA has considered the effects of this final rule under the Regulatory Flexibility Act. While it is true that the vast majority of intermediate and final stage manufacturers of vehicles built in two or more stages and alterers have 1,000 or fewer employees, we believe the impact of this final rule will not be detrimental. This final rule permits these companies to comply with the FMH impact requirements of FMVSS No. 201 for the front occupant compartment only, as opposed to the requirements that must be met by original manufacturers. Final stage manufacturers and alterers can either rely on the original equipment manufacturer's certification (using pass-through certification) or install interior padding and undertake available compliance testing. Also, final stage manufacturers and alterers using a ''stripped chassis'' vehicle are exempt from the FMH impact requirements. Finally, this rule delays the effective date of the requirements until September 1, 2009. Accordingly, there will be no significant economic impact on small businesses, small organizations, or small governmental units by these amendments. For these reasons the agency has not prepared a regulatory flexibility analysis.

c. National Environmental Policy Act

NHTSA has analyzed this proposal for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action will not have any significant impact on the quality of the human environment. Accordingly, no environmental assessment is required.

d. Executive Order 13132 (Federalism)

NHTSA has examined today's final rule pursuant to Executive Order 13132 (64 FR 43255, August 10, 1999) and concluded that no additional consultation with States, local governments or their representatives is mandated beyond the rulemaking process. The agency has concluded that the rulemaking would not have federalism implications because a final rule, if issued, would 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.''

Further, no consultation is needed to discuss the preemptive effect of today's rulemaking. NHTSA rules can have preemptive effect in at least two ways. First, the National Traffic and Motor Vehicle Safety Act contains an express preemptive provision: ''When a motor vehicle safety standard is in effect under this chapter, a State or a political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter.'' 49 U.S.C. 30103(b)(1). It is this statutory command that preempts State law, not today's rulemaking, so consultation would be inappropriate.

In addition to the express preemption noted above, the Supreme Court has also recognized that State requirements imposed on motor vehicle manufacturers, including sanctions imposed by State tort law, can stand as an obstacle to the accomplishment and execution of a NHTSA safety standard. When such a conflict is discerned, the Supremacy Clause of the Constitution makes their State requirements unenforceable. See *Geier* v. *American Honda Motor Co.,* 529 U.S.C. 861 (2000). NHTSA has not outlined such potential State requirements in today's rulemaking, however, in part because such conflicts can arise in varied contexts, but it is conceivable that such a conflict may become clear through subsequent experience with today's standard and test regime. NHTSA may opine on such conflicts in the future, if warranted. See id. at 883–86.

e. Executive Order 12988 (Civil Justice Reform)

This final rule would not have any retroactive effect. Under 49 U.S.C. 30103, whenever a Federal motor vehicle safety standard is in effect, a State may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance and applies only to vehicles procured for the State's use. 49 U.S.C. 30161 sets forth a procedure for judicial review of final rules establishing, amending, or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

f. Unfunded Mandates Act

The Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by

[8] The Small Business Administration's regulations at 13 CFR part 121 define a small business, in part, as a business entity ''which operates primarily within the United States.'' (13 CFR 121.105(a)).

State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted for inflation). The assessment may be combined with other assessments, as it is here.

This final rule is not likely to result in expenditures by State, local or tribal governments or automobile manufacturers and/or their suppliers of more than $100 million annually. If adopted, it would not impose any new burdens on manufacturers of vehicles built in two or more stages or vehicle alterers. Further, this final rule limits certain existing requirements as they apply to multistage vehicles, and exclude a narrow group of multistage vehicles manufactured from chassis without occupant compartments from the same requirements.

g. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA), a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. This final rule contains no reporting requirements or requests for information.

h. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

i. Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

VI. Regulatory Text

List of Subjects in 49 CFR Part 571

Motor vehicle safety, Reporting and recordkeeping requirements, Tires.

■ In consideration of the foregoing, NHTSA amends chapter V of title 49 of the Code of Federal Regulations by amending 49 CFR § 571.201 to read as follows:

PART 571—[AMENDED]

■ 1. The authority citation of Part 571 continues to read as follows:

Authority: 49 U.S.C. 322, 2011, 30115, 30116 and 30117; delegation of authority at 49 CFR 1.50.

■ 2. Section 571.201 is amended by revising S6.1.4 through S6.1.4.2, S6.3(b) and S6.3(c) to read as set forth below:

§ 571.201 Standard No. 201; Occupant protection in interior impact.

* * * * *

S6.1.4 *Phase-in Schedule #4* A final stage manufacturer or alterer may, at its option, comply with the requirements set forth in S6.1.4.1 and S6.1.4.2.

S6.1.4.1 Vehicles manufactured on or after September 1, 1998 and before September 1, 2009 are not required to comply with the requirements specified in S7.

S6.1.4.2 Vehicles manufactured on or after September 1, 2009 shall comply with the requirements specified in S7.

* * * * *

S6.3 * * *

(b) Any target located rearward of a vertical plane 600 mm behind the seating reference point of the rearmost designated seating position. For altered vehicles and vehicles built in two or more stages, including ambulances and motor homes, any target located rearward of a vertical plane 300 mm behind the seating reference point of the driver's designated seating position (tests for altered vehicles and vehicles built in two or more stages do not include, within the time period for measuring HIC(d), any free motion headform contact with components rearward of this plane). If an altered vehicle or vehicle built in two or more stages is equipped with a transverse vertical partition positioned between the seating reference point of the driver's designated seating position and a vertical plane 300 mm behind the seating reference point of the driver's designated seating position, any target located rearward of the vertical partition is excluded.

(c) Any target in a vehicle manufactured in two or more stages that is delivered to a final stage manufacturer without an occupant compartment. Note: Motor homes, ambulances, and other vehicles manufactured using a chassis cab, a cut-away van, or any other incomplete vehicle delivered to a final stage manufacturer with a furnished front compartment are not excluded under this S6.3(c).

* * * * *

Issued: August 30, 2007.

Nicole R. Nason,

Administrator.

[FR Doc. 07–4324 Filed 8–30–07; 4:52 pm]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration (NOAA)

50 CFR Part 660

[Docket No. 070323069–7117–02; I.D. 031907A]

RIN 0648–AV46

Pacific Coast Groundfish Fishery

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

ACTION: Final rule.

SUMMARY: NMFS issues a final rule to establish catch accounting requirements for persons who receive, buy, or accept Pacific whiting deliveries of 4,000 pounds (lb) (1.18 mt) or more from vessels using midwater trawl gear during the Pacific whiting primary season for the shore-based sector. This action is intended to improve NMFS's ability to effectively monitor the Pacific whiting shoreside fishery such that catch of Pacific whiting and incidentally caught species, including overfished groundfish species, do not result in a species' optimum yield (OY), harvest guideline, allocations, or bycatch limits being exceeded. This action is also intended to provide for timely reporting of Chinook salmon take as specified in the Endangered Species Act (ESA) Section 7 Biological Opinion for Chinook salmon catch in the Pacific groundfish fishery. This action is consistent with the conservation goals and objectives of the Pacific Coast Groundfish Fishery Management Plan (FMP).

DATES: Effective October 5, 2007.

ADDRESSES: Copies of the Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis (EA/RIR/IRFA), Finding of No Significant Impact (FONSI), Initial Regulatory Flexibility Analysis (IRFA), Final Regulatory Flexibility Analysis (FRFA), and the Small Entity Compliance Guide are available from D. Robert Lohn, Administrator, Northwest Region, NMFS, 7600 Sand Point Way NE, Seattle, WA 98115–0070, phone: 206–526–6150.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule may be submitted to D. Robert Lohn, Administrator, Northwest Region, NMFS, 7600 Sand Point Way NE, Seattle, WA 98115–0070, and by e-mail to *DavidRostker@omb.eop.gov*, or by fax to (202) 395–7285.

FOR FURTHER INFORMATION CONTACT: Becky Renko, phone: 206–526–6110, fax: 206–526–6736, or e-mail: *becky.renko@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also accessible via the internet at the website of the Office of the **Federal Register**: www.gpoaccess.gov/fr/index.html.

Background

This action establishes an electronic catch accounting system and other monitoring improvements for the shore-based sector of the Pacific whiting fishery. The shore-based Pacific whiting fishery needs to have a catch reporting system in place that: provides timely reporting of catch data so that Pacific whiting, overfished species and Chinook salmon can be adequately monitored and accounted for inseason; and, specifies catch sorting and weight requirements necessary to maintain the integrity of data used to manage groundfish species OYs, trip limits, and bycatch limits.

This final rule applies to persons called ''first receivers'' (generally, first receivers are Pacific whiting shoreside processing facilities, but may also include entities that truck Pacific whiting to other facilities.) This final rule requires first receivers who receive, buy, or accept Pacific whiting deliveries of 4,000 lb (1.8 mt) or more from vessels using midwater trawl gear during the Pacific whiting primary season to have and use a NMFS-approved electronic fish ticket software or a NMFS-approved software that meets defined data export specifications, and to send catch reports to the Pacific States Marine Fish Commission (PSMFC) within 24 hours of when the catch is landed. Electronic fish ticket reports will be used to track catch allocations, bycatch limits and prohibited species catch. First receivers will provide the computer hardware, software, and internet access necessary to support the NMFS-approved software and provide for e-mail transmissions.

The electronic fish tickets are used to collect information similar to information currently required by the States of Washington, Oregon and California on fish receiving tickets or landing receipts (state fish tickets). These Federal regulations will be in addition to the existing state fish ticket requirements and will not replace any state recordkeeping or reporting requirements.

New sorting requirements are specified in this final rule for Pacific whiting catch received by first receivers, as deliveries may contain groundfish in excess of trip limits, unmarketable groundfish, prohibited species, and protected species that are not addressed by current groundfish regulations. In addition, Federal groundfish regulations are revised to require deliveries from vessels participating in the Pacific whiting shoreside fishery to be adequately sorted by species or species group, and the catch be weighed following offloading from the vessel and prior to transporting the catch. First receivers are required to report, on electronic fish tickets, actual and accurate weights derived from scales. If sorting and weighing requirements specified in Federal regulation are more stringent than state fish ticket requirements, the first receiver is required to follow Federal requirements for sorting, weighing, and reporting species or species groups on electronic fish ticket submissions.

This final rule is part of an ongoing process to develop a maximized retention program for the Pacific whiting shoreside fishery. At its June 11–15, 2007, meeting in Foster City, California, the Council will consider recommending a rulemaking for 2008 and beyond for a related action titled ''A Maximized Retention and Monitoring Program for the Pacific Whiting Shoreside Fishery.''

Further detail on this action appears in the EA/RIR prepared by the NMFS for this action and in the proposed rule published on April 9, 2007 (72 FR 17469). NMFS requested public comment on the proposed rule through April 24, 2007. See the preamble to the proposed rule for additional background information on the fishery and on this rule.

Comments and Responses

NMFS received two e-mailed comments on the proposed rule: one email was received from a state government and the other email was from an industry organization. These comments are addressed here:

Comment 1: The commentor indicated that a reference on page 17470 of the proposed rule preamble, regarding the Pacific Fishery Management Council discussion on further rulemaking ''at its April 2007 meeting,'' should be revised or eliminated because the discussion did not occur.

Response: The preamble reference to Pacific Fishery Management Council discussion on further rulemaking has been revised in the final rule preamble to reference pending discussion at the June 11–15, 2007 Council meeting.

Comment 2: The commentor believes that the reliance on Research Group publications from 2006 based on 2004 fishery data, referenced on page 17471 of the proposed rule preamble, is questionable given the age of the data and the fact that no peer review of the information has been done for this analysis.

Response: NMFS recognizes that the Research Group publications are not peer reviewed documents. However, given the lack of available information on the West Coast seafood processing industry, NMFS must rely on various sorts of information to determine the classification of processing companies including determining whether various companies are ''affiliated'' according to Small Business Administration (SBA) standards. As stated in the analysis, the information was based on a review of company websites, state employment websites, and newpaper articles. The discussion drew no hard conclusions because the Research Group publications use data from various sources and such data may be of various vintages. NMFS believes that the information from the Research Group publications, although not peer-reviewed is credible supporting information given its consistency with other data sources. These publications are the only publications available that describe West Coast fishing industry in a manner useful for assessing ownership relationships between companies. NMFS believes it has used these Research publications in a credible manner as this information was used in conjunction with NMFS's own review of company websites, state employment websites, and newspaper articles. Because of this NMFS independent reviews, without the use of the Research Group publications, the same conclusions about company size and affiliation would have been made. The basic conclusion was that there appears to be 13 major Pacific whiting processors that can be grouped into nine SBA businesses based on analysis of affiliates and that among these businesses are three large and six small SBA businesses based on SBA size standards. One purpose of the IRFA is to solicit comments on the economic analysis in the proposed rule and

whether the basic conclusions are reasonable. This comment was the only one received on the economic analysis and it only questions the use of Research Group publications, but not the basic conclusions. The use of non-peer reviewed information in its conclusions is noted in the classifications section of this document.

Comment 3: The commentor objects to the inclusion of the proposed § 660.306 (f)(6)(i), which prohibits a first receiver from receiving Pacific whiting from a vessel that does not have a properly functioning electronic monitoring system (EMS), unless a waiver for EMS coverage was granted by NMFS for that trip. The commentor believes that a first receiver on shore has no way of knowing whether a vessel's EMS is operating or not, or whether it was properly deployed while the vessel was harvesting Pacific whiting. The commentor suggests the language be modified to insert ''knowingly'' at the start of the sentence to enable enforcement action to be taken, but not lead to action against a processor who buys from a vessel in good faith.

Response: NMFS has modified the proposed language in § 660.306 (f)(6)(i) so that an undue burden is not placed on the first receivers in 2007. In response to this comment, NMFS has removed the language in § 660.306 (f)(6)(i). Maintaining the integrity of catch data includes knowing that each delivery was properly monitored at-sea. Therefore, NMFS encourages processors to obtain verification from the vessel operator, that the EMS was working properly or that a waiver for EMS coverage was granted to the vessel for that trip. NMFS intends to address this issue in its entirety in a related action titled ''A Maximized Retention and Monitoring Program for the Pacific Whiting Shoreside Fishery.''

Comment 4: The commentor supports the language in § 660.373 (j)(1)(ii) indicating that first receivers have the choice of using either software supplied by the PSMFC or ''NMFS-approved'' software compatible with the software available from PSMFC. The commentor strongly supports having this choice, but believes it would be helpful to know what software is approved by NMFS and what format is considered compatible.

Response: In response to the commentor, NMFS has added clarifying language to § 660.373 (j)(1)(ii) which identifies where a first receiver may obtain the specifications for NMFS-approved software other than the software supplied by the PSMFC.

Comment 5: The commentor suggests that a definition be added for ''Electronic fish tickets.''

Response: NMFS has added a definition for electronic fish tickets. The term is defined as a software program or data files meeting data export specifications approved by NMFS that is used to send landing data to the Pacific States Marine Fisheries Commission. Electronic fish tickets are used to collect information similar to the information required in state fish receiving tickets or landing receipts, but do not replace or change any state requirements.

Comment 6: The commentor suggests that the term ''Pacific whiting shoreside vessel'', which has been defined in regulation, be used consistently throughout the regulations rather than using the terms ''delivery vessel'' and ''catcher vessel'' to describe the same group of vessels.

Response: NMFS has made the appropriate changes to the regulatory language.

Changes From the Proposed Rule

In response to the comments that were received, the following changes were made from the proposed rule: A definition for the term ''Electronic fish ticket'' was added to the regulations in § 660.302 Definitions; References to ''delivery vessel'' and ''catcher vessel'' were changed to Pacific whiting shoreside vessel in § 660.303, reporting and recordkeeping, paragraph (e)(1)(iii) and (iv)(B), and in § 660.306, prohibitions, (f)(6)(iii); and, in § 660.373, Pacific whiting fishery management, paragraph (j)(1)(ii)(A)(3) contact information for obtaining NMFS-approved software was added, proposed language in § 660.306 (f)(6)(i) was removed, and in paragraph (j)(1)(ii)(C)(3) the term first receivers was added.

Classification

An environmental assessment was prepared for this action. NMFS finds that no significant impact on the human environment will result from its implementation and has signed the Finding of No Significant Impacts (FONSI).

This final rule has been determined to be not significant for purposes of Executive Order 12866.

A final regulatory flexibility analysis (FRFA) was prepared. The FRFA incorporates the IRFA, and a summary of the analyses completed to support the action. A copy of this analysis is available from or NMFS (see ADDRESSES). A summary of the FRFA follows.

The Pacific whiting shoreside fishery needs to have a catch reporting system in place to: adequately track the incidental take of Chinook salmon as required in the ESA Section 7 Biological Opinion for Chinook salmon catch in the Pacific whiting fishery; and to track the catch of target and overfished groundfish species such that the fishing industry is not unnecessarily constrained and that the sector allocation and bycatch limits are not exceeded.

This action will allow NMFS to effectively manage the Pacific whiting fishery such that harvests of Pacific whiting and incidentally caught groundfish species, including overfished species, do not result in allocations, harvest guidelines, species' OY, or bycatch limits for overfished species being exceeded. One comment was received regarding the IRFA (see Comment 2 above). No changes to the proposed rule resulted from this comment. During 2006, 23 different processors/companies paid $17 million to fishers who delivered a combined 280 million lbs (127,002 mt) of Pacific whiting. A major processor is one that has purchased more than 1,000,000 lbs of Pacific whiting. There were 13 major Pacific whiting processors in 2006, with the remaining 10 processors all being minor processors, as their production levels ranged from 2 lbs to 7,000 lbs (3,175 kg). There were no processors in the 7,000 lb to 1,000,000 lb (4,536 kg) range. None of these minor processors were associated with a trawl landing that was greater than 4,000 lbs (1,814 kg) and so it is presumed they would be unaffected by these regulations. Note that not all minor entities are ''processors'' in the traditional sense since some of these entities may be fishers who directly sell their fish to a restaurant. These fishers, although they may be small businesses, are not affected because the direct sale of their landings would not be subject to this rule.

The SBA has established size criteria for all major industry sectors in the U.S. including fish harvesting entities, for-hire entities, fish processing businesses, and fish dealers. A business involved in fish harvesting is a small business if it is independently owned and operated and not major in the field of operation (including its affiliates) and if it has combined annual receipts not in excess of $3.5 million for all its affiliated operations worldwide. For-hire vessels are considered small entities, if they have annual receipts not in excess of $6 million. A seafood processor is a small business if it is independently owned and operated, not major in its field of

operation, and employs 500 or few persons on a full-time, part-time, temporary, or other basis, at all its affiliated operations world wide. Finally, a wholesale business servicing the fishing industry (fish dealer) is a small business if it employs 100 or few persons on a full time, part-time, temporary, or other basis, at all its affiliated operations worldwide. Because of the lack of available information on the West Coast seafood processing industry, NMFS must rely on various sorts of information to determine the classification of processing companies including determining if various companies are ''affiliated'' according to SBA standards.

Based on the SBA criteria and a review of company websites, state employment websites, newspaper articles, personal communications, and non-peered review research documents, it appears that the 13 major Pacific whiting processors can be grouped into nine SBA businesses based on analysis of affiliates. Within these nine SBA businesses, there appears to be three ''large'' businesses, each of which generated at least $500 million in sales in 2003 and employ over over 500 employees each. In addition, there are six ''small'' businesses that participated in the shorebased Pacific whiting processing sector in 2006. Annual sales information for these ''small'' businesses is unavailable, but total ex-vessel revenues (the value of the fish purchased from fisherman) is available. In 2006, these six businesses purchased approximately $40 million in hake and other fish and shellfish from west coast fishermen. This compares to the $60 million in hake and other fish and shellfish purchased by the three large businesses. These regulations would require Pacific whiting shoreside processors to have and use a NMFS approved electronic fish ticket program to send daily catch reports. The electronic fish tickets are based on information currently required in state fish receiving tickets or landing receipts (fish tickets). In the States of Washington and California, processors would continue to complete and submit the required paper fish tickets on forms provided by the state and then transfer the same information to the electronic fish ticket for submission. In the State of Oregon, processors could either complete paper fish ticket forms provided by the state, or as is allowed by state law, they could submit a printed and signed copy of the electronic fish tickets. The majority of the companies affected appear to be small businesses.

Given the relatively small numbers of applicants, separate requirements based on size of business were not developed. To the extent possible, however, this final rule builds on existing state reporting requirements or on equipment that the companies typically already have. Therefore, implementation of these rules will require firms to bear minimal costs in reporting data electronically that they already are required to report on paper to the states. In terms of equipment purchases, it is expected that there will be few if any instances where processors have to purchase computers or software because this is equipment that most business already have. It is also not expected that processors will need to purchase scale equipment as the presumption about this final rule is that it enhances existing state regulations that already require processors to use scales in conducting their businesses but may not specifically require the use of scale weights in reporting fisheries data to state agencies. There may be some interest by a few small processors to weigh and count fish at locations other than the point of first landing, but these instances appear to be few.

Additional measures were taken to minimize the costs of the catch accounting requirements by providing: (1) fish ticket software at no cost; (2) fish ticket software that used a standard operating system and common software already owned by most businesses; (3) fish ticket software that is compatible with the existing fish ticket requirements in each of the three states; and, (4) software that can be used to print a paper copy for submission to the state, when state law allows. Because the information is already being gathered by the processors there is no requirement that additional data be gathered. Only the minimum data required to meet the objectives are requested from all applicants. There were no other alternatives to the proposed rule that accomplish the stated objectives. Under Status Quo, general catch sorting requirements and prohibited actions would continue to be specified for limited entry trawl vessel; each state would continue to specify requirements for landing reports. This alternative was rejected because it does not meet the defined need for accurate catch accounting.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a public notice that also serves as small entity compliance guide (the guide) was prepared. The guide and final rule will be sent to all of the Pacific whiting shoreside processors that have been designated by the states of Washington, Oregon, or California as participants in the 2007 fishery. Copies of this final rule and the guide are available from the NMFS Northwest Regional Office (see **ADDRESSES**) and are available on our website at *www.nwr.noaa.gov* (Click on ''Groundfish Fishery Management,'' then on either ''Public Notices'' or ''Whiting management'').

This final rule contains a collection-of-information requirement subject to the Paperwork Reduction Act (PRA) and which has been approved by OMB under control number 0648–0563. Public reporting burden for preparing and submitting electronic fish tickets is estimated to average ten minutes per individual response for Pacific whiting shoreside processors/first receivers in the states of California and Washington, and two minutes per individual response for Pacific whiting shoreside processors/first receivers in the State of Oregon, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collected information. Send comments regarding these burden estimates or any other aspect of this data collection, including suggestions for reducing the burden, to NMFS (see **ADDRESSES**) and by e-mail to *David__Rostker@omb.eop.gov*, or fax to 202–395–7285.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

Pursuant to Executive Order 13175, this final rule was developed after meaningful consultation and collaboration with tribal officials from the area covered by the FMP. At the Council=s September and November 2006 meetings, NMFS informed the Council, which includes a tribal representative, of the intent to evaluate and implement catch accounting requirements for Pacific whiting shoreside processors. This action does not alter the treaty allocation of Pacific

whiting, nor does it affect the prosecution of the tribal fishery.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Indian fisheries.

Dated: August 29, 2007.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

■ For the reasons set out in the preamble, 50 CFR part 660 is amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

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

■ 2. In § 660.302, the definitions for ''Electronic Fish Ticket'',''Electronic Monitoring System,'' ''Pacific whiting shoreside or shore-based fishery,'' ''Pacific whiting shoreside first receiver,'' and ''Pacific whiting shoreside vessel'' are added to read as follows:

§ 660.302 Definitions.

* * * * *

Electronic fish ticket means a software program or data files meeting data export specifications approved by NMFS that is used to send landing data to the Pacific States Marine Fisheries Commission. Electronic fish tickets are used to collect information similar to the information required in state fish receiving tickets or landing receipts, but do not replace or change any state requirements.

Electronic Monitoring System (EMS) means a data collection tool that uses a software operating system connected to an assortment of electronic components, including video recorders, to create a collection of data on vessel activities.

* * * * *

Pacific whiting shoreside or shore-based fishery means Pacific whiting shoreside vessels and Pacific whiting shoreside first receivers.

Pacific whiting shoreside first receivers means persons who receive, purchase, or take custody, control, or possession of Pacific whiting onshore directly from a Pacific whiting shoreside vessel.

Pacific whiting shoreside vessel means any vessel that fishes using midwater trawl gear to take, retain, possess and land 4,000 lb (1,814 kg) or more of Pacific whiting per fishing trip from the Pacific whiting shore-based sector allocation for delivery to a Pacific whiting shoreside first receiver during the primary season.

* * * * *

■ 3. In § 660.303, paragraph (a) is revised and paragraph (e) is added to read as follows:

§ 660.303 Reporting and recordkeeping.

(a) This subpart recognizes that catch and effort data necessary for implementing the PCGFMP are collected by the States of Washington, Oregon, and California under existing state data collection requirements.

* * * * *

(e) *Participants in the Pacific whiting shoreside fishery.* Reporting requirements defined in the following section are in addition to reporting requirements under applicable state law and requirements described at § 660.303(b).

(1) *Reporting requirements for any Pacific whiting shoreside first receiver*—(i) *Responsibility for compliance.* The Pacific whiting shoreside first receiver is responsible for compliance with all reporting requirements described in this paragraph.

(ii) *General requirements.* All records or reports required by this paragraph must: be maintained in English, be accurate, be legible, be based on local time, and be submitted in a timely manner as required in paragraph (e)(1)(iv) of this section.

(iii) *Required information.* All Pacific whiting shoreside first receivers must provide the following types of information: date of landing, Pacific whiting shoreside vessel that made the delivery, gear type used, first receiver, round weights of species landed listed by species or species group including species with no value, number of salmon by species, number of Pacific halibut, and any other information deemed necessary by the Regional Administrator as specified on the appropriate electronic fish ticket form.

(iv) *Electronic fish ticket submissions.* The Pacific whiting shoreside first receiver must:

(A) Sort all fish, prior to first weighing, by species or

species groups as specified at § 660.370 (h)(6)(iii).

(B) Include as part of each electronic fish ticket submission, the actual scale weight for each groundfish species as specified by requirements at § 660.373 (j)(2)(i) and the Pacific whiting shoreside vessel identification number.

(C) Use for the purpose of submitting electronic fish tickets, and maintain in good working order, computer equipment as specified at § 660.373 (j)(2)(ii)(A);

(D) Install, use, and update as necessary, any NMFS-approved software described at § 660.373 (j)(2)(ii)(B);

(E) Submit a completed electronic fish ticket for every landing that includes 4,000 lb (1,814 kg) or more of Pacific whiting (round weight equivalent) no later than 24 hours after the date the fish are received, unless a waiver of this requirement has been granted under provisions specified at paragraph (e)(1)(vii) of this section.

(v) *Revising a submitted electronic fish ticket submission.* In the event that a data error is found, electronic fish ticket submissions may be revised by resubmitting the revised form. Electronic fish tickets are to be used for the submission of final data. Preliminary data, including estimates of fish weights or species composition, shall not be submitted on electronic fish tickets.

(vi) *Retention of records.* [Reserved]

(vii) *Waivers for submission of electronic fish tickets upon written request.* On a case-by-case basis, a temporary written waiver of the requirement to submit electronic fish tickets may be granted by the Assistant Regional Administrator or designee if he/she determines that circumstances beyond the control of a Pacific whiting shoreside first receiver would result in inadequate data submissions using the electronic fish ticket system. The duration of the waiver will be determined on a case-by-case basis.

(viii) *Reporting requirements when a temporary waiver has been granted.* Pacific whiting shoreside first receivers that have been granted a temporary waiver from the requirement to submit electronic fish tickets must submit on paper the same data as is required on electronic fish tickets within 24 hours of the date received during the period that the waiver is in effect. Paper fish tickets must be sent by facsimile to NMFS, Northwest Region, Sustainable Fisheries Division, 206–526–6736 or by delivering it in person to 7600 Sand Point Way NE, Seattle, WA 98115. The requirements for submissions of paper tickets in this paragraph are separate from, and in addition to existing state requirements for landing receipts or fish receiving tickets.

(2) [Reserved]

■ 4. In § 660.306, paragraphs (f)(6) is redesignated as (f)(7), and paragraph(b)(4) and a new (f)(6) are added to read as follows:

§ 660.306 Prohibitions.

* * * * *

(b) * * *

(4) Fail to comply with all requirements at § 660.303 (d); including failure to submit information, submission of inaccurate information, or intentionally submitting false information on any report required at § 660.303 (d) when participating in the Pacific whiting shoreside fishery.

* * * * *

(f) * * *

(6) *Pacific whiting shoreside first receivers.*

(i) [Reserved]

(ii) Fail to sort fish received from a Pacific whiting shoreside vessel prior to first weighing after offloading as specified at § 660.370 (h)(6)(iii) for the Pacific whiting fishery.

(iii) Process, sell, or discard any groundfish received from a Pacific whiting shoreside vessel that has not been weighed on a scale that is in compliance with requirements at § 660.373 (j)(1)(i) and accounted for on an electronic fish ticket with the identification number for the Pacific whiting shoreside vessel that delivered the fish.

(iv) Fail to weigh fish landed from a Pacific whiting shoreside vessel prior to transporting any fish from that landing away from the point of landing.

* * * * *

■ 5. In § 660.370, paragraph (h)(6)(iii) is added to read as follows:

§ 660.370 Specifications and management measures.

* * * * *

(h) * * *

(6) * * *

(iii) *Sorting requirements for the Pacific whiting shoreside fishery.* Fish delivered to Pacific whiting shoreside first receivers (including shoreside processing facilities and buying stations that intend to transport catch for processing elsewhere) must be sorted, prior to first weighing after offloading from the vessel and prior to transport away from the point of landing, to the species groups specified in paragraph (h)(6)(i)(A) of this section for vessels with limited entry permits. Prohibited species must be sorted according to the following species groups: Dungeness crab, Pacific halibut, Chinook salmon, Other salmon. Non-groundfish species must be sorted as required by the state of landing.

* * * * *

■ 6. In § 660.373, paragraph (j) is redesignated as (k), and a new paragraph (j) is added to read as follows:

§ 660.373 Pacific whiting (whiting) fishery management.

* * * * *

(j) *Additional requirements for participants in the Pacific Whiting Shoreside fishery*—(1) *Pacific whiting shoreside first receiver responsibilities*—(i) *Weights and measures.* All groundfish weights reported on fish tickets must be recorded from scales with appropriate weighing capacity that ensures accuracy for the amount of fish being weighed. For example: amounts of fish less than 1,000 lb (454 kg) should not be weighed on scales that have an accuracy range of 1,000 lb–7,000 lb (454 - 3,175 kg) and are therefore not capable of accurately weighing amounts less than 1,000 lb (454 kg).

(ii) *Electronic fish tickets*—(A) *Hardware and software requirements.* First receivers using the electronic fish ticket software provided by Pacific States Marine Fish Commission are required to meet the hardware and software requirements below. Those whiting first receivers who have NMFS-approved software compatible with the standards specified by Pacific States Marine Fish Commission for electronic fish tickets are not subject to any specific hardware or software requirements.

(*1*) A personal computer with Pentium 75–MHz or higher. Random Access Memory (RAM) must have sufficient megabyte (MB) space to run the operating system, plus an additional 8 MB for the software application and available hard disk space of 217 MB or greater. A CD-ROM drive with a Video Graphics Adapter(VGA) or higher resolution monitor (super VGA is recommended).

(*2*) Microsoft Windows 2000 (64 MB or greater RAM required), Windows XP (128 MB or greater RAM required) or later operating system.

(*3*) Microsoft Access 2003 or newer for:

(*i*) *NMFS Approved Software Standards and Internet Access.*

The Pacific whiting shoreside first receiver is responsible for obtaining, installing and updating electronic fish tickets software either provided by Pacific States Marine Fish Commission, or compatible with the data export specifications specified by Pacific States Marine Fish Commission and for maintaining internet access sufficient to transmit data files via email. Requests for data export specifications can be submitted to: Attn: Frank Lockhart, National Marine Fisheries Service, Northwest Region Sustainable Fisheries Division, 7600 Sand Point Way NE, Seattle, WA 98115, or via email to *frank.lockhart@noaa.gov*.

(*ii*) *Maintenance.* The Pacific whiting shoreside first receiver is responsible for ensuring that all hardware and software required under this subsection are fully operational and functional whenever the Pacific whiting primary season deliveries are accepted.

(2) Pacific whiting shoreside first receivers and processors that receive groundfish species other than Pacific whiting in excess of trip limits from Pacific whiting shoreside vessels fishing under an EFP issued by the Assistant Regional Administrator are authorized to possess the catch.

(3) Vessel owners and operators, first receivers, or shoreside processor owners, or managers may contact NMFS in writing to request assistance in improving data quality and resolving monitoring issues. Requests may be submitted to: Attn: Frank Lockhart, National Marine Fisheries Service, Northwest Region Sustainable Fisheries Division, 7600 Sand Point Way NE, Seattle, WA 98115, or via email to *frank.lockhart@noaa.gov*.

* * * * *

[FR Doc. E7–17523 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 72, No. 171
Wednesday, September 5, 2007

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

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Chapter VII

[Docket No. 070827486–7487–01]

Effects of Foreign Policy-Based Export Controls

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Request for Comments on Foreign Policy-based Export Controls.

SUMMARY: The Bureau of Industry and Security (BIS) is reviewing the foreign policy-based export controls in the Export Administration Regulations to determine whether they should be modified, rescinded or extended. To help make these determinations, BIS is seeking comments on how existing foreign policy-based export controls have affected exporters and the general public.

DATES: Comments must be received by October 5, 2007.

ADDRESSES: Written comments may be sent by e-mail to *publiccomments@bis.doc.gov.* Include ''FPBEC'' in the subject line of the message. Written comments (three copies) may be submitted by mail or hand delivery to Jeffery Lynch, Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, 14th Street & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Joan Roberts, Foreign Policy Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482–4252. Copies of the current Annual Foreign Policy Report to the Congress are available at *http://www.bis.doc.gov/PoliciesAndRegulations/07ForPolControls/index.htm* and copies may also be requested by calling the Office of Nonproliferation and Treaty Compliance at the number listed above.

SUPPLEMENTARY INFORMATION: Foreign policy-based controls in the Export Administration Regulations (EAR) are implemented pursuant to Section 6 of the Export Administration Act of 1979, as amended. The current foreign policy-based export controls maintained by the Bureau of Industry and Security (BIS) are set forth in the EAR, including in parts 742 (CCL Based Controls), 744 (End-User and End-Use Based Controls) and 746 (Embargoes and Special Country Controls). These controls apply to a range of countries, items, activities and persons, including: Certain general purpose microprocessors for 'military end-uses' and 'military end-users' (§ 744.17); significant items (SI): Hot section technology for the development, production, or overhaul of commercial aircraft engines, components, and systems (§ 742.14); encryption items (§§ 742.15 and 744.9); crime control and detection commodities (§ 742.7); specially designed implements of torture (§ 742.11); certain firearms included within the Inter-American Convention Against the Illicit Manufacturing of and Trafficking in Firearms, Ammunition, Explosives, and Other Related Materials (§ 742.17); regional stability items (§ 742.6); equipment and related technical data used in the design, development, production, or use of certain rocket systems and unmanned air vehicles (§§ 742.5 and 744.3); chemical precursors and biological agents, associated equipment, technical data, and software related to the production of chemical and biological agents (§§ 742.2 and 744.4) and various chemicals included in those controlled pursuant to the Chemical Weapons Convention (§ 742.18); nuclear propulsion (§ 744.5); aircraft and vessels (§ 744.7); communication intercepting devices (software and technology) (§ 742.13); embargoed countries (part 746); countries designated as supporters of acts of international terrorism (§§ 742.8, 742.9, 742.10, 742.19, 746.2, 746.4, 746.7, and 746.9); certain entities in Russia (§ 744.10); individual terrorists and terrorist organizations (§§ 744.12, 744.13 and 744.14); certain persons designated by Executive Order 13315 (''Blocking Property of the Former Iraqi Regime, Its Senior Officials and Their Family Members'') (§ 744.18); and certain sanctioned entities (§ 744.20). Attention is also given in this context to the controls on nuclear-related commodities and technology (§§ 742.3 and 744.2), which are, in part, implemented under section 309(c) of the Nuclear Non Proliferation Act.

Under the provisions of section 6 of the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401–2420 (2000)) (EAA), export controls maintained for foreign policy purposes require annual extension. Section 6 of the EAA requires a report to Congress when foreign policy-based export controls are extended. The EAA expired on August 20, 2001. Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp., p. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 15, 2007 (72 FR 46137, August 16, 2007), continues the EAR and, to the extent permitted by law, the provisions of the EAA, in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706 (2000)). The Department of Commerce, insofar as appropriate, is following the provisions of section 6 in reviewing foreign policy-based export controls, requesting public comments on such controls, and submitting a report to Congress.

In January 2007, the Secretary of Commerce, on the recommendation of the Secretary of State, extended for one year all foreign policy-based export controls then in effect.

To assure maximum public participation in the review process, comments are solicited on the extension or revision of the existing foreign policy-based export controls for another year. Among the criteria considered in determining whether to continue or revise U.S. foreign policy-based export controls are the following:

1. The likelihood that such controls will achieve the intended foreign policy purpose, in light of other factors, including the availability from other countries of the goods, software or technology proposed for such controls;

2. Whether the foreign policy purpose of such controls can be achieved through negotiations or other alternative means;

3. The compatibility of the controls with the foreign policy objectives of the United States and with overall United States policy toward the country subject to the controls;

4. Whether reaction of other countries to the extension of such controls by the

United States is not likely to render the controls ineffective in achieving the intended foreign policy purpose or be counterproductive to United States foreign policy interests;

5. The comparative benefits to U.S. foreign policy objectives versus the effect of the controls on the export performance of the United States, the competitive position of the United States in the international economy, the international reputation of the United States as a supplier of goods and technology; and

6. The ability of the United States to enforce the controls effectively.

BIS is particularly interested in receiving comments on the economic impact of proliferation controls. BIS is also interested in industry information relating to the following:

1. Information on the effect of foreign policy-based export controls on sales of U.S. products to third countries (i.e., those countries not targeted by sanctions), including the views of foreign purchasers or prospective customers regarding U.S. foreign policy-based export controls.

2. Information on controls maintained by U.S. trade partners. For example, to what extent do they have similar controls on goods and technology on a worldwide basis or to specific destinations?

3. Information on licensing policies or practices by our foreign trade partners which are similar to U.S. foreign policy-based export controls, including license review criteria, use of conditions, requirements for pre and post shipment verifications (preferably supported by examples of approvals, denials and foreign regulations).

4. Suggestions for revisions to foreign policy-based export controls that would bring them more into line with multilateral practice.

5. Comments or suggestions as to actions that would make multilateral controls more effective.

6. Information that illustrates the effect of foreign policy-based export controls on trade or acquisitions by intended targets of the controls.

7. Data or other information as to the effect of foreign policy-based export controls on overall trade at the level of individual industrial sectors.

8. Suggestions as to how to measure the effect of foreign policy-based export controls on trade.

9. Information on the use of foreign policy-based export controls on targeted countries, entities, or individuals.

BIS is also interested in comments relating generally to the extension or revision of existing foreign policy-based export controls.

Parties submitting comments are asked to be as specific as possible. All comments received before the close of the comment period will be considered by BIS in reviewing the controls and developing the report to Congress.

All information relating to the notice will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, BIS requires written comments. Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying.

The Office of Administration, Bureau of Industry and Security, U.S. Department of Commerce, displays these public comments on BIS's Freedom of Information Act (FOIA) Web site at *http://www.bis.doc.gov/foia.* This office does not maintain a separate public inspection facility. If you have technical difficulties accessing this Web site, please call BIS's Office of Administration at (202) 482–0637 for assistance.

Dated: August 29, 2007.

Christopher A. Padilla,

Assistant Secretary for Export Administration.

[FR Doc. E7–17525 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–33–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R07–OAR–2007–0655; FRL–8462–8]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Iowa; Clean Air Mercury Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve the State Plan submitted by Iowa on August 15, 2006, and revisions submitted on April 26, 2007. The plan addresses the requirements of EPA's Clean Air Mercury Rule (CAMR), promulgated on May 18, 2005, and subsequently revised on June 9, 2006. EPA is proposing to determine that the submitted State Plan fully meets the CAMR requirements for Iowa.

CAMR requires States to regulate emissions of mercury (Hg) from large coal-fired electric generating units (EGUs). CAMR establishes State budgets for annual EGU Hg emissions and requires States to submit State Plans to ensure that annual EGU Hg emissions will not exceed the applicable State budget. States have the flexibility to choose which control measures to adopt to achieve the budgets, including participating in the EPA-administered CAMR cap-and-trade program. In the State Plan that EPA is proposing to approve Iowa would meet CAMR requirements by participating in the EPA trading program.

DATES: Comments must be received on or before October 5, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2007–0655, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: jay.michael@epa.gov.*

3. *Mail:* Michael Jay, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

4. *Hand Delivery or Courier:* Deliver your comments to: Michael Jay, Environmental Protection Agency, 901 North 5th Street, Kansas City, Kansas 66101. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2007–0655. 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 through *http://www.regulations.gov* or e-mail, information that you consider to be CBI or otherwise protected. 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 and any form of encryption and should be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101. 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 a.m. to 4:30 p.m., excluding Federal holidays.

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

SUPPLEMENTARY INFORMATION:

Table of Contents

I. What Action Is EPA Proposing to Take?

EPA is proposing to approve Iowa's State Plan, submitted on August 15, 2006, and April 26, 2007. In its State Plan, Iowa would meet CAMR by requiring certain coal-fired EGUs to participate in the EPA-administered cap-and-trade program addressing Hg emissions. EPA is proposing to determine that the State Plan meets the applicable requirements of CAMR.

II. What Is the Regulatory History of CAMR?

CAMR was published by EPA on May 18, 2005 (70 FR 28606, ''Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units; Final Rule''). In this rule, acting pursuant to its authority under section 111(d) of the Clean Air Act (CAA), 42 U.S.C. 7411(d), EPA required that all States and the District of Columbia (all of which are referred to herein as States) meet Statewide annual budgets limiting Hg emissions from coal-fired EGUs (as defined in 40 CFR 60.24(h)(8)) under CAA section 111(d). EPA required all States to submit State Plans with control measures that ensure that total, annual Hg emissions from the coal-fired EGUs located in the respective States do not exceed the applicable statewide annual EGU mercury budget. Under CAMR, States may implement and enforce these reduction requirements by participating in the EPA-administered cap-and-trade program or by adopting any other effective and enforceable control measures.

CAA section 111(d) requires States, and along with CAA section 301(d) and the Tribal Air Rule (40 CFR part 49) allows Tribes granted treatment as States (TAS), to submit State Plans to EPA that implement and enforce the standards of performance. CAMR explains what must be included in State Plans to address the requirements of CAA section 111(d). The State Plans were due to EPA by November 17, 2006. Under 40 CFR 60.27(b), the Administrator will approve or disapprove the State Plans.

III. What Are the General Requirements of CAMR State Plans?

CAMR establishes Statewide annual EGU Hg emission budgets and is to be implemented in two phases. The first phase of reductions starts in 2010 and continues through 2017. The second phase of reductions starts in 2018 and continues thereafter. CAMR requires States to implement the budgets by either: (1) Requiring coal-fired EGUs to participate in the EPA-administered cap-and-trade program; or (2) adopting other coal-fired EGU control measures of the respective State's choosing and demonstrating that such control measures will result in compliance with the applicable State annual EGU Hg budget.

Each State Plan must require coal-fired EGUs to comply with the monitoring, recordkeeping, and reporting provisions of 40 CFR part 75 concerning Hg mass emissions. Each State Plan must also show that the State has the legal authority to adopt emission standards and compliance schedules necessary for attainment and maintenance of the State's annual EGU Hg budget and to require the owners and operators of coal-fired EGUs in the State to meet the monitoring, recordkeeping, and reporting requirements of 40 CFR part 75.

IV. How Can States Comply With CAMR?

Each State Plan must impose control requirements that the State demonstrates will limit Statewide annual Hg emissions from new and existing coal-fired EGUs to the amount of the State's applicable annual EGU Hg budget. States have the flexibility to choose the type of EGU control measures they will use to meet the requirements of CAMR. EPA anticipates that many States will choose to meet the CAMR requirements by selecting an option that requires EGUs to participate in the EPA-administered CAMR cap-and-trade program. EPA also anticipates that many States may chose to control Statewide annual Hg emissions for new and existing coal-fired EGUs through an alternative mechanism other than the EPA-administered CAMR cap-and-trade program. Each State that chooses an alternative mechanism must include with its plan a demonstration that the State Plan will ensure that the State will meet its assigned State annual EGU Hg emission budget.

A State submitting a State Plan that requires coal-fired EGUs to participate in the EPA-administered CAMR cap-and-trade program may either adopt regulations that are substantively identical to the EPA model Hg trading rule (40 CFR part 60, subpart HHHH) or incorporate by reference the model rule. CAMR provides that States may only make limited changes to the model rule if the States want to participate in the EPA-administered trading program. A State Plan may change the model rule only by altering the allowance allocation provisions to provide for State-specific allocation of Hg allowances using a methodology chosen by the State. A State's alternative allowance allocation provisions must meet certain allocation timing requirements and must ensure that total allocations for each calendar year will not exceed the State's annual EGU Hg budget for that year.

V. Analysis of Iowa's CAMR State Plan Submittal

A. State Budgets

In this action, EPA is proposing to approve Iowa's State Plan that adopts the annual EGU Hg budgets established for the State in CAMR, i.e., 0.727 tons for EGU Hg emissions in 2010–2017 and 0.287 tons for EGU Hg emissions in 2018 and thereafter. Iowa's State Plan sets these budgets as the total amount of allowances available for allocation for

each year under the EPA-administered CAMR cap-and-trade program.

B. CAMR State Plan

The Iowa State Plan requires coal-fired EGUs to participate in the EPA-administered CAMR cap-and-trade program. The State Plan incorporates by reference the EPA model Hg trading rule but has adopted an alternative allowance allocation methodology. Under the Hg allowance allocation methodology in the model rule, Hg allowances are allocated to units that have operated for 5 years, based on heat input data from a 3-year period that are adjusted for coal rank by using coal factors of 3.0 for the lignite combusted by the unit, 1.25 for the subbituminous combusted by the unit, and 1 for other coal ranks combusted by the unit. The model rule also provides a new unit set-aside from which units without 5 years of operation are allocated allowances based on the units' prior year emissions.

States may establish in their State Plan submissions a different Hg allowance allocation methodology that will be used to allocate allowances to sources in the States if certain requirements are met concerning the timing of submission of units' allocations to the Administrator for recordation and the total amount of allowances allocated for each control period. In adopting alternative Hg allowance allocation methodologies, States have flexibility with regard to:

1. The cost to recipients of the allowances, which may be distributed for free or auctioned;
2. The frequency of allocations;
3. The basis for allocating allowances, which may be distributed, for example, based on historical heat input or electric and thermal output; and
4. The use of allowance set-asides and, if used, their size.

In Iowa's alternative allowance methodology, Iowa has modified the portion of the model rule relating to the basis for allocating allowances to new units commencing operation on or after January 1, 2001. In Iowa's rule 567–34.304, the State has limited the timeframe within which a unit can meet the requirements to apply for allowances under the new unit set-aside to units that commence operation on or after January 1, 2001, and commence construction before January 1, 2006. As a result, one facility meets this criterion and is provided the full allocation under the new source set-aside for both phases amounting to 5 percent of the State's budget for phase I and 3 percent for phase II. Also in the section relating to new units, in the event a generator is served by two or more units, the nameplate capacity will be attributed to each unit in equal fraction of the total nameplate capacity multiplied by 7900 British Thermal Units per Kilowatt Hour for the determination of heat input for each unit.

Iowa's State Plan requires coal-fired EGUs to comply with the monitoring, recordkeeping, and reporting provisions of 40 CFR part 75 concerning Hg mass emissions. Iowa's State Plan also demonstrates that the State has the legal authority to adopt emission standards and compliance schedules necessary for attainment and maintenance of the State's annual EGU Hg budget and to require the owners and operators of coal-fired EGUs in the State to meet the monitoring, recordkeeping, and reporting requirements of 40 CFR part 75. Iowa cites Section 455B.133 of the Iowa Code, which contains the broad enabling authority for Iowa's air pollution control regulations, as containing the legal authority for the Iowa Environmental Protection Commission to adopt the State's rule that allows for Iowa's participation in the nationwide cap and trade program for mercury.

Iowa has committed to revise a definition in its rule to fully ensure allowances can be traded among all sources participating in the EPA-administered cap-and-trade program for mercury as intended. EPA discovered after review of other States' rules, but after Iowa had adopted its Clean Air Interstate Rule (CAIR) and CAMR rules, an issue related to the definition of ''permitting authority'' when it is revised to refer to a specific State's permitting authority.

In Iowa's rule designed to meet CAMR, the EPA model trading rule was revised to limit all references to ''permitting authority'' to refer to the Iowa Department of Natural Resources. This change is acceptable in most, but not all, instances under the current model rule. In certain definitions in the model rule incorporated by Iowa (i.e., ''allocate'' or ''allocation,'' and ''Hg allowance''), it is important that the term ''permitting authority'' cover permitting authorities in all States that choose to participate in the respective EPA-administered trading program. This is necessary to ensure that all allowances issued in the EPA-administered trading program are fungible and can be traded and used for compliance with the allowance-holding requirement in any State in the program.

On February 17, 2007, EPA provided a letter to Iowa that requested and outlined necessary definition revisions for all rules intended to meet CAIR and CAMR. EPA received a letter from Iowa on February 28, 2007, that provided a commitment to make the EPA suggested rule revisions as soon as is practicable upon publication of the final rule concerning the proposed Clean Air Mercury Rule (CAMR) Federal plan. The CAMR Federal plan was proposed on December 22, 2006, and the rulemaking also included changes to the CAMR model rule to integrate it with the proposed Federal plan. Any final changes will need to be incorporated in State rules, and Iowa prefers to wait and make one set of amendments to its State rule to address both the above-referenced definition changes and any final changes to the CAMR model rule reflecting the final Federal plan. On April 11, 2007, EPA received an electronic correspondence from Iowa stating that Iowa will, in any event, complete these rule revisions before January 1, 2008. The State will be able to simultaneously revise the ''permitting authority'' definition in all cap-and-trade rules for both CAIR and CAMR, and properly update the State's rule as necessary to meet the requirements of the EPA-administered cap-and-trade-program for mercury.

The final rule concerning the CAMR Federal plan is expected to be published before the earliest, major deadline for compliance with requirements for source owners and operators under the CAIR trading programs, i.e., the January 1, 2008, deadline for emissions monitoring requirements under the CAIR Annual Trading Program. EPA expects that, by timing adoption of the EPA requested rule revisions to both Iowa's CAIR and CAMR rules to be soon after the publication of the final rule concerning the CAMR Federal plan, the State will ensure the revisions to the definition of ''permitting authority'' will be completed prior to any of the major compliance deadlines for source owners and operators under the CAIR trading programs. Even if the final rule concerning the CAMR Federal plan is not published in the expected timeframe, the State will still need to ensure the necessary State rule revisions are completed and submitted to EPA in advance of January 1, 2008.

VI. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May

22, 2001). This action merely proposes to approve State law as meeting Federal requirements and would impose no additional requirements beyond those imposed by State law. Accordingly, the Administrator certifies that this proposed rule would 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 action proposes to approve pre-existing requirements under State law and would 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 proposal also does not have Tribal implications because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

This proposed action also does not have Federalism implications because it would 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 a State rule implementing a Federal standard. It does not alter the relationship or the distribution of power and responsibilities established in the CAA. 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 proposes to approve a State rule implementing a Federal standard.

Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' requires Federal agencies to consider the impact of programs, policies, and activities on minority populations and low-income populations. EPA guidance [1] states that EPA is to assess whether minority or low-income populations face risk or a rate of exposure to hazards that is significant and that ''appreciably exceed[s] or is likely to appreciably exceed the risk or rate to the general population or to the appropriate comparison group.'' (EPA, 1998) Because this rule merely proposes to approve a state rule implementing the Federal standard established by CAMR, EPA lacks the discretionary authority to modify today's regulatory decision on the basis of environmental justice considerations. However, EPA has already considered the impact of CAMR, including this Federal standard, on minority and low-income populations. In the context of EPA's CAMR published in the **Federal Register** on May 18, 2005, in accordance with Executive Order 12898, the Agency has considered whether CAMR may have disproportionate negative impacts on minority or low income populations and determined it would not.

In reviewing State Plan submissions, EPA's role is to approve State choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a State Plan for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a State Plan submission, to use VCS in place of a State Plan submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule would 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 Part 62

Environmental protection, Air pollution control, Electric utilities, Intergovernmental relations, Mercury, Reporting and recordkeeping requirements.

Dated: August 23, 2007.

John B. Askew,

Regional Administrator, Region 7.

[FR Doc. E7–17414 Filed 9–4–07; 8:45 am]

BILLING CODE 6560–50–P

[1] U.S. Environmental Protection Agency, 1998. Guidance for Incorporating Environmental Justice Concerns in EPA's NEPA Compliance Analyses. Office of Federal Activities, Washington, DC, April, 1998.

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

49 CFR Parts 1540, 1544, and 1560

[Docket No. TSA–2007–28572]

RIN 1652–ZA15

Public Meeting: Secure Flight Program

AGENCY: Transportation Security Administration, DHS.

ACTION: Notice of public meeting and request for comments.

SUMMARY: This notice provides the time and location of the public meeting which will be held by the Transportation Security Administration (TSA) regarding the Notice of Proposed Rulemaking (NPRM) entitled ''Secure Flight Program,'' which was published in the **Federal Register** on August 23, 2007 (72 FR 48356).

DATES: The public meeting will be on September 20, 2007, in Washington, DC. The meeting will begin at 9 am. Persons not able to attend the meeting are invited to provide written comments, which must be received by October 22, 2007.

ADDRESSES: The public meeting will be held at the Grand Hyatt Washington, 1000 H Street, NW., Washington, DC 20001. Participants should check in with Secure Flight staff.

Persons unable to attend the meeting may submit comments, identified by the TSA docket number to this rulemaking, using any one of the following methods:

Comments Filed Electronically: You may submit comments through the docket Web site at *http://dms.dot.gov.* You also may submit comments through the Federal eRulemaking portal at *http://www.regulations.gov.*

Comments Submitted by Mail, Fax, or In Person: Address or deliver your written, signed comments to the Docket Management System at: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Ave., SE., Washington, DC 20590; Fax: 202–493–2251.

See **SUPPLEMENTARY INFORMATION** for format and other information about comment submissions.

FOR FURTHER INFORMATION CONTACT: Kevin Knott, Policy Manager, Secure Flight, Office of Transportation Threat Assessment and Credentialing, TSA–19, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202–4220; Telephone (240) 568–5611.

SUPPLEMENTARY INFORMATION:

Comments Invited

TSA invites interested persons to participate in the public meeting by submitting written comments, data, or views. We invite comments relating to any aspect of the Secure Flight Program. The areas in particular in which TSA seeks information and comment at the public meeting are listed below in the ''Specific Issues for Discussion'' section. See **ADDRESSES** above for information on where to submit comments.

We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from this rulemaking action. See **ADDRESSES** above for information on where to submit comments.

With each comment, please include your name and address, identify the docket number at the beginning of your comments, and give the reason for each comment. The most helpful comments reference a specific topic, explain the reason for any recommendation, and include supporting data. You may submit comments and material electronically, in person, by mail, or fax as provided under **ADDRESSES**, but please submit your comments and material by only one means. If you submit comments by mail or delivery, submit them in two copies, in an unbound format, no larger than 8.5 by 11 inches, suitable for copying and electronic filing.

If you want TSA to acknowledge receipt of comments submitted by mail, include with your comments a self-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it to you.

TSA will file in the public docket all comments received by TSA, except for comments containing confidential information and sensitive security information (SSI),[1] TSA will consider all comments received on or before the closing date for comments and will consider comments filed late to the extent practicable. The docket is available for public inspection before and after the comment closing date.

Handling of Confidential or Proprietary Information and Sensitive Security Information (SSI) Submitted in Public Comments

Do not submit comments that include trade secrets, confidential commercial or financial information, or SSI to the public regulatory docket. Please submit such comments separately from other comments on the rulemaking. Comments containing this type of information should be appropriately marked as containing such information and submitted by mail to the address listed in **FOR FURTHER INFORMATION CONTACT** section.

Upon receipt of such comments, TSA will not place the comments in the public docket and will handle them in accordance with applicable safeguards and restrictions on access. TSA will hold them in a separate file to which the public does not have access, and place a note in the public docket that TSA has received such materials from the commenter. If TSA receives a request to examine or copy this information, TSA will treat it as any other request under the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the Department of Homeland Security's (DHS's) FOIA regulation found in 6 CFR part 5.

Reviewing Comments in the Docket

Please be aware that 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 applicable Privacy Act Statement published in the **Federal Register** on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov.*

You may review the comments in the public docket by visiting the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Dockets Office is located in the West Building Ground Floor, Room W12–140, at the Department of Transportation address, previously provided under **ADDRESSES**. Also, you may review public dockets on the Internet at *http://dms.dot.gov.*

Availability of Document

You can get an electronic copy using the Internet by—

(1) Searching the Department of Transportation's electronic Docket Management System (DMS) Web page (*http://dms.dot.gov/search*); or

(2) Visiting TSA's Security Regulations Web page at *http://www.tsa.gov* and accessing the link for ''Research Center'' at the top of the page.

In addition, copies are available by writing or calling the individual in the **FOR FURTHER INFORMATION CONTACT** section. Make sure to identify the docket number of this action.

Background

TSA performs passenger and baggage screening at the Nation's commercial airports.[2] Aircraft operators currently supplement this security screening by performing passenger watch list matching using the Federal No Fly and Selectee Lists, as required under security directives that TSA issued following the terrorist attacks of September 11, 2001. Aircraft operators also conduct this watch list matching process for non-traveling individuals[3] authorized to enter the sterile area[4] of an airport in order to escort a passenger or for some other purpose approved by TSA.

The Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA) requires TSA to assume from air carriers the comparison of passenger information to the automatic Selectee and No Fly Lists and to utilize all appropriate records in the consolidated and integrated watch list that the Federal Government maintains.[5] The final report of the National Commission on Terrorist Attacks Upon the United States (9/11 Commission Report) recommends that the watch list matching function ''should be performed by TSA and it should utilize the larger set of watch lists maintained by the Federal Government.'' See 9/11 Commission Report at 393.

On August 23, 2007, TSA published in the **Federal Register** (72 FR 48356) the NPRM for the Secure Flight Program describing TSA's proposal for assuming the responsibility for passenger watch list matching from covered aircraft operators.[6] TSA seeks comment on the

[1] ''Sensitive Security Information'' or ''SSI'' is information obtained or developed in the conduct of security activities, the disclosure of which would constitute an unwarranted invasion of privacy, reveal trade secrets or privileged or confidential information, or be detrimental to the security of transportation. The protection of SSI is governed by 49 CFR part 1520.

[2] See the Aviation and Transportation Security Act (ATSA) (Pub. L. 107–71, 115 Stat. 597, Nov. 19, 2001).

[3] ''Non-traveling individual'' is defined in the NPRM for the Secure Flight Program as an individual to whom a covered aircraft operator or covered airport operator seeks to issue an authorization to enter the sterile area of an airport in order to escort a minor or a passenger with disabilities or for some other purpose permitted by TSA. It would not include employees or agents of airport or aircraft operators or other individuals whose access to a sterile area is governed by another TSA regulation or security directive. Proposed 49 CFR 1560.3.

[4] ''Sterile area'' is defined in 49 CFR 1520.5 as ''a portion of an airport defined in the airport security program that provides passengers access to boarding aircraft and to which the access generally is controlled by TSA, or by an aircraft operator under part 1544 of this chapter or a foreign air carrier under part 1546 of this chapter, through the screening of persons and property.''

[5] Pub. L. 108–458, 118 Stat. 3638, Dec. 17, 2004.

[6] TSA proposes to define a ''covered aircraft operator'' as a U.S. aircraft operator that is required to have a full program under 49 CFR 1544.101(a) or a foreign air carrier that is required to have a security program under 49 CFR 1546.101(a) or (b). Proposed § 1560.3.

proposal described in the NPRM. TSA intends to analyze the public comments and issue a final rule.

Specific Issues for Discussion

There are several areas in particular in which TSA seeks information and comment from the industry at the public meeting, listed below. These key issues are intended to help focus public comments on subjects that TSA must explore in order to complete its review of the proposed Secure Flight program. The comments at the meeting need not be limited to these issues, and TSA invites comments on any other aspect of the proposed Secure Flight program. These are:

(1) Proposed data elements.

(2) Proposed data retention schedule.

(3) Proposed 72-hour data transmission requirement.

(4) Proposed watch list matching procedures for overflights.

(5) Proposed watch list matching procedures for international 2-leg boarding pass issuance.

(6) Proposed requirement for placing a code, such as a bar code, on boarding passes.

(7) Proposed privacy notice requirement.

(8) Proposed compliance schedule and estimated compliance costs.

Participation at the Meeting

The meeting is expected to begin at 9 a.m. Following an introduction by TSA, members of the public will be invited to ask clarifying questions or present their views.

Anyone wishing to present an oral statement at the meeting must register to present comments between 8 and 9:30 a.m. on the day of the meeting, and provide his or her name and affiliation. Such requests will be met on a first-come, first-served basis. Speakers should keep comments brief and plan to speak for no more than five minutes when presenting comments.

Public Meeting Procedures

TSA will use the following procedures to facilitate the meeting:

(1) There will be no admission fee or other charge to attend or to participate in the meeting. The meeting will be open to all persons. All persons who wish to present an oral statement must register to present comments between 8 and 9:30 a.m. on the day of the meeting. TSA will make every effort to accommodate all persons who wish to participate, but admission will be subject to availability of space in the meeting room. The meeting may adjourn early if scheduled speakers complete their statements or questions in less time than is scheduled for the meeting.

(2) An individual, whether speaking in a personal or a representative capacity on behalf of an organization, will be limited to a five-minute statement and scheduled on a first-come, first-served basis.

(3) Any speaker prevented by time constraints from speaking will be encouraged to submit written remarks, which will be made part of the record.

(4) For information on facilities or services for individuals with disabilities or to request assistance at the meeting, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above before September 13, 2007.

(5) Representatives of TSA will preside over the meeting.

(6) The meeting will be recorded by a court reporter. Any person who is interested in purchasing a copy of the transcript should contact the court reporter directly.

(7) Statements made by TSA representatives are intended to facilitate discussion of the issues or to clarify issues. Any statement made during the meeting by a TSA representative is not intended to be, and should not be construed as, a position of TSA.

(8) The meeting is designed to invite public views and gather additional information. No individual will be subject to cross-examination by any other participant; however, TSA representatives may ask questions to clarify a statement.

Issued in Arlington, Virginia, on August 31, 2007.

Stephanie Rowe,

Assistant Administrator for Transportation Threat Assessment & Credentialing.

[FR Doc. E7–17607 Filed 9–4–07; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AU68

Endangered and Threatened Wildlife and Plants; Establishment of a Nonessential Experimental Population of Rio Grande Silvery Minnow in the Big Bend Reach of the Rio Grande in Texas

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of availability of draft environmental assessment; notice of public hearing.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), in cooperation with the National Park Service, and the United States Section of the International Boundary and Water Commission, propose to reestablish the Rio Grande silvery minnow (*Hybognathus amarus*), a Federally listed endangered fish, into its historic habitat in the Big Bend reach of the Rio Grande in Presidio, Brewster, and Terrell counties, Texas.

We propose to reestablish the Rio Grande silvery minnow under section 10(j) of the Endangered Species Act of 1973, as amended (ESA), and to classify it as a nonessential experimental population (NEP). On the Rio Grande, the geographic boundaries of the NEP would extend from Little Box Canyon downstream of Ft. Quitman, Hudspeth County, Texas, through Big Bend National Park and the Rio Grande Wild and Scenic River, to Amistad Dam and the nearby railroad bridge (Big Bend reach of the Rio Grande). On the Pecos River, the geographic boundaries of the NEP would extend from the river's confluence with Independence Creek to its confluence with the Rio Grande.

This proposed reestablishment is part of the recovery actions that the Service, Federal and State agencies, and other partners are conducting throughout the species' historic range. This proposed rule provides a plan for establishing the NEP and provides for limited allowable legal taking of Rio Grande silvery minnows within the defined NEP area.

A draft environmental assessment (EA) has been prepared on this proposed action and is available for comment (see **ADDRESSES** section below).

DATES: We request that comments on this proposal be submitted by the close of business on November 5, 2007. We will also hold one public hearing on this proposed rule on October 10, 2007, at 7 p.m.

ADDRESSES: Written Comments. You may submit written comments and other information by any of the following methods (please see ''Public Comments Solicited'' section below for additional guidance):

1. *Mail or hand delivery:* Field Supervisor, Austin Ecological Services Field Office, 107011 Burnet Road, Suite 200, Austin, TX 78758.

2. *Fax:* (512) 490–0974.

3. *E-mail: Aimee_Roberson@fws.gov.*

Obtaining information from the Service. You may obtain copies of the proposed rule and the draft EA from the street address given above or by calling (512) 490–0057. The proposed rule and draft EA are also available from our Web site at *http://www.fws.gov/southwest/es/Library/.*

The supporting file for this proposed rule will be available for public inspection, by appointment, during normal business hours, at the New Mexico Ecological Services Field Office, 2105 Osuna Road NE., Albuquerque, New Mexico 87113 and at the Fish and Wildlife Service's office at 500 West Avenue H, Suite 104F, Alpine, Texas 79830.

Public Hearing

The public hearing will be held October 10, 2007, at Sul Ross State University, Gallego Center, Room 129, Alpine, Texas. The hearing will begin at 7 p.m. and last until 8:45 p.m., with an informal question and answer session beginning at 6 p.m.

FOR FURTHER INFORMATION CONTACT: Adam Zerrenner, Field Supervisor, Austin Ecological Services Field Office, telephone (512)–490–0057 (see **ADDRESSES** above).

SUPPLEMENTARY INFORMATION:

Public Comments Solicited

We want the final rule to be as effective as possible and the final EA on the proposed action to evaluate all potential issues associated with this action. Therefore, we invite the public, Tribal and government agencies, the scientific community, industry, and other interested parties to submit comments or recommendations concerning any aspect of this proposed rule and the draft EA. Comments should be as specific as possible.

To issue a final rule to implement this proposed action and to determine whether to prepare a finding of no significant impact or an environmental impact statement, we will take into consideration all comments and any additional information we receive. Such communications may lead to a final rule that differs from this proposal. All comments, including commenters' names and addresses, if provided to us, will become part of the supporting record.

If you wish to provide comments and/or information, you may submit your comments and materials by any one of several methods (see **ADDRESSES** section). Comments submitted electronically should be in the body of the e-mail message itself or attached as a text file (ASCII), and should not use special characters or encryption. Please also include ''Attn: RGSM Proposed 10(j) Designation,'' in your e-mail message.

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.

Background

Legislative

The ESA provides that species listed as endangered or threatened are afforded protection primarily through the prohibitions of section 9 and the requirements of section 7. Section 9 of the ESA, among other things, prohibits the take of endangered wildlife. ''Take'' is defined by the ESA as harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct. Service regulations (50 CFR 17.31) generally extend the prohibitions of take to threatened wildlife. Section 7 of the ESA outlines the procedures for Federal interagency cooperation to conserve federally listed species and protect designated critical habitat. It mandates that all Federal agencies use their existing authorities to further the purposes of the ESA by carrying out programs for the conservation of listed species. It also states that Federal agencies will, in consultation with the Service, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Section 7 of the ESA does not affect activities undertaken on private land unless they are authorized, funded, or carried out by a Federal agency.

Under section 10(j) of the ESA, the Secretary of the Department of the Interior can designate reintroduced populations established outside the species' current range, but within its historic range, as ''experimental.'' With the experimental population designation, the relevant population is treated as threatened for purposes of section 9 of the ESA, regardless of the species' designation elsewhere in its range. Threatened designation allows us greater discretion in devising management programs and special regulations for such a population. Section 4(d) of the ESA allows us to adopt whatever regulations are necessary and advisable to provide for the conservation of a threatened species. In these situations, the general regulations that extend most section 9 prohibitions to threatened species do not apply to that species, and the 10(j) rule contains the prohibitions and exemptions necessary and appropriate to conserve that species.

Based on the best scientific and commercial data available, we must determine whether the experimental population is *essential* or *nonessential* to the continued existence of the species. The regulations (50 CFR 17.80b) state that an experimental population is considered essential if its loss would be likely to appreciably reduce the likelihood of survival of that species in the wild. All other populations are considered nonessential. We have determined that this experimental population would not be essential to the continued existence of the species in the wild. Therefore, the Service is proposing to designate a nonessential experimental population (NEP) for the species in this area.

For the purposes of section 7 of the ESA, we treat an NEP as a threatened species when the NEP is located within a National Wildlife Refuge or National Park, and section 7(a)(1) and the consultation requirements of section 7(a)(2) of the ESA apply. Section 7(a)(1) requires all Federal agencies to use their authorities to carry out programs for the conservation of listed species. Section 7(a)(2) requires that Federal agencies, in consultation with the Service, insure that any action authorized, funded, or carried out is not likely to jeopardize the continued existence of a listed species or adversely modify its critical habitat. When NEPs are located outside a National Wildlife Refuge or National Park, we treat the population as proposed for listing, and only two provisions of section 7 apply—section 7(a)(1) and section 7(a)(4). In these instances, NEPs provide additional flexibility because Federal agencies are not required to consult with us under section 7(a)(2). Section 7(a)(4) requires Federal agencies to confer (rather than consult) with the Service on actions that are likely to jeopardize the continued existence of a species proposed to be listed. The results of a conference are in the form of conservation recommendations that are optional as the agencies carry out, fund, or authorize activities. Activities that are not carried out, funded, or authorized by Federal agencies, and are not on Federal lands are not affected by a NEP designation.

Rio Grande silvery minnows that are used to establish an experimental population may come from a donor population, provided their removal will not create adverse impacts upon the parent population, and provided appropriate permits are issued in accordance with our regulations (50 CFR 17.22) prior to their removal. In the

case of the Rio Grande silvery minnow, the donor population is a captive-bred population that was propagated with the intention of re-establishing wild populations to achieve recovery goals. In addition, it is possible that stock raised from wild eggs could also be released into the NEP area. Rio Grande silvery minnow eggs are collected from the wild population in New Mexico each year and are raised in captivity to provide individuals for captive propagation and augmentation of the wild population.

Critical habitat has been designated for the Rio Grande silvery minnow in New Mexico (68 FR 8088–8135; February 19, 2003), and the designated critical habitat does not include this NEP area. Section 10(j)(2)(C)(ii) of the ESA states that critical habitat shall not be designated for any experimental population that is determined to be nonessential. Accordingly, we cannot designate critical habitat in areas where we have already established an NEP.

Biological

The Rio Grande silvery minnow is one of seven species in the genus *Hybognathus* found in the United States (Pflieger 1980, p. 177). The species was first described by Girard (1856 in Service 1999, p. 38) from specimens taken from the Rio Grande near Fort Brown, Cameron County, Texas. It is a stout silvery minnow with moderately small eyes and a small, slightly oblique mouth. Adults may reach 5 inches (in) (125 millimeters (mm)) in total length (Remshardt 2006b). Its dorsal fin is distinctly pointed with the front of it located slightly closer to the tip of the snout than to the base of the tail. The fish is silver with emerald reflections. Its belly is silvery white, its fins are plain, and barbels are absent (Sublette *et al.* 1990, pp. 129–130).

This species was historically one of the most abundant and widespread fishes in the Rio Grande Basin, occurring from Española, New Mexico, to the Gulf of Mexico (Bestgen and Platania 1991, p. 225). It was also found in, but is now absent from, the Pecos River, a major tributary of the Rio Grande, from Santa Rosa, New Mexico, downstream to its confluence with the Rio Grande (Pflieger 1980, p. 177). The Rio Grande silvery minnow is extirpated from the Pecos River and also from the Rio Grande downstream of Elephant Butte Reservoir and upstream of Cochiti Reservoir (Bestgen and Platania 1991, pp. 226–229). The current distribution of the Rio Grande silvery minnow is limited to the Rio Grande between Cochiti Dam and Elephant Butte Reservoir in New Mexico, which is only about 5 percent of its historic range (Bestgen and Platania 1991, pp. 226–229). Throughout much of its historic range, the decline of the Rio Grande silvery minnow has been attributed to modification of the flow regime (hydrological pattern of flows that vary seasonally in magnitude and duration, depending on annual precipitation patterns such as runoff from snowmelt), channel drying, reservoirs and dams, stream channelization, and perhaps interactions with nonnative fish and decreasing water quality (Cook *et al.* 1992, p. 42; Bestgen and Platania 1991, pp. 229–230; Service 1999, pp. 1–2). Development of agriculture and the growth of cities within the historic range of the Rio Grande silvery minnow resulted in a decrease in the quality of river water caused by municipal and agricultural runoff (i.e., sewage and pesticides) that may have also adversely affected the range and distribution of the Rio Grande silvery minnow (Service 1999, p. 2).

The various life history stages of the Rio Grande silvery minnow require low velocity habitats with a sandy and silty substrate that is generally associated with a meandering river that includes side channels, oxbows, and backwaters (Bestgen and Platania 1991, pp. 227–228). Although the Rio Grande silvery minnow is a hardy fish, capable of withstanding many of the natural stresses of the desert aquatic environment, its maximum documented longevity in the wild is about 25 months, and very few survive more than 13 months. However, it is not uncommon for Rio Grande silvery minnows in captivity to live beyond 2 years (Service 2007, p. 8). Thus, a successful annual spawn is key to the survival of the species (Service 1999, p. 20; Dudley and Platania 2001, pp. 16–21; Dudley and Platania 2002, p. 3). More information about the life history and decline of the Rio Grande silvery minnow can be found in the final designation of critical habitat for the species (February 19, 2003; 68 FR 8088–8090) and in the Rio Grande Silvery Minnow Recovery Plan (Recovery Plan; Service 1999, pp. 1–38).

The Rio Grande silvery minnow is extirpated from the Big Bend reach of the Rio Grande (Service 2007). Natural repopulation is not possible without human assistance due to extensive reaches of river with no Rio Grande silvery minnow habitat (including large reservoirs, where this species cannot survive) between where the species currently exists in the wild in New Mexico and the Big Bend reach. Reasons for the species' extirpation in the Rio Grande in Texas are uncertain, but are believed to have been due to a combination of low flows caused by drought and diversions and of water pollution in the 1950s (Edwards 2005, p. 3). The last documentation of a Rio Grande silvery minnow in the Big Bend reach of the Rio Grande was in 1960 (Bestgen and Platania 1991, p. 229). However, the Big Bend reach has not experienced extensive drying since the drought of the 1950s, and the continuing presence of members of the pelagic spawning guild with life history requirements similar to the Rio Grande Silvery minnow are evidence that the Big Bend reach of the Rio Grande may support reestablishment of Rio Grande silvery minnow (Edwards 2005, pp. 37–38). Water quality in the Big Bend reach appears to be generally improving over time, and we do not believe it is a primary determinant of the survivability of the Rio Grande silvery minnow in this reach (Edwards 2005). In addition, most of the Rio Grande in the Big Bend Reach on both sides of the river is designated as a conservation area and managed for habitat protection and improvement by the State of Texas, the National Park Service, and governmental agencies and private organizations in Mexico (Edwards 2005, p. 11).

The Service contracted a study examining the suitability of the habitat in the Big Bend reach of the Rio Grande for the Rio Grande silvery minnow. The completed study indicates that there is a reasonable likelihood that Rio Grande silvery minnows will survive in this portion of the Rio Grande. It also identifies the need for habitat restoration projects, with an emphasis on the removal of invasive, nonnative species, such as salt cedar (*Tamarix chinensis*) and giant river cane (also known as giant reed; *Arundo donax*), which can prevent sediment from entering the river in amounts that are needed to form Rio Grande silvery minnow habitat (Edwards 2005, pp. 43–44). We anticipate working with land managers and other interested parties, on a voluntary basis, to develop plans to further guide and accomplish habitat management and restoration activities, including removal and control of invasive, nonnative species, such as salt cedar and giant river cane.

Recovery Efforts

We published the final rule to federally list the Rio Grande silvery minnow on July 20, 1994 (59 FR 36988). Restoring an endangered or threatened species to the point where it is recovered is a primary goal of our endangered species program. Thus, on July 1, 1994, the Rio Grande Silvery

Minnow Recovery Team (Recovery Team) was established under section 4(f)(2) of the ESA and our cooperative policy on recovery plan participation, a policy intended to involve stakeholders in recovery planning (July 1, 1994; 59 FR 34272). Numerous individuals, agencies, and affected parties were involved in the development of the Recovery Plan or otherwise provided assistance and review (Service 1999, pp. 63–67). On July 8, 1999, we finalized the Recovery Plan (Service 1999, 71 pp.). The Recovery Plan has been updated and revised, and a draft revised Recovery Plan (Service 2007) was released for public comment on January 18, 2007 (72 FR 2301).

The draft revised Recovery Plan describes recovery goals for the Rio Grande silvery minnow (Service 2007, pp. 66–73) and actions for their completion (Service 2007, pp. 74–109). The three goals identified for the recovery and delisting of the Rio Grande silvery minnow are:

(1) Prevent the extinction of the Rio Grande silvery minnow in the middle Rio Grande of New Mexico;

(2) Recover the Rio Grande silvery minnow to an extent sufficient to change its status on the List of Endangered and Threatened Wildlife from endangered to threatened (downlisting). This may be considered when three populations (including at least two that are self-sustaining) of the species have been established within the historic range of the species and have been maintained for at least 5 years; and

(3) Recover the Rio Grande silvery minnow to an extent sufficient to remove it from the List of Endangered and Threatened Wildlife (delisting). This may be considered when three self-sustaining populations have been established within the historic range of the species, and they have been maintained for at least 10 years (Service 2007, p. 66).

The Rio Grande silvery minnow's range has been so greatly restricted that the species is extremely vulnerable to catastrophic events, such as a prolonged period of low or no flow in its habitat in the middle Rio Grande in New Mexico (i.e., the loss of all surface water) (Dudley and Platania 2001, p. 21). Reestablishment of the Rio Grande silvery minnow into other areas of its historic range will assist in the species' recovery and long-term survival in part because it is unlikely that any single event would simultaneously eliminate the Rio Grande silvery minnow from three geographic areas (Service 1999, pp. 57–61).

The Recovery Team developed a reach-by-reach analysis of the Rio Grande and Pecos River basins to identify the salient hydrological, chemical, and biological features of each reach. This analysis addressed the threats to the Rio Grande silvery minnow and considered the suitability of each reach for potential reestablishment (Service 2007).

The Recovery Team's reach-by-reach analysis considered: (1) The reasons for the species' extirpation from the selected reach; (2) the presence of other members of the reproductive guild (pelagic spawner; non-adhesive, semibuoyant eggs); (3) habitat conditions (including susceptibility to river drying and presence of diversion structures); and (4) the presence of congeners (i.e., other species of *Hybognathus*). After completing their analysis, the Recovery Team identified the Big Bend reach of the Rio Grande as the first priority for reestablishment efforts (Service 2007, p. 160) (see ''Reestablishment Area'' below for more details).

In accordance with the Recovery Plan, we have initiated a captive propagation program for the Rio Grande silvery minnow (Service 1999, pp. 60–61). We currently have Rio Grande silvery minnows housed at: (1) The Service's Dexter National Fish Hatchery and Technology Center, Dexter, New Mexico; (2) the City of Albuquerque's Biological Park, Albuquerque, New Mexico; and (3) the New Mexico State University, Las Cruces, New Mexico. These facilities are actively propagating and rearing Rio Grande silvery minnows. Offspring of these fish are being used to augment the Rio Grande silvery minnow population in the middle Rio Grande, New Mexico.

Ongoing recovery efforts involving the release of captive-bred Rio Grande silvery minnows for augmentation of the population in the middle Rio Grande of New Mexico have demonstrated the potential viability of reestablishment as a tool for Rio Grande silvery minnow conservation. In 2000, the Service initiated captive propagation as a strategy to assist in the recovery of the Rio Grande silvery minnow. Captive propagation is conducted in a manner that will, to the maximum extent possible, preserve the genetic and ecological distinctiveness of the Rio Grande silvery minnow and minimize risks to existing wild populations.

Since 2000, approximately one million silvery minnows have been propagated (using both adult wild silvery minnows and wild-caught eggs) and then released into the wild in New Mexico. Wild gravid adults are successfully spawned in captivity at the City of Albuquerque's propagation facilities. Eggs left in the wild have a very low survivorship and spawning in captivity ensures that an adequate number of spawning adults are present to repopulate the river each year. While hatcheries continue to successfully spawn silvery minnows, wild eggs are collected to ensure genetic diversity within the remaining population. This program is carefully monitored so that it will not have an adverse effect on the wild population of Rio Grande silvery minnows in New Mexico.

Direct and indirect evidence from the Rio Grande silvery minnow monitoring program indicates that augmentation efforts in the Rio Grande near Albuquerque, New Mexico, are contributing to an increase in catch (*i.e.*, during seining) rates of Rio Grande silvery minnows. The success of this augmentation effort indicates that hatchery-raised individuals can be released back to the wild with adequate retention in or near original release sites, can experience survival of at least 2 years after release, and ultimately can contribute to future spawning efforts (Remshardt 2006, pp. 11–12).

The source of Rio Grande silvery minnows for releases in the Big Bend reach will likely be from the Service's Dexter National Fish Hatchery and Technology Center, or another Service facility set up to provide fish specifically for this purpose. Expanding the Rio Grande silvery minnow's propagation program for potential releases into the Big Bend reach will result in more fish being produced overall and will not negatively impact the current program, which is producing Rio Grande silvery minnows for augmentation of the population in New Mexico.

Reestablishment Area

The primary factors resulting in the determination by the Recovery Team that the Rio Grande reach from Presidio to Amistad Reservoir is the most suitable for reintroduction efforts are water quality and quantity; the presence of suitable habitat; a lack of barriers to fish movement; a lack of ongoing activities that are likely to adversely affect the Rio Grande silvery minnow; and that most of the Rio Grande in the Big Bend Reach on both sides of the river is designated as a conservation area and managed for habitat protection and improvement by the State of Texas, the National Park Service, and governmental agencies and private organizations in Mexico (Edwards 2005, p. 11).

The Big Bend reach is generally perennial with a base flow of approximately 400 cubic feet per second (cfs). Severe flow reductions only occurred during the severest droughts in the 1950s. A period of intermittent drying did occur in 2003. However, this drying event appears to have been brief and occurred in a small area. In addition, this reach is not levied and has small rock dam weirs, all but one of which (Foster's weir, at the end of the reach deemed suitable) does not appear to be a barrier to fish movement. The substrate ranges from silt to cobble and boulder depending on local conditions. Almost half of this reach is in canyons, including the Big Bend National Park. The lower canyons reach has spring input resulting in improved water quality and quantity. Outside the canyon reaches, the river is braided in some sections with a moderate gradient, providing areas of suitable habitat for Rio Grande silvery minnows. In addition, there are no regular channel maintenance activities in this reach.

Based on the above information, we believe that the Rio Grande, from Mulato Dam (near the western border of Big Bend Ranch State Park) to Foster's Weir, east of the Terrell/Val Verde county line, contains suitable habitat for the Rio Grande silvery minnow and that it is likely the species can be successfully reestablished in the Big Bend reach. Establishment of a viable population of Rio Grande silvery minnows in the Big Bend reach of the Rio Grande under this proposed NEP designation would help achieve one of the primary recovery goals for downlisting and eventually delisting this species (see ''Recovery Efforts'' section above for more information). However, it would take several years of monitoring to fully evaluate if Rio Grande silvery minnows have become established and remain viable in this river reach.

Therefore, we are proposing to release the Rio Grande silvery minnow into its historic habitat in this area. The NEP area, which encompasses all potential release sites, will be located (1) in the Rio Grande, from Little Box Canyon downstream of Ft. Quitman, Hudspeth County, Texas, through Big Bend National Park and the Rio Grande Wild and Scenic River, to Amistad Dam and the nearby railroad bridge; and (2) in the Pecos River, from its confluence with Independence Creek to its confluence with the Rio Grande.

Section 10(j) of the ESA requires that an experimental population be geographically separate from other wild populations of the same species. This NEP area is totally isolated from existing populations of this species by large reservoirs, and this fish is not known to move through large reservoirs. Therefore, the reservoirs would act as barriers to the species' downstream movement in the Rio Grande below Amistad Reservoir, and would ensure that this NEP remains geographically isolated and easily distinguishable from existing upstream wild populations in New Mexico. Based on the habitat requirements of the Rio Grande silvery minnow, we do not expect them to become established outside the NEP.

The geographic extent being proposed for NEP designation is larger than needed as only portions of this proposed NEP area contain suitable habitat. However, this area represents what we believe to be the maximum geographic extent to which the fish could move if released in the Big Bend reach of the Rio Grande. We believe including this additional area provides a more effective recovery strategy by eliminating changing regulatory requirements in case Rio Grande silvery minnows unexpectedly move beyond the expected establishment area. If any of the released Rio Grande silvery minnows, or their offspring, move outside the designated NEP area, then the Service would consider these fish to have come from the NEP area, and we would propose to amend this 10(j) rule to enlarge the boundaries of the NEP area to include the entire range of the expanded populations.

Release Procedures

The exact dates for releases have not been determined at this time. However, an implementation plan, including information about potential release sites, methods, and the number of individuals to be released, is appended to the draft EA and is also available for public comment.

As part of the Rio Grande silvery minnow augmentation program in New Mexico, the Service evaluated different release strategies such as time of year, time of day, specific release habitats, and various hatchery environments (natural outdoor ponds versus indoor facilities). All of this information adds to our knowledge of the species and will assist us in future recovery actions, such as providing release procedures and monitoring strategies for the proposed reestablishment of Rio Grande silvery minnows in the Big Bend reach (Remshardt 2006, pp. v, 13–15).

Status of Reestablished Population

As stated earlier, we have determined that this reintroduced population is nonessential. This determination has been made for the following reasons:

(a) An established population of Rio Grande silvery minnows exists in the middle Rio Grande, New Mexico;

(b) Captive propagation facilities maintain a captive population and provide adequate numbers of Rio Grande silvery minnows to maintain the wild New Mexico population at current levels;

(c) The additional number of silvery minnows needed for reestablishment would not inhibit the augmentation efforts to maintain the established population in the middle Rio Grande, New Mexico; and

(d) The possible failure of this proposed action would not appreciably reduce the likelihood of survival of the species in the wild.

If this proposal is adopted, we would ensure, through our section 10 permitting authority and the section 7 consultation process, that the use of Rio Grande silvery minnows from any donor population for releases in the Big Bend reach is not likely to jeopardize the continued existence of the species in the wild. Reestablishment of populations within the Rio Grande silvery minnow's historic range is necessary to further the recovery of this species (Service 2007, p. 67).

We believe that incidental take of members of the NEP associated with otherwise lawful activities would not pose a substantial threat to Rio Grande silvery minnow recovery, as activities that currently occur in the NEP area are compatible with Rio Grande silvery minnow recovery. For example, there are no major dams or diversions in the Big Bend reach, which are the primary threats to the species within its current range in the Rio Grande in New Mexico. Also, most of the portion of the Big Bend reach in which we expect Rio Grande silvery minnows to become established is protected and managed for fish and wildlife and other natural resources by State and Federal agencies in both the United States and Mexico. Thus, the more stringent legal protections provided under an essential experimental population are unnecessary. The anticipated success of this reestablishment would enhance the conservation and recovery potential of this species by extending its present range into currently unoccupied historic habitat (Service 2007, pp. 159–171).

Management

The aquatic resources in the reestablishment area are managed by the National Park Service, the International Boundary and Water Commission, the State of Texas, and private landowners. Multiple-use management of these waters would not change as a result of

the experimental population designation. Agricultural, recreational, and other activities by private landowners within and near the NEP area would not be affected by this rule and the subsequent release of the Rio Grande silvery minnow. Because of the exceptions provided by NEP designation, we do not believe the reestablishment of Rio Grande silvery minnows would conflict with existing human activities or hinder public use of the area.

The Service, the National Park Service, the International Boundary and Water Commission, and Texas Parks and Wildlife Department employees would plan and manage the reestablishment of Rio Grande silvery minnows. This group would closely coordinate on releases, monitoring, coordination with landowners and land managers, and public awareness, among other tasks necessary to ensure successful reestablishment of the species. The Service has also convened a Technical Team comprised of representatives from these agencies and other experts. This Technical Team assisted in the development of the Implementation and Monitoring Plan that is appended to the draft EA.

(a) *Mortality:* The regulations implementing the ESA define ''incidental take'' as take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity (50 CFR 17.3) such as recreation (e.g., fishing, boating, wading, trapping or swimming), forestry, agriculture, and other activities that are in accordance with Federal, Tribal, State, and local laws and regulations. If this 10(j) rule is finalized, take of a Rio Grande silvery minnows within the experimental population area would be allowed provided that the take is unintentional and is not due to negligent conduct. However, if there is evidence of intentional take of a Rio Grande silvery minnow within the experimental population area, we would refer the matter to the appropriate entities for investigation. We expect levels of incidental take to be low since the reestablishment is compatible with existing human use activities and practices for the area. More specific information regarding take can be found in the Proposed Regulation Promulgation section of this proposed rule.

(b) *Special handling:* In accordance with 50 CFR 17.21(c)(3), any employee or agent of the Service, any other Federal land management agency, or State personnel, designated for such purposes, may, in the course of their official duties, handle Rio Grande silvery minnows for scientific purposes; relocate Rio Grande silvery minnows to avoid conflict with human activities; relocate Rio Grande silvery minnows to other release sites for recovery purposes; aid sick or injured Rio Grande silvery minnows; and, salvage dead Rio Grande silvery minnows. However, non-Service personnel and their agents would need to acquire permits from the Service for these activities.

(c) *Coordination with landowners and land managers:* The Service and cooperators have identified issues and concerns associated with the proposed Rio Grande silvery minnow reestablishment through the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) scoping comment period. The proposed reestablishment also has been discussed with potentially affected State agencies and private landowners. Affected State agencies, landowners, and land managers have indicated support for the proposed reestablishment, provided a NEP is designated and land and water use activities in the proposed NEP area are not constrained.

(d) *Monitoring:* After the initial release of Rio Grande silvery minnows, we would monitor their presence or absence at least annually and document any spawning behavior or young-of-year fish that might be present. Depending on available resources, monitoring may occur more frequently, especially during the first few years of reestablishment efforts. This monitoring would be conducted primarily by seining and would be accomplished by Service, National Park Service, or State employees or by contracting with the appropriate species experts. Annual reports would be produced detailing stocking and monitoring activities that took place during the previous year. We would also fully evaluate these reestablishment efforts every 5 years to determine whether to continue or terminate them.

(e) *Public awareness and cooperation:* On August 9, 2005, we mailed letters to potentially affected Congressional offices, Federal and State agencies, local governments, landowners, and interested parties to notify them that we were considering proposing NEP status in the Rio Grande and Pecos River for the Rio Grande silvery minnow. We received a total of 10 responses during the September 2005 scoping meetings and comment period. The comments received are listed in the EA and have been considered in the formulation of alternatives considered in the NEPA process.

Public Hearings

The ESA provides for one or more public hearings on this proposed rule, if requested. Given the likelihood of a request, we have scheduled one public hearing. We will hold a public hearing as specified above in the **DATES** and **ADDRESSES** section above. Announcements for the public hearing will be made in local newspapers. Appropriate County and State officials, as well as Mexican officials, will be notified.

Public hearings are designed to gather relevant information that the public may have and that we should consider in our rulemaking. During the hearing, we will present information about the proposed action. We invite the public to submit information and comments at the hearing or in writing during the open public comment period. We encourage persons wishing to comment at the hearing to provide a written copy of their statement at the start of the hearing. This notice and public hearing will allow all interested parties to submit comments on the proposed NEP rule for the Rio Grande silvery minnow. We are seeking comments from the public, other concerned governmental agencies, Tribes, the scientific community, industry, or any other interested parties concerning the proposal. Persons may send written comments to the Austin Ecological Services Field Office (see **ADDRESSES** section) at any time during the open comment period (See **DATES** section). We will give equal consideration to oral and written comments.

Peer Review

In accordance with our policy on peer review, published on July 1, 1994 (59 FR 34270), we will provide copies of this proposed rule to three appropriate and independent specialists in order to solicit comments on the scientific data and assumptions relating to the supportive biological and ecological information for this proposed NEP designation. The purpose of such review is to ensure that the proposed NEP designation is based on the best scientific information available. We will invite these peer reviewers to comment during the public comment period and will consider their comments and information on this proposed rule during preparation of a final determination.

Required Determinations

Regulatory Planning and Review (E.O. 12866)

In accordance with the criteria in Executive Order 12866, this proposed

rule to designate NEP status for the Rio Grande silvery minnow in the Big Bend reach of the Rio Grande, Texas, is not a significant regulatory action subject to Office of Management and Budget review. This rule will not have an annual economic effect of $100 million or more on the economy and will not have an adverse effect on any economic sector, productivity, competition, jobs, the environment, or other units of government. Therefore, a cost-benefit and economic analysis is not required.

We do not expect this rule to have significant impacts to existing human activities (e.g., agricultural activities, ranching, grazing, salt cedar and giant river cane control, forestry, fishing, boating, wading, swimming, trapping) in the watershed. The reestablishment of this federally listed species, which will be accomplished under NEP status with its associated regulatory relief, is not expected to impact Federal agency actions. Because of the substantial regulatory relief, we do not believe the proposed reestablishment of this species would conflict with existing or proposed human activities or hinder public use of the Big Bend reach of the Rio Grande or its tributaries.

This rule will not create inconsistencies with other agencies' actions or otherwise interfere with an action taken or planned by another agency. Federal agencies most interested in this rulemaking are primarily the National Park Service and the International Boundary and Water Commission. Both Federal agencies support the reestablishment. Because of the substantial regulatory relief provided by the NEP designation, we believe the reestablishment of the Rio Grande silvery minnow in the areas described would not conflict with existing human activities or hinder public utilization of the area.

This rule will not materially affect entitlements, grants, user fees, or loan programs, or the rights and obligations of their recipients. Because there are no expected impacts or restrictions to existing human uses of the Big Bend reach of the Rio Grande or its tributaries as a result of this rule, no entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients are expected to occur.

This rule does not raise novel legal or policy issues. Since 1984, we have promulgated section 10(j) rules for many other species in various localities.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 601 *et seq.*, whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare, and make available for public comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. We are certifying that this rule will not have a significant economic effect on a substantial number of small entities. The following discussion explains our rationale.

The area that would be affected if this proposed rule is adopted includes the Big Bend reach of the Rio Grande in Texas. Because of the substantial regulatory relief provided by NEP designations, we do not expect this rule to have any significant effect on recreational, agricultural, or development activities within the NEP area. In addition, when NEPs are located outside a National Wildlife Refuge or unit of the National Park System, we treat the population as proposed for listing and only two provisions of section 7 would apply: section 7(a)(1) and section 7(a)(4). In these instances, NEPs provide additional flexibility because Federal agencies are not required to consult with us under section 7(a)(2). Section 7(a)(1) requires Federal agencies to use their authorities to carry out programs to further the conservation of listed species. Section 7(a)(4) requires Federal agencies to confer (rather than consult) with the Service on actions that are likely to jeopardize the continued existence of a proposed species. The results of a conference are advisory in nature and do not restrict agencies from carrying out, funding, or authorizing activities.

If finalized, this rule would authorize incidental take of Rio Grande silvery minnows within the NEP area. The regulations implementing the Act define ''incidental take'' as take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity such as military training, livestock grazing, recreation, and other activities that are in accordance with Federal, Tribal, State, and local laws and regulations. Intentional take for purposes other than authorized data collection would not be permitted. Intentional take for research or educational purposes would require a section 10 recovery permit under the ESA.

This action would not affect recreational fishing or conservation actions, including removal of nonnative vegetation along the Rio Grande, such as salt cedar and giant river cane. The principal activities on private property near the NEP are agriculture, ranching, and recreation. We believe the presence of the Rio Grande silvery minnow would not affect the use of lands for these purposes because there would be no new or additional economic or regulatory restrictions imposed upon States, non-federal entities, or members of the public due to the presence of the Rio Grande silvery minnow and Federal agencies would only have to comply with sections 7(a)(2) and 7(a)(4) of the ESA. Therefore, this rulemaking is not expected to have any significant adverse impacts to recreation, agriculture, or any development activities.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

1. On the basis of information contained in the ''Required Determinations'' section above, this rule will not ''significantly or uniquely'' affect small governments. We have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.*, that this proposed rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities. A Small Government Agency Plan is not required. As explained above, small governments would not be affected because the proposed NEP designation will not place additional requirements on any city, county, or other local municipalities.

2. This rule will not produce a Federal mandate of $100 million or greater in any year (i.e., it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act). This proposed NEP designation for the Rio Grande silvery minnow would not impose any additional management or protection requirements on the States or other entities.

Takings (E.O. 12630)

In accordance with Executive Order 12630, the proposed rule does not have significant takings implications. When reestablished populations of federally listed species are designated as NEPs, the ESA's regulatory requirements

regarding the reestablished listed species within the NEP are significantly reduced. Section 10(j) of the ESA can provide regulatory relief with regard to the taking of reestablished species within an NEP area. For example, this rule would allow for the taking of reestablished Rio Grande silvery minnows when such take is incidental to an otherwise legal activity, such as recreation (e.g., fishing, boating, wading, trapping, swimming), forestry, agriculture, salt cedar and giant river cane control, and other activities that are in accordance with Federal, State, and local laws and regulations. Because of the substantial regulatory relief provided by NEP designations, we do not believe the reestablishment of this fish would conflict with existing or proposed human activities or hinder public use of the Big Bend reach of the Rio Grande and its tributaries.

A takings implication assessment is not required because this rule (1) will not effectively compel a property owner to suffer a physical invasion of property and (2) will not deny all economically beneficial or productive use of the land or aquatic resources. This rule would substantially advance a legitimate government interest (conservation and recovery of a listed fish species) and would not present a barrier to all reasonable and expected beneficial use of private property.

Federalism (E.O. 13132)

In accordance with Executive Order 13132, we have considered whether this proposed rule has significant Federalism effects and have determined that a Federalism assessment is not required. This rule would not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. In keeping with Department of the Interior policy, we requested information from and coordinated development of this proposed rule with the affected resource agencies in Texas. Achieving the recovery goals for this species would contribute to its eventual delisting and its return to State management. No intrusion on State policy or administration is expected; roles or responsibilities of Federal or State governments would not change; and fiscal capacity would not be substantially directly affected. The special rule operates to maintain the existing relationship between the State and the Federal Government and is being undertaken in coordination with the State of Texas. Therefore, this rule does not have significant Federalism effects or implications to warrant the preparation of a Federalism Assessment under the provisions of Executive Order 13132.

Civil Justice Reform (E.O. 12988)

In accordance with Executive Order 12988 (February 7, 1996; 61 FR 4729), the Office of the Solicitor has determined that this rule would not unduly burden the judicial system and would meet the requirements of sections (3)(a) and (3)(b)(2) of the Order.

Paperwork Reduction Act

Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), require that Federal agencies obtain approval from OMB before collecting information from the public. The Office of Management and Budget has approved our collection of information associated with reporting the taking of experimental populations (50 CFR 17.84(p)(6)) and assigned control number 1018–0095. We may not collect or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

We have prepared a draft EA as defined under the authority of the National Environmental Policy Act of 1969. It is available from the Austin Ecological Services Field Office (see **ADDRESSES** section) and from our Web site at *http://www.fws.gov/southwest/es/Library/*. We published a notice of intent to prepare an EA and a notice of public scoping meetings in the August 3, 2005, **Federal Register** (70 FR 44681).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and the Department of the Interior Manual Chapter 512 DM 2, we have evaluated possible effects on federally recognized Indian tribes and have determined that there are no effects because there is no tribal land within the NEP.

Energy Supply, Distribution or Use (E.O. 13211)

On May 18, 2001, the President issued Executive Order 13211 on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This rule is not expected to significantly affect energy supplies, distribution, and use. Because this action is not a significant energy action, no Statement of Energy Effects is required.

Clarity of This Regulation (E.O. 12866)

Executive Order 12866 requires each agency to write regulations that are easy to understand. We invite your comments on how to make this proposed rule easier to understand including answers to questions such as the following: (1) Are the requirements in the proposed rule clearly stated? (2) Does the proposed rule contain technical language or jargon that interferes with its clarity? (3) Does the format of the proposed rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Would the proposed rule be easier to understand if it were divided into more (but shorter) sections? (5) Is the description of the proposed rule in the Supplementary Information section of the preamble helpful in understanding the proposed rule? What else could we do to make the proposed rule easier to understand? Send your comments concerning how we could make this proposed rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240. You may also e-mail your comments to: *Exsec@ios.doi.gov.*

References Cited

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

Authors

The primary authors of this proposed rule are staff of the Austin Ecological Services Field Office (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

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

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Amend § 17.11(h) by revising the entry for ''Minnow, Rio Grande silvery'' under ''FISHES'' in the List of Endangered and Threatened Wildlife to read as follows:

17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
FISHES							
*	*	*	*	*	*		*
Minnow, Rio Grande silvery.	*Hybognathus amarus*.	U.S.A. (NM, TX), Mexico.	Entire, except where listed as an experimental population.	E	543	17.95(e)	NA
Minnow, Rio Grande silvery.	*Hybognathus amarus*.	U.S.A. (NM, TX), Mexico.	Rio Grande, from Little Box Canyon (approximately 10.4 river miles downstream of Ft. Quitman, TX) to Amistad Dam and the nearby railroad bridge; and on the Pecos River, from its confluence with Independence Creek to its confluence with the Rio Grande.	XN	.....	NA	17.84(u)
*	*	*	*	*	*		*

3. Amend § 17.84 by adding a new paragraph (u) to read as follows:

§ 17.84 Special rules—vertebrates.

* * * * *

(u) Rio Grande silvery minnow (*Hybognathus amarus*).

(1) *Where are populations of this fish designated as nonessential experimental populations (NEP)?*

(i) The NEP area for the Rio Grande silvery minnow is within the species' historic range and is defined as follows: Rio Grande, from Little Box Canyon downstream of Ft. Quitman, Hudspeth County, Texas, through Big Bend National Park and the Rio Grande Wild and Scenic River, to Amistad Dam and the nearby railroad bridge; and on the Pecos River, from its confluence with Independence Creek to its confluence with the Rio Grande.

(ii) The Rio Grande silvery minnow is not currently known to exist in the Rio Grande or Pecos River in Texas. Based on the habitat requirements of this fish, we do not expect it to become established outside the NEP area. However, if any individuals of this species move upstream or downstream or into tributaries outside the designated NEP area, we would presume that they came from the reestablished populations. We would then amend paragraph (u)(1)(i) of this section to enlarge the boundaries of the NEP to include the entire range of the expanded population.

(iii) We do not intend to change the NEP designation to ''essential experimental,'' ''threatened,'' or ''endangered'' within the NEP area. Additionally, we will not designate critical habitat for this NEP, as provided by 16 U.S.C. 1539(j)(2)(C)(ii).

(2) *What take is allowed of this species in the NEP area?*

(i) A Rio Grande silvery minnow may be taken within the NEP area, provided that such take is not willful, knowing, or due to negligence, or is incidental to and not the purpose of the carrying out of an otherwise lawful activity, such as recreation (e.g., fishing, boating, wading, trapping, or swimming), agriculture, and other activities that are in accordance with Federal, State, and local laws and regulations; and provided that such taking is reported within 24 hours, as provided under paragraph (u)(2)(iii) of this section.

(ii) Any person with a valid permit issued by the U.S. Fish and Wildlife Service (Service) under 50 CFR 17.32 may take Rio Grande silvery minnows for educational purposes, scientific purposes, the enhancement of propagation or survival of the species, zoological exhibition, and other conservation purposes consistent with the Endangered Species Act (ESA);

(iii) Any taking pursuant to paragraph (u)(2)(i) or (ii) of this section must be reported within 24 hours by contacting the Service, Austin Ecological Services Field Office, 107011 Burnet Road, Suite 200, Austin, TX 78758; (512) 490–0057. Once the Service is contacted, a determination will be made as to the disposition of any live or dead specimens.

(3) *What take of this species is not allowed in the NEP area?*

(i) Except as expressly allowed in paragraph (u)(2) of this section, all the provisions of 50 CFR 17.31(a) and (b) apply to the fish identified in paragraph (u)(1) of this section.

(ii) Any manner of take not described under paragraph (u)(2) of this section is prohibited in the NEP area.

(iii) You may not possess, sell, deliver, carry, transport, ship, import, or export by any means whatsoever any of the identified fishes, or parts thereof, that are taken or possessed in violation of paragraph (u)(3) of this section or in

violation of the applicable State or local fish and wildlife laws or regulations or the ESA.

(iv) You may not attempt to commit, solicit another to commit, or cause to be committed any offense defined in paragraph (u)(3) of this section.

(4) *How will the effectiveness of the re-establishment be monitored?* After the initial stocking of this fish, we will monitor their presence or absence at least annually and document any spawning behavior or young-of-year fish that might be present. Depending on available resources, monitoring may occur more frequently, especially during the first few years of re-establishment efforts. This monitoring will be conducted primarily by seining and will be accomplished by Service, National Park Service, or State employees or by contracting with the appropriate species experts. Annual reports will be produced detailing stocking and monitoring activities that took place during the previous year.

(5) The Service will also fully evaluate these re-establishment efforts every 5 years to determine whether to continue or terminate them.

(6) Note: Map of the proposed NEP area for the Rio Grande silvery minnow in Texas:

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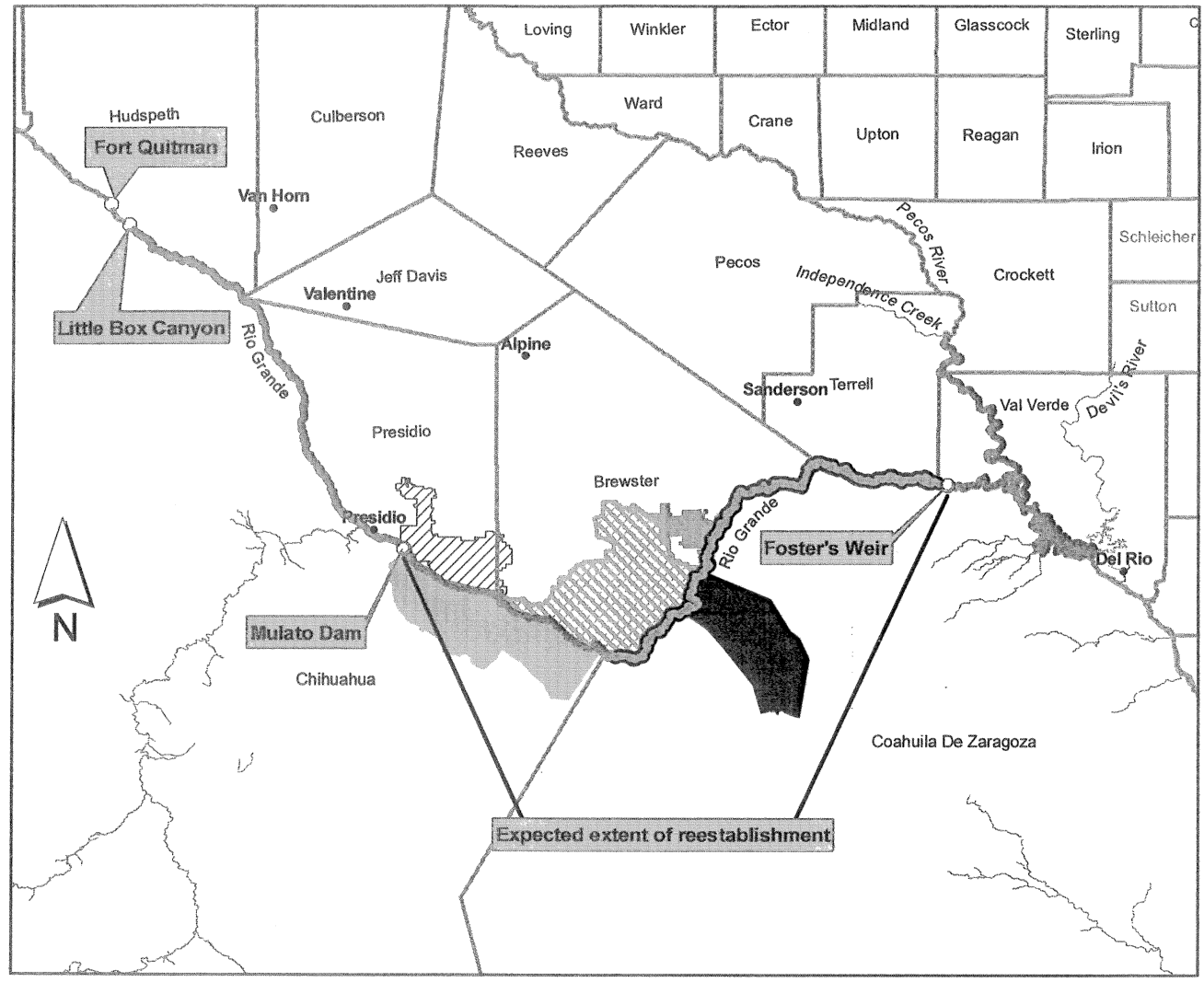
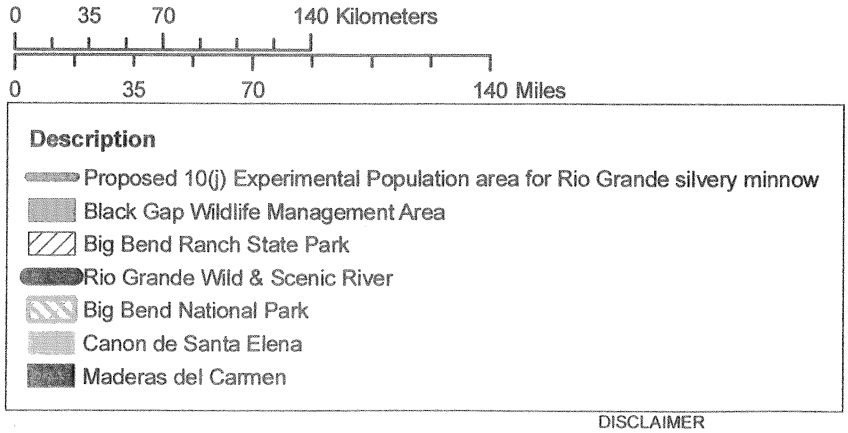
Proposed 10(j) Experimental Population area for Rio Grande silvery minnow





DISCLAIMER

This map is a graphical representation of the Potential 10(j) Experimental Population area for Rio Grande silvery minnow and is provided for illustrative purposes only. The map and [GIS (vector and/or raster)] files used to create this map are not the definitive source for determining these area boundaries. While the Service makes every effort to represent the area shown on this map as completely and accurately as possible (given existing time, resource, data and display constraints), the USFWS gives no warranty, expressed or implied, as to the accuracy, reliability, or completeness of these data.

Dated: August 15, 2007.

Mitchell Butler,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 07–4286 Filed 9–4–07; 8:45 am]

BILLING CODE 4310–55–C

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AU37; RIN 1018–AU91

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Marbled Murrelet (Brachyramphus marmoratus, Designation of Critical Habitat for the Northern Spotted Owl (Strix occidentalis caurina), Draft Recovery Plan for the Northern Spotted Owl

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Reopening of comment periods for two proposed revised critical habitat rules and a draft recovery plan.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of comment periods for three actions that are being promulgated under the Endangered Species Act of 1973, as amended (Act): (1) A proposed revision of critical habitat for the marbled murrelet (*Brachyramphus marmoratus*) and its associated draft economic analysis; (2) a proposed revision of critical habitat for the northern spotted owl (*Strix occidentalis caurina*); and (3) the development of a recovery plan for the northern spotted owl. In order to provide a combined comment period for these three actions, we are reopening the comment periods to allow additional time for interested parties to comment on any or all of these actions. Comments previously submitted need not be resubmitted as they are already part of the public record and will be fully considered in preparation of any critical habitat rule(s) and the recovery plan.

DATES: We will accept public comments on any of the above actions until October 5, 2007.

ADDRESSES: If you wish to comment, you may submit your comments and materials by any one of several methods:

1. By mail or hand-delivery to Patrick Sousa, Chief, Endangered Species, U.S. Fish and Wildlife Service, Ecological Services, Pacific Regional Office, 911 NE. 11th Avenue, Portland, OR 97232.

2. By electronic mail (e-mail) to: *owl-murrelet@fws.gov.* Please see the Public Comments Solicited section below for other information about electronic filing.

3. By fax to: the attention of Patrick Sousa at (503) 231–6243.

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

FOR FURTHER INFORMATION CONTACT: Patrick Sousa, Chief, Endangered Species, Pacific Regional Office, U.S. Fish and Wildlife Service, Ecological Services, 911 NE. 11th Avenue, Portland, OR 97232 (telephone: 503–231–6158; facsimile: 503–231–6243). If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Public Comments Solicited

We solicit comments on the following three actions:

(1) Our proposal to revise currently designated critical habitat for the marbled murrelet published in the **Federal Register** on September 12, 2006 (71 FR 53838), and on our associated draft economic analysis of the proposed revision that was made available on June 26, 2007 (72 FR 35025);

(2) Our proposal to revise currently designated critical habitat for the northern spotted owl published in the **Federal Register** on June 12, 2007 (72 FR 32450); and

(3) Our draft recovery plan for the northern spotted owl announced in the **Federal Register** on April 26, 2007 (72 FR 20865), including the associated peer review.

We will consider information and recommendations from all interested parties. For the marbled murrelet and northern spotted owl proposed revised critical habitat rules, we particularly seek comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including whether the benefits of designation would outweigh threats to the species caused by designation such that the designation of critical habitat is prudent;

(2) Specific information on the amount and distribution of marbled murrelet and/or northern spotted owl habitat, what areas occupied at the time of listing that contain features essential to the conservation of the species should be included in the revised designation and why, and what areas not occupied at the time of listing are essential to the conservation of the species and why;

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed revised critical habitat;

(4) Any foreseeable economic, national security, or other potential impacts resulting from the proposed revised designation, and in particular, any impacts on small entities, and the benefits of including or excluding areas that exhibit these impacts;

(5) Whether our approach to designating critical habitat could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concerns and comments; and

(6) Whether the benefits of exclusion in any particular area outweigh the benefits of inclusion under section 4(b)(2) of the Act.

For the proposed marbled murrelet critical habitat revision, we are also interested in comments on the draft economic analysis, including:

(1) The extent to which the description of economic impacts in the draft economic analysis is complete and accurate;

(2) The likelihood of adverse social reactions to the designation of revised critical habitat, as discussed in the draft economic analysis, and how the consequences of such reactions, if likely to occur, would relate to the conservation and regulatory benefits of the proposed revised critical habitat designation; and

(3) Economic data on the incremental effects that would result from designating any particular area as revised critical habitat, since it is our intent to include the incremental costs attributed to the revised critical habitat designation in the final economic analysis.

A draft economic analysis of the proposed revision of critical habitat for the northern spotted owl is not yet available. Public comment will be solicited separately at the time the availability of a draft economic analysis for the proposed northern spotted owl critical habitat revision is published in the **Federal Register**.

For the draft recovery plan for the northern spotted owl, we particularly seek comments concerning:

(1) The methods used to determine desired habitat percentages listed in Recovery Criterion 4. If recommendations are offered, respondents are asked to explain the scientific foundation supporting their comments;

(2) The biological need, design and feasibility of attempting to provide connectivity between the Olympic Peninsula and central Washington northern spotted owl populations;

(3) The biological value in identifying owl conservation areas in southwest Washington and northwest Oregon;

(4) Appendix E, which provides examples of how a salvage logging action (Recovery Action 22) may be implemented;

(5) The identified boundaries of the Managed Owl Conservation Areas (option 1 only) and the Conservation Support Areas;

(6) Methods for managing the threat posed by barred owls; and

(7) Ways to create incentives for private land owners and managers to support recovery of the northern spotted owl.

You may submit your comments and material concerning the above actions by any one of several methods (see **ADDRESSES**). If you use e-mail to submit your comments, please include ''Attn: RIN 1018–AU37; RIN 1018–AU91'' in your e-mail subject header, preferably with your name and return address in the body of your message. If you do not receive a confirmation from the system that we have received your e-mail, contact us directly by calling our Pacific Regional Office at 503–231–6158. Please note that the e-mail address *owl-murrelet@fws.gov* will be closed out at the termination of the public comment period.

Before including your address, phone number, e-mail address, or other personal identifying information in your comments, you should be aware that your entire comments—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.

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rules and the draft recovery plan, will be available for public inspection, by appointment, during normal business hours at the Western Washington Fish and Wildlife Office, 510 Desmond Drive, SE., Suite 101, Lacey, WA 98503–1273 for the marbled murrelet, and at the Oregon Fish and Wildlife Office, 2600 SE. 98th Avenue, Suite 100, Portland, OR 97266 for actions related to the northern spotted owl. Copies of the proposed revised rules for the marbled murrelet and the northern spotted owl, the draft economic analysis for the marbled murrelet, and the draft recovery plan and the associated peer review for the northern spotted owl are available on the Internet at *http://www.fws.gov/pacific/ecoservices/endangered/index.html* or by request to the Chief of Endangered Species (see **FOR FURTHER INFORMATION CONTACT**).

Background

On January 13, 2003, we entered into a settlement agreement with the American Forest Resource Council and the Western Council of Industrial Workers to complete a rulemaking for critical habitat for the marbled murrelet that considers new relevant information. The terms of that agreement, as amended, required that we submit any final regulation revising marbled murrelet critical habitat to the **Federal Register** by August 30, 2007. On September 12, 2006, we published a proposed rule to revise critical habitat for the marbled murrelet in Washington, Oregon, and California (71 FR 53838). On June 26, 2007, we published a notice of the availability of the draft economic analysis; reopened the comment period on the September 12, 2006, proposed rule for 30 days; and amended certain required determinations (72 FR 35025). However, because of unforeseen delays in publishing the June 26, 2007, notice and in light of the final rule's August 30, 2007, due date to the **Federal Register**, we and the American Forest Resource Council mutually agreed to extend the **Federal Register** submission due date for the final rule for 6 months from the August 30, 2007, date. This extension was approved by the court to allow additional time for us to consider all comments received before making a final critical habitat determination for the marbled murrelet. Accordingly, we will submit for publication to the **Federal Register** any final regulation revising critical habitat for the marbled murrelet by March 1, 2008.

On January 13, 2003, we entered into a settlement agreement with the American Forest Resource Council, Western Council of Industrial Workers, Swanson Group Inc., and Rough & Ready Lumber Company to conduct a rulemaking to consider potential revisions to critical habitat for the northern spotted owl that includes a revised consideration of economic impacts and other relevant aspects of designation. The settlement agreement dates for completion of this review have been extended and currently call for the Service to submit a final revised critical habitat designation for the northern spotted owl to the **Federal Register** by June 1, 2008.

In addition, the Bureau of Land Management published a notice of availability in the **Federal Register** for the Draft Environmental Impact Statement (DEIS) for the Western Oregon Plan Revision on August 10, 2007 (72 FR 45062). With this notice, we are providing a combined comment period for the proposed revised critical habitat designations for the marbled murrelet and northern spotted owl, and the draft recovery plan for the northern spotted owl, to allow additional time for interested parties to comment on any or all of these actions within the context of the Western Oregon Plan Revision DEIS.

Authors

The authors of this notice are the staff of the Division of Endangered Species, Pacific Regional Office, U.S. Fish and Wildlife Service.

Authority

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

Dated: August 24, 2007.

David M. Verhey,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. E7–17236 Filed 9–4–07; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register
Vol. 72, No. 171
Wednesday, September 5, 2007

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

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Generic Clearance for Data User Evaluation Surveys.

Form Number(s): Various.

OMB Control Number: 0607–0760.

Type of Request: Regular submission.

Burden Hours: 7,500.

Number of Respondents: 90,000.

Average Hours Per Response: 5 minutes.

Needs and Uses: The U.S. Census Bureau plans to extend for an additional three years its generic clearance to conduct customer/product-based research.

This extension will allow continued use of customer satisfaction surveys, personal interviews, or focus group research to effectively improve and make more customer-oriented programs, products, and services.

The extended clearance for data collections would continue to cover customer/program-based research for any Census Bureau program area that needs to measure customer needs, uses, and preferences for statistical information and services. The customer base includes, but is not limited to previous, existing, and potential businesses and organizations, alternate Census Bureau data disseminators like State Data Centers, Business and Industry Data Centers, Census Information Centers, Federal or Census Depository Libraries, educational institutions, and not-for-profit or other organizations.

The generic clearance operates as a pre-approval from OMB to conduct various and unspecified customer surveys and includes an annual burden hour ceiling. Detailed information about individual customer surveys is provided to OMB for review a minimum of two weeks in advance of their planned start date. An annual report is provided to OMB recapping the surveys conducted over the past year.

Information collected from customer research helps the Census Bureau to measure its customer base—their use, satisfaction, and preferences for existing and future programs, products and services.

Affected Public: Individuals or households; Business or other for-profit organizations; Not-for-profit institutions; Federal government; State, Local or Tribal government.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

Legal Authority: Executive Order 12862.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at dhynek@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or e-mail (*bharrisk@omb.eop.gov*).

Dated: August 30, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–17539 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

(A–549–822)

Certain Frozen Warmwater Shrimp from Thailand; Partial Rescission of Antidumping Duty Administrative Review

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

EFFECTIVE DATE: September 5, 2007.

FOR FURTHER INFORMATION CONTACT: Irina Itkin, AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–0656.

SUPPLEMENTARY INFORMATION:

Background

On February 2, 2007, the Department of Commerce (the Department) published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on certain frozen warmwater shrimp from Thailand for the period February 1, 2006, through January 31, 2007. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review*, 72 FR 5007 (Feb. 2, 2007). On February 28, 2007, in accordance with 19 CFR 351.213(b)(2), certain respondents requested a review of the antidumping duty order on certain frozen warmwater shrimp from Thailand. In addition, on February 28, 2007, the petitioner [1] and the Louisiana Shrimp Association (LSA), a domestic interested party, also requested administrative reviews for numerous Thai exporters of subject merchandise in accordance with 19 CFR 351.213(b)(2)(1).

On March 16, 2007, in accordance with 19 CFR 351.213(d)(1), the petitioner withdrew its request for review for six companies (*i.e.*, Anglo–Siam Seafoods Co., Ltd. (Anglo–Siam Seafoods); Gallant Ocean (Thailand) Co., Ltd. (Gallant Ocean); Li–Thai Frozen Foods Co., Ltd. (Li–Thai); Queen Marine Food Co., Ltd. (Queen Marine); Smile Heart Foods Co., Ltd. (Smile Heart Foods); and Thai World Imports and Exports).

On April 6, 2007, the Department initiated an administrative review for 142 companies and requested that each provide data on the quantity and value (Q&V) of its exports of subject merchandise to the United States during the period of review (POR). These companies are listed in the Department's notice of initiation. *See Notice of Initiation of Administrative*

[1] The petitioner in this proceeding is the Ad Hoc Shrimp Trade Action Committee.

Reviews of the Antidumping Duty Orders on Certain Frozen Warmwater Shrimp from Brazil, Ecuador, India and Thailand, 72 FR 17100, 17107–09 (Apr. 6, 2007). The Department was unable to locate three of these companies due to ''undeliverable'' addresses.

Between April and July 2007 the Department received Q&V questionnaire responses from certain companies that indicated that either they had no shipments of subject merchandise to the United States during the POR or the company name was a duplicate of a name already included in the initiation notice.

On July 5, 2007, in accordance with 19 CFR 351.213(d)(1), the LSA withdrew its request for review for six companies (*i.e.*, Anglo–Siam Seafoods, Gallant Ocean, Li–Thai, Queen Marine, Smile Heart Foods, and Thai World Imports and Exports).

Partial Rescission of Review

On March 16, 2007, and July 5, 2007, the requests for administrative review were withdrawn for six companies, in accordance with 19 CFR 351.213(d)(1). These companies are: 1) Anglo–Siam Seafoods; 2) Gallant Ocean; 3) Li–Thai; 4) Queen Marine; 5) Smile Heart Foods; and 6) Thai World Imports and Exports. Section 351.213(d)(1) of the Department's regulations requires that the Secretary rescind an administrative review if a party requesting a review withdraws the request within 90 days of the date of publication of the notice of initiation. Therefore, because all requests for administrative reviews were timely withdrawn for the companies listed above, in accordance with 19 CFR 351.213(d)(1), we are rescinding this review with regard to these companies.

In addition, in accordance with 19 CFR 351.213(d)(3), we are rescinding the review with respect to the following 57 companies because these companies had no shipments of subject merchandise during the POR:

1) Ampai Frozen Foods Ltd.
2) A.S. Intermarine Foods Co., Ltd.
3) ACU Transport
4) Chaivaree Marine Products Co., Ltd.
5) Chue Eiw Mong Eak
6) Core Seafood Processing Co., Ltd.
7) Daedong (Thailand) Co., Ltd.
8) Dynamic Intertransport
9) Earth Food Manufacturing Co., Ltd.
10) Fait
11) Far East Cold Storage Co., Ltd.
12) Findus (Thailand) Ltd.
13) Grobest Frozen Foods Co., Ltd.
14) H.A.M. International Co., Ltd.
15) Heng Seafood Ltd. Part.
16) Heritrade
17) HIC (Thailand) Co., Ltd.
18) Inter–Oceanic Resources Co., Ltd.
19) K D Trdg
20) Lee Heng Seafood Co., Ltd.
21) Leo Transports
22) Magnate and Syndicate Co., Ltd.
23) Mahachai Food Processing Co., Ltd.
24) MKF Interfood
25) Namprik Maesri
26) N&N Foods Co., Ltd.
27) NR Instant Produce
28) Pacific Queen Co., Ltd.
29) Penta Impex
30) Premier Frozen Products Co., Ltd.
31) Preserved Foods
32) Rayong Coldstorage (1987) Co., Ltd.
33) S. Chaivaree Cold Storage Co., Ltd.
34) S Khonkaen Food Ind Public
35) Samui Foods
36) Sea Bonanza Foods Co., Ltd.
37) Siam Canadian Foods Co., Ltd.
38) Siam Food Supply Co., Ltd.
39) Siam Marine Products Co., Ltd.
40) Siam Ocean Frozen Foods Co., Ltd.
41) Siamchai International Food Co., Ltd.
42) Sky Fresh
43) Suntechthai Intertrdg
44) Surapon Nichirei Foods Co., Ltd.
45) Suratthani Marine Products Co., Ltd.
46) Suree Interfoods Co., Ltd.
47) T.S.F. Seafood Co., Ltd.
48) Tanaya Intl.
49) Tep Kinsho Foods
50) Teppitak Seafood
51) Thai Agri Foods Public Co., Ltd.
52) Thai Excel Foods Co., Ltd.
53) Thai Mahachai Seafood Products Co., Ltd.
54) Thai Ocean Venture
55) Thai Spring Fish Co., Ltd.
56) Thai Yoo
57) Trang Seafood Products Public Co., Ltd.

We reviewed U.S. Customs and Border Protection (CBP) data and confirmed that there were no entries of subject merchandise from any of these companies. Consequently, in accordance with 19 CFR 351.213(d)(3) and consistent with our practice, we are rescinding our review for the companies listed above. *See*, *e.g.*, *Certain Steel Concrete Reinforcing Bars From Turkey; Final Results and Rescission of Antidumping Duty Administrative Review in Part*, 71 FR 65082, 65083 (Nov. 7, 2006) (Rebar from Turkey). We are also rescinding the review with respect to the following three companies because the Q&V questionnaires sent to these companies were returned to the Department because of ''undeliverable'' addresses: 1) Capital Food Trade Limited; 2) Shianlin Bangkok Co., Ltd. (at 148 Moo 5, Tambol Tasai, Muang, Samut Sakorn, Thailand); and 3) United Cold Storage Co., Ltd. (United Cold Storage). *See* the July 10, 2007, Memorandum to the File from Brianne Riker entitled, ''Placing Information Regarding 'Undeliverable' Addresses on the Record in the 2006–2007 Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from Thailand.'' Subsequently, we contacted the petitioners and the LSA and requested that they provide alternate addresses for these companies; however, they were unable to do so.[2] Consequently, in accordance with our practice, we are also rescinding our review with respect to these companies. *See Rebar from Turkey*, 71 FR at 65083.

Further, the Department has received information that the following company names are duplicate names: 1) Fishery Cold Storage Public; 2) Instant Produce; 3) International Pacific Marine Products; and 4) Thanaya Intl. These names are partial or misspelled versions of names of other companies for which we initiated an administrative review (*i.e.*, Thailand Fishery Cold Storage Public Co., Ltd.; NR Instant Produce; Inter–Pacific Marine Products Co., Ltd.; and Tanaya Intl., respectively). Therefore, we are also rescinding the review with respect to these duplicate company names.

Finally, the Department received no–shipment responses from the following companies for which there appeared to be U.S. customs entries of subject merchandise: 1) A. Wattanachai Frozen Products Co., Ltd.; 2) Bangkok Dehydrated Marine Products Co., Ltd.; 3) Daiei Taigen (Thailand) Co., Ltd.; 4) K.L. Cold Storage Co., Ltd.; and 5) Piti Seafoods Co., Ltd. We requested data on the relevant entries from CBP and determined that the entries were not reportable transactions because they were either: 1) non–subject merchandise (*i.e.*, dried shrimp); or, 2) reported by another company in its quantity and value questionnaire. Therefore, in accordance with 19 CFR 351.213(d)(3), and consistent with the Department's practice, we are rescinding the review with respect to these companies. *See*, *e.g.*, *Certain Steel Concrete Reinforcing Bars from Turkey; Final Results, Rescission of Antidumping Duty Administrative Review in Part, and Determination to Revoke in Part*, 70 FR 67665, 67666 (Nov. 8, 2005).

This notice is published in accordance with section 751 of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

[2] We note that, while the petitioner and the LSA provided an alternate address for United Cold Storage, this address was also ''undeliverable.''

Dated: August 29, 2007.

Stephen J. Claeys,

Assistant Secretaryfor Import Administration.

[FR Doc. E7–17517 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

A–570–890

Wooden Bedroom Furniture From The People's Republic of China: Notice of Partial Rescission of New Shipper Review

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

SUMMARY: On May 29, 2007, Golden Well International (HK) Ltd. (''Golden Well'') submitted a letter to the Department of Commerce (''the Department'') stating that its sale had been cancelled and withdrawing its request for the new shipper review. Accordingly, we are rescinding the new shipper review with respect to Golden Well.

SUPPLEMENTARY INFORMATION:

Background

On January 24, 2007, the Department of Commerce (''the Department'') received a timely request for a new shipper review of the antidumping order on wooden bedroom furniture (''WBF'') from the People's Republic of China (''PRC'') from Golden Well. On March 7, 2007, the Department initiated a new shipper review of shipments of WBF from the PRC exported by Golden Well during the POR. *See Wooden Bedroom Furniture from the People's Republic of China: Initiation of New Shipper Reviews*, 72 FR 10158 (March 7, 2007). On May 29, 2007, Golden Well withdrew its request for a new shipper review.

Rescission of New Shipper Review

Pursuant to 19 CFR 351.214(f)(1), the Department may rescind a new shipper review if the party that requested the review withdraws its request for review within 60 days of the date of publication of the notice of initiation of the requested review. Although Golden Well withdrew its request after the 60-day deadline, we find it reasonable to allow it to withdraw its request because we have not yet committed significant resources to this proceeding. Further, no party has opposed Golden Well's request to withdraw. Therefore, we are rescinding the 2006 new shipper review of the antidumping duty order on wooden bedroom furniture from the PRC with respect to Golden Well in accordance with 19 CFR 351.214(f)(1). *See Freshwater Crawfish Tail Meat from the People's Republic of China; Notice of Rescission of Antidumping Duty New Shipper Review*, 72 FR 43591 (August 6, 2007).

Notification

We will issue assessment instructions after 15 days of the date of the publication of this notice and, in accordance with 19 CFR 351.212(c), we will instruct U.S. Customs and Border Protection to assess antidumping duties at the cash deposit rate in effect at the time of entry for all shipments of WBF from the PRC produced and exported by Golden Well and entered, or withdrawn from warehouse, for consumption during the period January 1, 2006, through December 31, 2006.

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

This notice is published in accordance with section 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4) of the Department's regulations.

Dated: August 27, 2007.

Gary Taverman,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. E7–17518 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–DS–S3

DEPARTMENT OF COMMERCE.

International Trade Administration

Applications for Duty–Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, as amended by Pub. L. 106–36; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States. Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be postmarked on or before September 25, 2007. Address written comments to Statutory Import Programs Staff, Room 2104, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. at the U.S. Department of Commerce in Room 2104.

Docket Number: 07–054. Applicant: University of California at Irvine, Reeve–Irvine Research Center, Dept. Of Anatomy & Neurobiology, 837 Health Science Rd., Irvine, CA 92697. Instrument: Electron Microscope, Model JEM–1400. Manufacturer: JEOL, Ltd., Japan. Intended Use: The instrument is intended to be used for research related to the development of strategies to limit degeneration and enhance regeneration after spinal cord injury and reduce or eliminate the post–traumatic enlargement of spinal cord injury sites that normally occur after traumatic injury. The electron microscope will be used to observe structures and phenomena within laboratory animal tissue. Application accepted by Commissioner of Customs: August 10, 2007.

Docket Number: 07–058. Applicant: Drexel University, 3141 Chestnut Street, Philadelphia, PA 19104. Instrument: Electron Microscope, Model JEM–2100. Manufacturer: Jeol, Ltd., Japan. Intended Use: The instrument is intended to be used to study materials and phenomena that will include metals, ceramics, semiconductors, polymers, biomaterials, atomic diffusion, nanocrystal and thin film growth and evolution, and phase precipitation. The experiments to be conducted involve the high–resolution imaging of nanostructured materials and thin films to evaluate growth mechanisms, crystal structure, and phase stability in inorganic and organic materials and devices. Application accepted by Commissioner of Customs: August 20, 2007.

Docket Number: 07–060. Applicant: University of Pennsylvania School of Dental Medicine, 240 South 40th Street, Philadelphia, PA 19104. Instrument: Electron Microscope, Model H–7650. Manufacturer: Hitachi High–Technologies Corp., Japan. Intended Use: The instrument is intended to be used to study virus entry into cells, extracellular matrix formation and architecture, muscle structure in dystrophic humans and animal models, the sarcolemma structure of bladder smooth muscle cells, animal models of bladder dysfunction, the conformation of a toxin that injures oral cells, the mineral composition of bones and teeth and the structure of the retina. Application accepted by Commissioner of Customs: August 15, 2007.

Docket Number: 07–058. Applicant: Drexel University, 3141 Chestnut Street,

Philadelphia, PA 19104. Instrument: Electron Microscope, Model JEM–2100. Manufacturer: Jeol, Ltd., Japan. Intended Use: The instrument is intended to be used to study materials and phenomena that will include metals, ceramics, semiconductors, polymers, biomaterials, atomic diffusion, nanocrystal and thin film growth and evolution, and phase precipitation. The experiments to be conducted involve the high–resolution imaging of nanostructured materials and thin films to evaluate growth mechanisms, crystal structure, and phase stability in inorganic and organic materials and devices. Application accepted by Commissioner of Customs: August 20, 2007.

Faye Robinson,

Director.

Statutory Import Programs Staff Import Administration.

[FR Doc. E7–17516 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free-Trade Agreement, Article 1904 NAFTA Panel Reviews; Completion of Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of Completion of Panel Review of the final remand determination made by the U.S. International Trade Administration, in the matter of Oil Country Tubular Goods from Mexico, Secretariat File No. USA–MEX–2001–1904–03.

SUMMARY: Pursuant to the Order of the Binational Panel dated July 19, 2007, affirming the final remand determination described above was completed on August 30, 2007.

FOR FURTHER INFORMATION CONTACT: Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: On July 19, 2007, the Binational Panel issued an order, which affirmed the final remand determination of the United States International Trade Administration concerning Oil Country Tubular Goods from Mexico. The Secretariat was instructed to issue a Notice of Completion of Panel Review on the 31st day following the issuance of the Notice of Final Panel Action, if no request for an Extraordinary Challenge was filed. No such request was filed. Therefore, on the basis of the Panel Order and Rule 80 of the *Article 1904 Panel Rules,* the Panel Review was completed and the panelists discharged from their duties effective August 30, 2007.

Dated: August 30, 2007.

Caratina L. Alston,

United States Secretary, NAFTA Secretariat.

[FR Doc. E7–17506 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Solicitation of Applications for Allocation of Tariff Rate Quotas on the Import of Certain Worsted Wool Fabrics to Persons Who Weave Such Fabrics in the United States

AGENCY: Department of Commerce, International Trade Administration.

ACTION: The Department of Commerce (Department) is soliciting applications for an allocation of the 2008 tariff rate quotas on certain worsted wool fabric to persons who weave such fabrics in the United States.

SUMMARY: The Department hereby solicits applications from persons (including firms, corporations, or other legal entities) who weave worsted wool fabrics in the United States for an allocation of the 2008 tariff rate quotas on certain worsted wool fabric. Interested persons must submit an application on the form provided to the address listed below by October 5, 2007. The Department will cause to be published in the **Federal Register** its determination to allocate the 2008 tariff rate quotas and will notify applicants of their respective allocation as soon as possible after that date. Promptly thereafter, the Department will issue licenses to eligible applicants.

DATES: To be considered, applications must be received or postmarked by 5 p.m. on October 5, 2007.

ADDRESSES: Applications must be submitted to the Industry Assessment Division, Office of Textiles and Apparel, Room 3001, United States Department of Commerce, Washington, DC 20230 (telephone: (202) 482-4058). Application forms may be obtained from that office (via facsimile or mail) or from the following Internet address: **http://web.ita.doc.gov/tacgi/wooltrq.nsf/TRQApp/fabric**

FOR FURTHER INFORMATION CONTACT: Sergio Botero, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4058.

SUPPLEMENTARY INFORMATION:

BACKGROUND:

Title V of the Trade and Development Act of 2000 (the Act) created two tariff rate quotas (TRQs), providing for temporary reductions in the import duties on limited quantities of two categories of worsted wool fabrics suitable for use in making suits, suit-type jackets, or trousers: (1) For worsted wool fabric with average fiber diameters greater than 18.5 microns (Harmonized Tariff Schedule of the United States (HTS) heading 9902.51.11); and (2) for worsted wool fabric with average fiber diameters of 18.5 microns or less (HTS heading 9902.51.12). On August 6, 2002, President Bush signed into law the Trade Act of 2002, which includes several amendments to Title V of the Act. On December 3, 2004, the Act was further amended pursuant to the Miscellaneous Trade Act of 2004, Public Law 108-429. The 2004 amendment included authority for the Department to allocate a TRQ for new HTS category, HTS 9902.51.16. This HTS category refers to worsted wool fabric with average fiber diameter of 18.5 microns or less. The amendment provided that HTS 9902.51.16 is for the benefit of persons (including firms, corporations, or other legal entities) who weave such worsted wool fabric in the United States that is suitable for making men's and boys' suits. The TRQ for HTS 9902.51.16 provided for temporary reductions in the import duties on 2,000,000 square meters annually for 2005 and 2006. The amendment requires that the TRQ be allocated to persons who weave worsted wool fabric with average fiber diameter of 18.5 microns or less, which is suitable for use in making men's and boys' suits, in the United States. On August 17, 2006, the Act was further amended pursuant to the Pension Protection Act of 2006, Public Law 109-280, which extended the TRQ for HTS 9902.51.16 through 2009.

On October 24, 2005, the Department adopted final regulations establishing procedures for allocating the TRQ. See 70 FR 61363; 19 CFR 335. In order to be eligible for an allocation, an applicant must submit an application on the form provided at **http://web.ita.doc.gov/tacgi/wooltrq.nsf/TRQApp/fabric** to the address listed above by 5 p.m. on October 5, 2007 in compliance with the requirements of 15 CFR 335. Any business confidential information that is marked business confidential will be kept confidential and protected from disclosure to the full extent permitted by law.

Dated: August 30, 2007.

R. Matthew Priest,

Deputy Assistant Secretary for Textiles and Apparel.

[FR Doc. E7–17541 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–DS

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Solicitation of Applications for Allocation of Tariff Rate Quotas on the Import of Certain Worsted Wool Fabrics to Persons Who Cut and Sew Men's and Boys' Worsted Wool Suits, Suit-Type Jackets and Trousers in the United States

AGENCY: Department of Commerce, International Trade Administration.

ACTION: The Department of Commerce (Department) is soliciting applications for an allocation of the 2008 tariff rate quotas on certain worsted wool fabric to persons who cut and sew men's and boys' worsted wool suits, suit-type jackets and trousers in the United States.

SUMMARY: The Department hereby solicits applications from persons (including firms, corporations, or other legal entities) who cut and sew men's and boys' worsted wool suits and suit-like jackets and trousers in the United States for an allocation of the 2008 tariff rate quotas on certain worsted wool fabric. Interested persons must submit an application on the form provided to the address listed below by October 5, 2007. The Department will cause to be published in the **Federal Register** its determination to allocate the 2008 tariff rate quotas and will notify applicants of their respective allocation as soon as possible after that date. Promptly thereafter, the Department will issue licenses to eligible applicants.

DATES: To be considered, applications must be received or postmarked by 5 p.m. October 5, 2007.

ADDRESSES: Applications must be submitted to the Industry Assessment Division, Office of Textiles and Apparel, Room 3001, United States Department of Commerce, Washington, D.C. 20230 (telephone: (202) 482-4058). Application forms may be obtained from that office (via facsimile or mail) or from the following Internet address: *http://web.ita.doc.gov/tacgi/wooltrq.nsf/TRQApp*.

FOR FURTHER INFORMATION CONTACT: Sergio Botero, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4058.

SUPPLEMENTARY INFORMATION:

BACKGROUND:

Title V of the Trade and Development Act of 2000 (the Act) created two tariff rate quotas (TRQs), providing for temporary reductions in the import duties on limited quantities of two categories of worsted wool fabrics suitable for use in making suits, suit-type jackets, or trousers: (1) for worsted wool fabric with average fiber diameters greater than 18.5 microns (Harmonized Tariff Schedule of the United States (HTS) heading 9902.51.11); and (2) for worsted wool fabric with average fiber diameters of 18.5 microns or less (HTS heading 9902.51.12). On August 6, 2002, President Bush signed into law the Trade Act of 2002, which includes several amendments to Title V of the Act. On December 3, 2004, the Act was further amended pursuant to the Miscellaneous Trade Act of 2004, Public Law 108-429, by increasing the TRQ for worsted wool fabric with average fiber diameters greater than 18.5 microns, HTS 9902.51.11, to an annual total level of 5.5 million square meters, and extending it through 2007, and increasing the TRQ for average fiber diameters of 18.5 microns or less, HTS 9902.51.15 (previously 9902.51.12), to an annual total level of 5 million square meters and extending it through 2006. On August 17, 2006 the Act was further amended pursuant to the Pension Protection Act of 2006, Public Law 109-280, which extended both TRQs, 9902.51.11 and 9902.51.15, through 2009.

The Act requires that the TRQs be allocated to persons who cut and sew men's and boys' worsted wool suits, suit-type jackets and trousers in the United States. On October 24, 2005, the Department adopted final regulations establishing procedures for allocating the TRQ. See 70 FR 61363; 19 CFR 335. In order to be eligible for an allocation, an applicant must submit an application on the form provided at *http://web.ita.doc.gov/tacgi/wooltrq.nsf/TRQApp* to the address listed above by 5 p.m. on October 5, 2007 in compliance with the requirements of 15 CFR 335. Any business confidential information that is marked business confidential will be kept confidential and protected from disclosure to the full extent permitted by law.

Dated: August 30, 2007.

R. Matthew Priest,

Deputy Assistant Secretary for Textiles and Apparel.

[FR Doc. E7–17548 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–DS

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Special Subsistence Permits and Harvest Logs for Pacific Halibut in Waters Off Alaska

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

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 November 5, 2007.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instruments and instructions should be directed to Patsy A. Bearden, 907–586–7008 or *patsy.bearden@noaa.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Marine Fisheries Service (NMFS) designed the halibut subsistence fishing reporting instruments in this collection to work in conjunction with other halibut harvest assessment measures to retrieve essential Pacific halibut information while minimizing the reporting burden on subsistence halibut fishermen. Ceremonial and Educational Permits in International Pacific Halibut Commission (IPHC) Area 2C or 3A are available exclusively to Alaska Native Tribes listed in 50 CFR 300.65(f)(2). The permits consist of a laminated permit card and a harvest log. Eligible Alaska Native tribes are limited to one Ceremonial Permit Coordinator per tribe, and one authorized instructor per Educational Program. Both permits expire 30 days from date of issuance.

A Community Harvest Permit (CHP) is issued to an Alaska Native Tribe, or to eligible rural communities in the absence of a tribe, provided the tribe or community is listed in § 300.65(f)(1) or

(f)(2). An eligible tribe or community selects individual harvesters who possess particular expertise in halibut fishing to harvest halibut on behalf of the community or tribe under reduced gear and harvest restrictions. A CHP Coordinator maintains possession of the CHP log at all times and issues the CHP permit card to each eligible subsistence fisherman. The CHP Coordinator records harvest information from each fisherman in the CHP log and returns it to NMFS. The CHP permit expires one year from the date of issuance.

II. Method of Collection

Ceremonial harvest and Community harvest applications may be applied for online through the Internet. Educational Permit applications may be completed on-screen, printed, and submitted by mail or fax. The permit applications may be submitted as a list of multiple individuals from an Alaska Native tribe.

III. Data

OMB Number: 0648–0512.
Form Number: None.
Type of Review: Regular submission.
Affected Public: Individuals or households; State, Local or Tribal Government.
Estimated Number of Respondents: 109.
Estimated Time Per Response: 10 minutes to complete and submit online a special permit application (Community Harvest, Ceremonial Harvest, or Education Harvest); 30 minutes to complete and submit log (Community Harvest, Ceremonial Harvest, or Education Harvest) by mail; and 4 hours to complete and submit appeal for denial of special permit.
Estimated Total Annual Burden Hours: 140.
Estimated Total Annual Cost to Public: $983.

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: August 30, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–17529 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Alaska Region Arbitration

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

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 November 5, 2007.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instruments and instructions should be directed to Patsy A. Bearden, 907–586–7008 or *patsy.bearden@noaa.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

Under the authority of the Magnuson-Stevens Fishery Conservation and Management Act, National Marine Fisheries Service (NMFS), Alaska Region manages the crab fisheries in the waters off the coast of Alaska through the Crab Rationalization (CR) Program. The CR Program reallocates Bering Sea and Aleutian Islands (BSAI) crab resources among harvesters, processors, and coastal communities. The Program Arbitration System is designed to accommodate the varied interests of the parties involved as well as reflect the historical negotiations between harvesters and processors. The Arbitration System identifies the general structure of the system and the general principles that guide oversight and management. It also identifies the (1) roles and fundamental standards for the Market Analyst in developing and producing a preseason Market Report for each fishery: (2) Formula Arbitrator in developing a single annual fleet-wide pricing formula (non-binding price formula); (3) Contract Arbitrators in making decisions; and (4) last best offer binding arbitration method as the arbitration procedure for participants.

II. Method of Collection

Paper format submitted by mail or hand delivery.

III. Data

OMB Number: 0648–0516.
Form Number: None.
Type of Review: Regular submission.
Affected Public: Business or other for-profit organizations.
Estimated Number of Respondents: 49.
Estimated Time Per Response: 40 hours to complete and submit a Market Report; 4 hours to complete and submit an Arbitration Organization Report; 1 hour to complete and submit Arbitration Organization Miscellaneous Reporting; 40 hours to complete and submit Non-binding Price Formula Report; and 45 minutes to complete and submit an Established Price for Arbitration Negotiations.
Estimated Total Annual Burden Hours: 742.
Estimated Total Annual Cost to Public: $ 5,372.

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: August 30, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–17531 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Crab Economic Data Reports (EDRs)

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

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 November 5, 2007.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th St. 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 instruments and instructions should be directed to Patsy A. Bearden, 907–586–7008 or *patsy.bearden@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

National Marine Fisheries Service, Alaska Region (NMFS) manages the crab fisheries in the waters off the coast of Alaska through the Crab Rationalization (CR) Program. The CR Program reallocates Bering Sea and Aleutian Islands (BSAI) crab resources among harvesters, processors, and coastal communities. Section 313(j) of the Magnuson-Stevens Fishery Conservation and Management Act authorizes a mandatory data collection program for the fisheries of the CR Program. According to section 313(j)(1), the data from the economic data report (EDR) will be used ''to study the impacts of the crab rationalization program,'' to ensure that the program will achieve ''equity between the harvesting and processing sectors,'' and to monitor the ''economic stability for harvesters, processors and coastal communities.''

An EDR is required from any owner or leaseholder of a vessel or processing plant that harvested or processed crab in specified BSAI crab fisheries during the prior calendar year.

II. Method of Collection

The EDRs may be completed on-screen, printed, and submitted by mail, fax, or hand delivery. Four versions of the EDR exist, one each for catcher vessels, catcher/processors, stationary floating crab processors, and shoreside processors. In addition, a Web-based system is available for catcher vessels.

III. Data

OMB Number: 0648–0518.

Form Number: None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 187.

Estimated Time per Response: 7 hours and 30 minutes to complete and submit an Annual Catcher Vessel EDR; 12 hours and 30 minutes to complete and submit an Annual Catcher/Processor EDR; 10 hours to complete and submit an Annual Stationary Floating Crab Processor EDR; and 10 hours to complete and submit an Annual Shoreside Processor EDR.

Estimated Total Annual Burden Hours: 5,429.

Estimated Total Annual Cost to Public: $ 3,307.

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: August 30, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–17534 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Alaska Region BSAI Crab Permits

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

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 November 5, 2007.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th St. 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 instruments and instructions should be directed to Patsy A. Bearden, 907–586–7008 or *patsy.bearden@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Under the authority of the Magnuson-Stevens Fishery Conservation and Management Act, National Marine Fisheries Service (NMFS), Alaska Region manages the crab fisheries, in the waters off the coast of Alaska, under the Fishery Management Plan for Bering Sea and Aleutian Islands Management Area (BSAI) Crab through the Crab Rationalization Program (Program). BSAI crab resources are allocated among harvesters, processors, and coastal communities. This collection-of-information addresses the permits, transfers, and cost recovery procedures for the Program. Implementing regulations may be found at 50 CFR part 680.

II. Method of Collection

The applications can be completed on-screen, printed, and submitted by mail, fax, or hand delivery. However, some applications require notary certification and therefore cannot be faxed. The cost recovery information may be submitted online.

III. Data

OMB Number: 0648–0514.

Form Number: None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,480.

Estimated Time per Response: 2 hours to complete and submit Application for Crab Quota Share (QS) and Processor Quota Share (PQS); 2 hours to complete and submit Application for Crab Individual Fishing Quota (IFQ) Permit or Crab Individual Processor Quota (IPQ) permit; 2 hours and 30 minutes to complete and submit Application for Crab Harvesting Cooperative IFQ Permit; 30 minutes to complete and submit Application for Registered Crab Receiver (RCR) Permit; 30 minutes to complete and submit Application for Crab IFQ Hired Master; 21 minutes to complete and submit Application for Federal Crab Vessel Permit; 2 hours and 30 minutes to complete and submit Application To Become an Eligible Crab Community Organization (ECCO); 2 hours to complete and submit Application for Eligibility To Receive Crab QS/IFQ or PQS/IPQ by Transfer; 2 hours to complete and submit Application for Transfer of QS, IFQ, and IPQ; 2 hours to complete and submit Application for Transfer of Crab QS/IFQ to or From an ECCO; 2 hours to complete and submit Application for Inter-cooperative Transfer; 30 minutes to complete and submit RCR Fee Submission; 40 hours to prepare and submit Right of First Refusal Provisions (ROFR) Contracts; 30 minutes to complete and submit a ROFR Waiver; and 4 hours to complete and submit an appeal on NMFS decisions.

Estimated Total Annual Burden Hours: 8,466.

Estimated Total Annual Cost to Public: $ 31,742.

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: August 30, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–17537 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA88

Marine Mammals; File No. 1034–1685

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

ACTION: Notice; issuance of permit amendment.

SUMMARY: Notice is hereby given that Dr. Markus Horning has been issued an amendment to scientific research Permit No. 1034–1685–01.

ADDRESSES: The amendment and related documents are available for review upon written request or by appointment in the following office(s):

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)427–2521; and

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562)980–4001; fax (562)980–4018.

FOR FURTHER INFORMATION CONTACT: Amy Sloan or Jaclyn Daly, (301)713–2289.

SUPPLEMENTARY INFORMATION: On June 20, 2007, notice was published in the **Federal Register** (72 FR 33981) that an amendment to Permit No. 1034–1685–01 had been requested by the above-named individual. The requested amendment has been granted under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

Permit No. 1034–1685–01, issued on November 12, 2004 (72 FR 69585), authorized the permit holder to surgically implant transmitters, attach tags, collect blood, and perform blubber biopsy and ultrasound and bioelectrical impedance analysis on up to 30 California sea lions (*Zalophus californianus*) undergoing rehabilitation at The Marine Mammal Center (TMMC). In addition, the permit authorized intramuscular injections of adrenocorticotropic hormone (ACTH), pre-and post blood collection under anesthesia, and fecal sampling for up to 6 California sea lions at TMMC. The amended Permit No. 1034–1685–02 authorizes the permit holder to increase the number of California sea lions at The Marine Mammal Center that receive ACTH injections to 12 animals and inject 6 animals with a sterile saline solution as a control group. In addition, a new Co-investigator has been added to the permit.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: August 28, 2007.

Tammy C. Adams,

Acting Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E7–17512 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN: 0648–XC36

Western Pacific Regional Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The 96th meeting of the Western Pacific Regional Fishery Management Council's (Council) Scientific and Statistical Committee (SSC) will convene Tuesday, September 25, 2007, through Thursday September 27, 2007(see **SUPPLEMENTARY INFORMATION** for specific times, dates, and agenda items).

ADDRESSES: The SSC meeting will be held at the Council Office Conference Room, 1164 Bishop St., Suite 1400, Honolulu, HI; telephone: (808) 522–8220.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION:

Dates and Times and Locations

The SSC meeting will be held between 9 a.m. and 5 p.m. on Tuesday, September 25, 2007, and between 8:30 a.m. and 5 p.m. on Wednesday and Thursday September 26–27, 2007 at the Council Office Conference Room, 1164 Bishop St., Suite 1400, Honolulu, HI; telephone: (808) 522–8220.

Tuesday, September 25, 2007, 9 a.m.

1. Introductions
2. Approval of Draft Agenda and Assignment of Rapporteurs
3. Approval of the Minutes of the 95th SSC Meeting
4. Report from the Pacific Fisheries Science Center Director
5. The New Role of the SSC
A. The 2–Tier System
B. Magnuson Stevens Act Five-Year Research Plan
C. Annual Catch Limits
D. Stock Assessment Reviews
6. Data Collection
A. Federal Management Unit Species Fishery Permitting and Reporting Options (ACTION ITEM)
B. Report on status of Marine Recreational Information Program
C. Public Comment
7. Insular Fisheries
A. Bottomfish Management
1. Bottomfish Risk Assessment Model (ACTION ITEM)
B. Public Comment
C. Discussion and Recommendations

Wednesday, September 26, 2007, 8:30 a.m.

8. Rights-based Management
9. Pelagic Fisheries
A. Longline Management
1. Hawaii Swordfish Fishery Effort Options (ACTION ITEM)
2. Pelagics Total Allowable Catch Amendment (ACTION ITEM)
3. Commonwealth of the Northern Mariana Islands Closed Area Options (ACTION ITEM)
4. American Samoa Program Modifications (ACTION ITEM)
B. Non-Longline Management
1. Purse-Seine Closed Areas (ACTION ITEM)
a. Marianas Archipelago
b. American Samoa
2. Non-Longline Pelagic Fishery Management Options (ACTION ITEM)
C. American Samoa and Hawaii Longline Quarterly Reports
D. Stock Assessment Review
1. Western & Central Pacific Ocean Yellowfin Tuna
2. North Pacific Blue Shark
3. North Pacific Albacore Tuna
4. North Pacific Striped Marlin
E. International Fisheries
1. Inter-American Tropical Tuna Commission Meeting
2. International Scientific Committee Meeting
3. Western & Central Pacific Fisheries Commission (WCPFC) Science Committee Meeting
4. WCPFC Northern Committee Meeting
5. Bellagio II 'Comeback Leatherback'
F. Public Comment
G. Discussion and Recommendations

Thursday, September 27, 2007, 8:30 a.m.

10. Program Planning
A. Community Development Plan Process Options
B. Hawaii Marine Conservation Plan
C. Public Comment
D. Discussion and Recommendations
11. Other Business
A. 97th SSC Meeting
12. Summary of SSC Recommendations to the Council

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

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: August 29, 2007.

Tracey L. Thompson,

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

[FR Doc. E7–17466 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

National Estuarine Research Reserve System

AGENCY: Estuarine Reserves Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice of Approval and Availability of the Revised Management Plan for the Wells (Maine) National Estuarine Research Reserve.

SUMMARY: Notice is hereby given that the Estuarine Reserves Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce has approved the revised management plan, which includes an expansion of the boundary of the reserve, for the Wells National Estuarine Research Reserve.

The Wells Reserve was designated in February 1984 pursuant to Section 315 of the Coastal Zone Management Act of 1972, as amended, 16 U.S.C. 1461. The reserve has been operating under a management plan approved in 1996. Pursuant to 15 CFR 921.33(c), a state must revise their management plan every five years. The submission of this plan fulfills this requirement and sets a course for successful implementation of the goals and objectives of the reserve.

Since the last management plan, the Wells Reserve acquired two key parcels of land, changed its boundary, constructed needed facilities, and implemented several system-wide programs. It acquired the 27-acre Alheim property and the 2½-acre Lord parcel, and changed its boundary to include 359 acres of the watershed areas of the Reserve. The Reserve built the Maine Coastal Ecology Center, new interpretive exhibits, the Alheim Commons dormitory, and the Forest Learning Shelter, and equipped and opened the Coastal Resource Library. This new management plan serves as the primary guidance document for the operation of the Wells Reserve's core and system-wide programs in research and monitoring, education and coastal training, and resource management and stewardship. The plan provides guidance on the acquisition of land to be added to the Reserve and on the construction and renovation of buildings and exhibits that support reserve programs. It also guides the

Reserve in important related programs, such as volunteerism and outreach to communities to encourage stewardship of coastal resources in southern Maine.

The Wells Reserve is a public/private partnership whose administrative oversight is vested in the Reserve Management Authority (RMA). This independent state agency was established in 1990 to support and promote the interests of the Wells Reserve. The RMA has a Board of Directors composed of representatives having a property, management, or program interest in the Wells Reserve. The RMA members represent the Maine Department of conservation, the U.S. Fish and Wildlife Service, the Town of Wells, the Laudholm Trust, the Maine State Planning Office, and the National Oceanic and Atmospheric Administration.

FOR FURTHER INFORMATION CONTACT: Doris Grimm at (301) 563–7107 or Laurie McGilvray at (301) 563–1158 of NOAA's National Ocean Service, Estuarine Reserves Division, 1305 East-West Highway, N/ORM5, 10th floor, Silver Spring, MD 20910.

Dated: August 27, 2007.

David M. Kennedy,

Director, Office of Ocean and Coastal Resource Management, National Oceanic and Atmospheric Administration.

[FR Doc. E7–17482 Filed 9–4–07; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee on Military Personnel Testing

AGENCY: Under Secretary of Defense for Personnel and Readiness, DoD.

ACTION: Notice.

SUMMARY: Pursuant to Public Law 92–463, notice is hereby given that a meeting of the Defense Advisory Committee on Military Personnel Testing is scheduled to be held. The purpose of the meeting is to review planned changes and progress in developing computerized and paper-and-pencil enlistment tests.

DATES: September 20, 2007, from 8 a.m. to 4 p.m., and September 21, from 8 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Sheraton Ferncroft Resort, 50 Ferncroft Road, Danvers, Massachusetts 01923.

FOR FURTHER INFORMATION CONTACT: Dr. Jane M. Arabian, Assistant Director, Accession Policy, Officer of the Under Secretary of Defense (Personnel and Readiness), Room 2B271, The Pentagon, Washington, DC 20301–4000, telephone (703) 697–9271.

SUPPLEMENTARY INFORMATION: Persons desiring to make oral presentations or submit written statements for consideration at the Committee meeting must contact Dr. Jane M. Arabian at the address or telephone number above no later than September 10, 2007.

Dated: August 29, 2007.

L.M. Bynum,

Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4314 Filed 9–4–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Air Force

Air Force Special Operations Command Assets Beddown, Cannon Air Force Base, NM

AGENCY: Department of the Air Force, DOD.

ACTION: Record of Decision.

SUMMARY: On August 20, 2007, the United States Air Force signed the Record of Decision (ROD) for the Air Force Special Operations Command Assets Beddown at Cannon Air Force Base (AFB), New Mexico. The ROD states the Air Force decision to implement the Preferred Alternative (East West Airfield Alternative at Cannon AFB, the Two Target Alternative at Melrose Air Force Range, and the use of Cannon scheduled airspace).

The decision was based on matters discussed in the Final Environmental Impact Statement (EIS), inputs from the public and regulatory agencies, and other relevant factors. The Final EIS was made available on July 20, 2007 in the **Federal Register** (Volume 72, Number 139, Page 39808) with a wait period ending August 20, 2007. The ROD documents only the decision of the Air Force with respect to the proposed Air Force actions analyzed in the Final EIS.

FOR FURTHER INFORMATION CONTACT: Mr. Carl T. Hoffman, Headquarters Air Force Special Operations Command/A7PP, Hurlburt Field, FL, 32544–5434 or call (850) 884–5984.

Bao-Anh Trinh,

Air Force Federal Register Liaison Officer.

[FR Doc. E7–17515 Filed 9–4–07; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF DEFENSE

Department of the Navy

Revised Notice of Intent To Prepare an Environmental Impact Statement/ Overseas Environmental Impact Statement for the Virginia Capes Range Complex and Notice of Request for Public Scoping Comments

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: This notice is to inform the public that the Department of the Navy is expanding the Virginia Capes (VACAPES) Range Complex Environmental Impact Statement/ Overseas Environmental Impact Statement (EIS/OEIS) area of consideration and to invite the public to provide comments for consideration during preparation of the EIS/OEIS. Since the December 2006 EIS/OEIS scoping notice [FR 71143], potential shallow water inert mine warfare training areas have been identified in the southern portion of the Chesapeake Bay, south of latitude 37° 25′N. The proposed training areas would consist of instrumented shapes placed temporarily for training purposes. Each of the two proposed training areas would be approximately one by four square nautical miles in area. Training in these mine warfare areas would not involve use of active sonar. Arrangement could vary periodically and location within the proposed training areas would vary depending on operational requirements; however shipping lanes will be avoided. Divers will be required to perform periodic maintenance and replacement of the instrumented shapes.

Scoping comments previously submitted following publication of the December 2006 Notice of Intent to Prepare an EIS/OEIS for the VACAPES Range Complex are still valid and need not be resubmitted. The Navy encourages additional comments or concerns on the expanded area of consideration. VACAPES Range Complex requirements, additional EIS/OEIS information, proposed action background, alternatives, environmental considerations, and public participation inputs can be found at *http://www.vacapesrangecomplexeis.com.* More detailed information regarding this notice of intent can be found on the project Web site.

FOR FURTHER INFORMATION CONTACT: Ms. Erin Swiader, Naval Facilities Engineering Command Atlantic, 6506 Hampton Boulevard, Norfolk, Virginia 23508–1278; telephone: 757–322–4960. You may submit written comments to

Naval Facilities Engineering Command Atlantic, 6506 Hampton Boulevard, Norfolk, Virginia 23508–1278, Attn: Code EV22 (VACAPES Range Complex EIS PM), facsimile: 757–322–4894. Comments will be accepted via mail, fax, and on the Web site at *http://www.vacapesrangecomplexeis.com* until September 30, 2007.

Dated: August 30, 2007.

T.M. Cruz,

Lieutenant, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E7–17521 Filed 9–4–07; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meetings of the Naval Research Advisory Committee

AGENCY: Department of the Navy, DoD.

ACTION: Notice of Closed Meetings.

SUMMARY: The Naval Research Advisory Committee (NRAC) will meet to discuss classified information from government organizations and proprietary information from commercial organizations. All sessions of the September 26 Plenary Session will be devoted to briefings and discussions focusing on emerging threats posed by potential adversaries, the exploitation of physical vulnerabilities and the tactical applications of known and emerging technologies. These sessions will also include proprietary information regarding technology applications and systems under development in the private sector between competing companies. In addition, these sessions will focus on the assessment of the emerging concepts of operations in each of these areas and evaluate appropriate options in such areas as: Training, S&T funding allocation, technology monitoring, and progress assessments; and probable time frames for transformation and implementation. Furthermore, these sessions will identify, review, and assess challenges with the utilization and fielding of various technology applications. All sessions on September 27 will be open to the public except for the meeting period from 4 p.m. to 5 p.m. dealing with the security and counterintelligence briefing which will involve discussions of security policies and procedures classified at the SECRET level.

DATES: The Fall Meetings will be held on Wednesday, September 26, and Thursday, September 27. The sessions open to the public will be on Thursday morning, September 27 at the Pentagon auditorium from 8:30 a.m. to 12 p.m. and on Thursday afternoon from 1:30 p.m. to 4 p.m. The security and counterintelligence briefing on the afternoon of September 27 from 4 p.m. to 5 p.m. and all sessions of September 26 will be closed to the public.

ADDRESSES: The meetings will be held at the Pentagon auditorium and the Headquarters, Office of Naval Research, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Mr. William H. Ellis, Jr., Program Director, Naval Research Advisory Committee, 875 North Randolph Street, Arlington, VA 22203–1995, 703–696–5775.

SUPPLEMENTARY INFORMATION: This notice is provided in accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2). All sessions of the first day of the meeting will be devoted to executive sessions that will include discussions and technical examination of information related to the application of research and development to current and projected Navy and Marine Corps issues. Briefings classified at the SECRET level from the Assistant Secretary of the Navy (Research, Development and Acquisition) and high level Navy and Marine Corps officers are scheduled to provide candid assessments of threats, countermeasures and current and projected issues. All sessions of the second day of the meeting will be open to the public, with the exception of one session from 4 p.m. to 5 p.m. devoted to a security and counterintelligence briefing for new members of the committee. This security and counterintelligence briefing has been developed in its entirety for new members of the NRAC, and will outline security policies and procedures as they apply to the NRAC member.

These briefings and discussions will contain proprietary information and information classified at the SECRET level that is specifically authorized under criteria established by Executive Order to be kept SECRET in the interest of national defense and is in fact properly classified pursuant to such Executive Order. The proprietary, classified and non-classified matters to be discussed are so inextricably intertwined as to preclude opening these sessions of the meeting. In accordance with 5 U.S.C. App. 2, section 10(d), the Secretary of the Navy has determined in writing that the public interest requires that these sessions of the meetings be closed to the public because they will be concerned with matters listed in 5 U.S.C. section 552b(c)(1) and (4).

Dated: August 29, 2007.

T.M. Cruz,

Lieutenant, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E7–17508 Filed 9–4–07; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Exclusive Patent License to Annapolis Remote Acquisitions, LLC

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to Annapolis Remote Acquisitions, LLC, a revocable, non-assignable, partially exclusive license to practice throughout the United States the Government-owned inventions described in U.S. Patent No. 6,717,525, TACTICAL VECTORING EQUIPMENT; U.S. Patent No. 6,820,025, METHOD AND APPARATUS FOR MOTION TRACKING OF AN ARTICULATED RIGID BODY; U.S. Patent No. 6,980,168, ULTRA-WIDEBAND ANTENNA WITH WAVE DRIVER AND BEAM SHAPER; U.S. Patent No. 7,089,148, METHOD AND APPRATUS FOR MOTION TRACKING OF AN ARTICULATED RIGID BODY; and U.S. Patent No. 7,154,431, SIGNAL SYNTHESIZER AND METHOD THEREFOR.

DATES: Anyone wishing to object to the grant of this license has fifteen (15) days from the date of this notice to file written objections along with supporting evidence, if any.

ADDRESSES: Written objections are to be filed with the President, Naval Postgraduate School; Office of Counsel, Code 00C, 1 University Circle, Room 131, Monterey, CA 93943.

FOR FURTHER INFORMATION CONTACT: Danielle Kuska, Director, Research and Sponsored Programs Office, Office of the Associate Provost and Dean of Research; Halligan Hall, Room 222; Naval Postgraduate School; Monterey, CA 93943–5138; telephone: 831–656–2209 or e-mail: *dkuska@nps.edu.*

(Authority: 35 U.S.C. 207, 37 CFR Part 404)

Dated: August 29, 2007.

T.M. Cruz,

Lieutenant, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E7–17510 Filed 9–4–07; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Office of Postsecondary Education; Overview Information; Fulbright-Hays Doctoral Dissertation Research Abroad (DDRA) Fellowship Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2008

Catalog of Federal Domestic Assistance (CFDA) Number: 84.022A.

Dates:

Applications Available: September 5, 2007.

Deadline for Transmittal of Applications: November 5, 2007.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The Fulbright-Hays Doctoral Dissertation Research Abroad Fellowship Program provides opportunities to doctoral candidates to engage in full-time dissertation research abroad in modern foreign languages and area studies. The program is designed to contribute to the development and improvement of the study of modern foreign languages and area studies in the United States.

Priorities: In accordance with 34 CFR 75.105(b)(2)(ii), this priority is from the regulations for this program (34 CFR 662.21(d)).

Absolute Priority: For FY 2008 this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

A research project that focuses on one or more of the following geographic areas: Africa, East Asia, Southeast Asia and the Pacific Islands, South Asia, the Near East, East Central Europe and Eurasia, and the Western Hemisphere (excluding the United States and its territories). Please note that applications that propose projects focused on Western Europe are not eligible.

Competitive Preference Priority: Within this absolute priority, we give competitive preference to applications that address the following priority.

Under 34 CFR 75.105(c)(2)(i) and 34 CFR 662.21(d) we award an additional five (5) points to an application that meets this priority.

This priority is:

A research project that utilizes one or more of the following critical languages: Arabic, Chinese, Japanese, Korean, Russian, as well as Indic, Iranian, and Turkic language families.

Program Authority: 22 U.S.C. 2452(b)(6).

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 81, 82, 84, 85, 86, 97, 98, and 99. (b) The regulations for this program in 34 CFR part 662.

Note: The regulations in 34 CFR part 86 apply to Institutions of Higher Education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants redistributed as fellowships to individual beneficiaries. As part of its FY 2008 budget request, the Administration proposed to continue to allow funds to be used to support the applications of individuals who plan both to utilize their language skills in world areas vital to the United States national security and to apply their language skills and knowledge of these countries in the fields of government, international development, and various professions. Therefore, students planning to apply their language skills in such fields are eligible to apply for this program, in addition to those planning teaching careers. However, authority to use funds in this manner depends on final Congressional action. Applicants will be given an opportunity to amend their applications if such authority is not provided.

Estimated Available Funds: The Administration has requested $4,400,000 for new awards for this program for FY 2008. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Estimated Range of Fellowship Awards: $15,000–$60,000.

Estimated Average Size of Fellowship Awards: $37,000.

Estimated Number of Fellowship Awards: 118.

Note: The Department is not bound by any estimates in this notice.

Project Period: The institutional project period is 18 months beginning July 1, 2008. Students may request funding for a period of no less than six months nor more than twelve months.

III. Eligibility Information

1. *Eligible Applicants:* IHEs. As part of the application process, students submit individual applications to the IHE. The IHE then officially submits all eligible individual student applications with its grant application to the Department.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

IV. Application and Submission Information

1. *Address To Request Application Package:* Both IHEs and student applicants can obtain an application package via the Internet. To obtain a copy via the Internet, use the following address: *http://www.ed.gov/programs/iegpsddrap/index.html.*

IHEs and student applicants may also obtain a copy of the application package by contacting Carla White, International Education Programs Service, U.S. Department of Education, 1990 K Street, NW., Suite 6000, Washington, DC 20006–8521. Telephone: (202) 502–7700 or by e-mail: *ddra@ed.gov.*

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) by contacting the program contact person listed in this section.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program.

Page Limit: The application narrative is where the student applicant addresses the selection criteria that reviewers use to evaluate the application. The student applicant must limit the application narrative to 10 pages and the bibliography to two (2) pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative. However, student applicants may single space all text in charts, tables, figures, graphs, titles, headings, footnotes, endnotes, quotations, bibliography, and captions.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Student applicants may use a 10 point font in charts, tables, figures, graphs, footnotes, and endnotes. However, these items are considered part of the narrative and counted within the 10 page limit.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit only applies to the application narrative and bibliography.

However, student applicants must include their complete responses to the selection criteria in the application narrative.

We will reject a student applicant's application if the student applicant exceeds the page limits.

3. *Submission Dates and Times:*

Applications Available: September 5, 2007.

Deadline for Transmittal of Applications: November 5, 2007.

Applications for grants under this program must be submitted electronically using the Electronic Grant Application System (e-Application) available through the Department's e-Grants system. Please note that the application availability date for this competition is September 5, 2007. The application will not be available on the e-Application system until September 5, 2007. For information (including dates and times) about how to submit an IHE's application electronically, or in paper format by mail or hand delivery if an IHE qualifies for an exception to the electronic submission requirement, please refer to Section IV.6. *Other Submission Requirements* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

4. *Intergovernmental Review:* This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

5. *Funding Restrictions:* We specify allowable costs in 34 CFR part 662. We reference regulations outlining funding restrictions in the *Applicable Regulations* section in this notice.

6. *Other Submission Requirements:* Applications for grants under this program must be submitted electronically, unless an IHE qualifies for an exception to this requirement in accordance with the instructions in this section.

a. Electronic Submission of Applications

Applications for grants under the Fulbright-Hays Doctoral Dissertation Research Abroad Fellowship Program, CFDA Number 84.022A, must be submitted electronically using e-Application available through the Department's e-Grants system, accessible through the e-Grants portal page at: *http://e-grants.ed.gov.*

We will reject an application if an IHE submits it in paper format unless, as described elsewhere in this section, the IHE qualifies for one of the exceptions to the electronic submission requirement *and* submits, no later than two weeks before the application deadline date, a written statement to the Department that the IHE qualifies for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

While completing the electronic application, both the IHE and the student applicant will be entering data online that will be saved into a database. Neither the IHE nor the student applicant may e-mail an electronic copy of a grant application to us.

Please note the following:

• The process for submitting applications electronically under the Fulbright-Hays Doctoral Dissertation Research Abroad Fellowship Program has several parts. The following is a brief summary of the process; however, all applicants should review and follow the detailed description of the application process that is contained in the application package. In summary, the major parts are as follows: (1) IHEs must e-mail the following information to *ddra@ed.gov:* Name of university, and full name and e-mail address of potential project director. We recommend that applicant IHEs submit this information as soon as possible to ensure that applicant IHEs obtain access to the e-Application system well before the application deadline date. We suggest that applicant IHEs send this information no later than August 29, 2007, in order to facilitate timely submission of their applications; (2) Students must complete their individual applications and submit them to their IHE's project director using e-Application; (3) Persons providing references for individual students must complete and submit reference forms for the students and submit them to the IHE's project director using e-Application; and 4) The IHE's project director must officially submit the IHE's application, which must include all eligible individual student applications, reference forms, and other required forms, using e-Application. Student transcripts, however, must be mailed or hand delivered to the Department on or before the application deadline date using the applicable mail or hand delivery instructions for paper applications in this notice.

• The IHE must complete the electronic submission of the grant application by 4:30 p.m., Washington, DC time, on the application deadline date. The e-Application system will not accept an application for this program after 4:30 p.m., Washington, DC time, on the application deadline date. Therefore, we strongly recommend that both the IHE and the student applicant not wait until the application deadline date to begin the application process.

• The regular hours of operation of the e-Grants Web site are 6 a.m. Monday until 7 p.m. Wednesday; and 6 a.m. Thursday until midnight Saturday, Washington, DC time. Please note that the system is unavailable on Sundays, and between 7 p.m. on Wednesdays and 6 a.m. on Thursdays, Washington, DC time, for maintenance. Any modifications to these hours are posted on the e-Grants Web site.

• Student applicants will not receive additional point value because the student submits his or her application in electronic format, nor will we penalize the IHE or student applicant if the applicant qualifies for an exception to the electronic submission requirement, as described elsewhere in this section, and submits an application in paper format.

• IHEs must submit all documents, except for student transcripts, electronically, including the Application for Federal Assistance (SF 424), the Supplement to the SF 424, and all necessary assurances and certifications. Both IHEs and student applicants must attach any narrative sections of the application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If an IHE or a student applicant uploads a file type other than the three file types specified above or submits a password protected file, we will not review that material.

• Student transcripts must be mailed or hand delivered to the Department on or before the application deadline date in accordance with the applicable mail or hand delivery instructions for paper applications described in this notice.

• Both the IHE's and the student applicant's electronic application must comply with any page limit requirements described in this notice.

• Prior to submitting your electronic application, you may wish to print a copy of it for your records.

• After the individual student applicant electronically submits his or

her application to the student's IHE, the student will receive an automatic acknowledgment. In addition, the applicant IHE's Project Director will receive a copy of this acknowledgment by email. After a person submits a reference electronically, he or she will receive an online confirmation. After the applicant IHE submits its application, including all eligible individual student applications, to the Department, the applicant IHE will receive an automatic acknowledgment, which will include a PR/Award number (an identifying number unique to the IHE's application).

• Within three working days after submitting the IHE's electronic application, the IHE must fax a signed copy of the SF 424 to the Application Control Center after following these steps:

(1) Print SF 424 from e-Application.

(2) The applicant IHE's Authorizing Representative must sign this form.

(3) Place the PR/Award number in the upper right hand corner of the hard-copy signature page of the SF 424.

(4) Fax the signed SF 424 to the Application Control Center at (202) 245–6272

We may request that you provide us original signatures on the SF 424 and other forms at a later date. *Application Deadline Date Extension in Case of e-Application System Unavailability:* If an IHE is prevented from electronically submitting its application on the application deadline date because the e-Application system is unavailable, we will grant the IHE an extension of one business day to enable the IHE to transmit its application electronically, by mail, or by hand delivery. We will grant this extension if—

(1) The IHE is a registered user of e-Application and the IHE has initiated an electronic application for this competition; and

(2) (a) The e-Application system is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the application deadline date; or

(b) The e-Application system is unavailable for any period of time between 3:30 p.m. and 4:30 p.m., Washington, DC time, on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting the IHE an extension. To request this extension or to confirm our acknowledgement of any system unavailability, an IHE may contact either (1) the person listed elsewhere in this notice under **FOR FURTHER INFORMATION CONTACT** (see VII. Agency Contact) or (2) the e-Grants help desk at 1–888–336–8930. If the system is down and therefore the application deadline is extended, an e-mail will be sent to all registered users who have initiated an e-Application. Extensions referred to in this section apply only to the unavailability of the Department's e-Application system.

Exception to Electronic Submission Requirement: An IHE qualifies for an exception to the electronic submission requirement, and may submit its application in paper format, if the IHE is unable to submit an application through the e-Application system because—

• The IHE or a student applicant does not have access to the Internet; or

• the IHE or a student applicant does not have the capacity to upload large documents to the Department's e-Application system;

and

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), the IHE mails or faxes a written statement to the Department, explaining which of the two grounds for an exception prevent the IHE from using the Internet to submit its application. If an IHE mails a written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If an IHE faxes its written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax this statement to: Carla White, U.S. Department of Education, 1990 K. Street, NW., Suite 6000, Washington, DC 20006–8521. FAX: (202) 502–7860.

The IHE's paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail

If an IHE qualifies for an exception to the electronic submission requirement, the IHE may mail (through the U.S. Postal Service or a commercial carrier) its application to the Department. The IHE must mail the original and two copies of the application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.022A), 400 Maryland Avenue, SW., Washington, DC 20202–4260;

or

By mail through a commercial carrier: U.S. Department of Education, Application Control Center—Stop 4260, Attention: (CFDA Number 84.022A), 7100 Old Landover Road, Landover, MD 20785–1506.

Regardless of which address the IHE uses, the IHE must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark,

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service,

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

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If the IHE mails its application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark, or

(2) A mail receipt that is not dated by the U.S. Postal Service.

If the IHE's application is postmarked after the application deadline date, we will not consider its application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, the IHE should check with its local post office.

c. Submission of Paper Applications by Hand Delivery

If an IHE qualifies for an exception to the electronic submission requirement, the IHE (or a courier service) may deliver its paper application to the Department by hand. The IHE must deliver the original and two copies of the application, by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.022A), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If an IHE mails or hand delivers its application to the Department:

(1) The IHE must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, and suffix letter, if any, of the competition under which the IHE is submitting its application.

(2) The Application Control Center will mail a grant application receipt

acknowledgment to the IHE. If the IHE does not receive the grant application receipt acknowledgment within 15 business days from the application deadline date, the IHE should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

Student applications are divided into seven categories based on the world area focus of their research projects, as described in the absolute priority listed in this notice. Language and area studies experts in seven discrete world area-based panels will review the student applications. Each panel reviews, scores and ranks its applications separately from the applications assigned to the other world area panels. However, all fellowship applications will be ranked together from the highest to lowest score for funding purposes.

Selection Criteria: The selection criteria for this competition are from 34 CFR 662.21 and are listed in the following paragraphs. The maximum score for all of the criteria, including the competitive preference priority, is 105 points. The maximum score for each criterion is indicated in parentheses.

Quality of proposed project (60 points): In determining the quality of the research project proposed by the applicant, the Secretary considers: (1) The statement of the major hypotheses to be tested or questions to be examined, and the description and justification of the research methods to be used (10 points); (2) the relationship of the research to the literature on the topic and to major theoretical issues in the field, and the project's originality and importance in terms of the concerns of the discipline (10 points); (3) the preliminary research already completed in the United States and overseas or plans for such research prior to going overseas, and the kinds, quality and availability of data for the research in the host country or countries (10 points); (4) the justification for overseas field research and preparations to establish appropriate and sufficient research contacts and affiliations abroad (10 points); (5) the applicant's plans to share the results of the research in progress and a copy of the dissertation with scholars and officials of the host country or countries (10 points); and (6) the guidance and supervision of the dissertation advisor or committee at all stages of the project, including guidance in developing the project, understanding research conditions abroad, and acquainting the applicant with research in the field (10 points).

Qualifications of the applicant (40 points): In determining the qualifications of the applicant, the Secretary considers (1) the overall strength of the applicant's graduate academic record (10 points); (2) the extent to which the applicant's academic record demonstrates strength in area studies relevant to the proposed project (10 points); (3) the applicant's proficiency in one or more of the languages (other than English and the applicant's native language) of the country or countries of research, and the specific measures to be taken to overcome any anticipated language barriers (15 points); and (4) the applicant's ability to conduct research in a foreign cultural context, as evidenced by the applicant's references or previous overseas experience, or both (5 points).

VI. Award Administration Information

1. *Award Notices:* If a student application is successful, we notify the IHE's U.S. Representative and U.S. Senators and send the IHE a Grant Award Notice (GAN). We may notify the IHE informally, also.

If a student application is not evaluated or not selected for funding, we notify the IHE.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section in this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section in this notice and include these and other specific conditions in the GAN. The GAN also incorporates its approved application as part of its binding commitments under the grant.

3. *Reporting:* At the end of the project period, the IHE must submit a final performance report, including the final reports of all of the IHE's fellows, and financial information, as directed by the Secretary. The IHE and fellows are required to use the electronic reporting system International Resource Information System (IRIS) to complete the final report.

4. *Performance Measures:* The objective of the Fulbright-Hays Doctoral Dissertation Research Abroad Fellowship Program is to maintain a U.S. higher education system able to produce experts in less commonly taught languages and area studies who are capable of contributing to the needs of the U.S. government, academic, and business institutions.

The following performance measure has been developed to evaluate the overall effectiveness of the DDRA program—the improvement of language proficiency of fellows. All grantees will be expected to provide documentation of the improved language proficiency of the fellows through the IRIS system. Reporting screens for institutions and fellows may be viewed at: *http://www.ieps-iris.org/iris/pdfs/DDRA_fellow.pdf. http://www.ieps-iris.org/iris/pdfs/DDRA_director.pdf.*

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Carla White, International Education Programs Service, U.S. Department of Education, 1990 K Street, NW., Suite 6000, Washington, DC 20006–8521. Telephone: (202) 502–7700 or by e-mail: *ddra@ed.gov.*

If you use a TDD, call the FRS, toll free at 1–800–877–8339.

VIII. Other Information

Alternative Format: Individuals with disabilities can obtain this document and a copy of the application package in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in this notice.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: August 30, 2007.

Diane Auer Jones,

Assistant Secretary for Postsecondary Education.

[FR Doc. E7–17526 Filed 9–4–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services; Overview Information; State Personnel Development Grants Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2008

Catalog of Federal Domestic Assistance (CFDA) Number: 84.323A.

Dates:

Applications Available: September 5, 2007.

Deadline for Transmittal of Applications: January 3, 2008.

Deadline for Intergovernmental Review: March 3, 2008.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of this program is to assist State educational agencies (SEAs) in reforming and improving their systems for personnel preparation and professional development in early intervention, educational, and transition services in order to improve results for children with disabilities.

Priority: This priority is from the notice of final priority for this program, published in the **Federal Register** on June 9, 2006 (71 FR 33578).

Absolute Priority: For FY 2008 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

Priority:

The Assistant Secretary establishes a priority to assist SEAs in reforming and improving their personnel preparation and professional development systems for teachers, principals, administrators, related services personnel, paraprofessionals, and early intervention personnel. The intent of this priority is to improve educational results for children with disabilities through the delivery of high quality instruction and the recruitment, hiring, and retention of highly qualified special education teachers.

In order to meet this priority an applicant must demonstrate that the project for which it seeks funding— (1) Provides professional development activities that improve the knowledge and skills of personnel as defined in section 651(b) of the Individuals with Disabilities Education Act (IDEA) in delivering scientifically-based instruction to meet the needs of, and improve the performance and achievement of infants, toddlers, preschoolers, and children with disabilities; (2) Implements practices to sustain the knowledge and skills of personnel who have received training in scientifically-based instruction; and (3) Implements strategies that are effective in promoting the recruitment, hiring, and retention of highly qualified special education teachers in accordance with section 602(10) and section 612(a)(14) of IDEA.

Projects funded under this priority must also:

(a) Budget for a three-day Project Directors' meeting in Washington, DC during each year of the project;

(b) Budget $4,000 annually for support of the State Personnel Development Grants Program Web site currently administered by the University of Oregon (*http://www.signetwork.org*); and

(c) If a project receiving assistance under this program authority maintains a Web site, include relevant information and documents in a form that meets a government or industry-recognized standard for accessibility.

Statutory Requirements

State Personnel Development Plan

Applicants must submit a State Personnel Development Plan that identifies and addresses the State and local needs for personnel preparation and professional development of personnel, as well as individuals who provide direct supplementary aids and services to children with disabilities, and that—

(a) Is designed to enable the State to meet the requirements of section 612(a)(14) and section 635(a)(8) and (9) of IDEA;

(b) Is based on an assessment of State and local needs that identifies critical aspects and areas in need of improvement related to the preparation, ongoing training, and professional development of personnel who serve infants, toddlers, preschoolers, and children with disabilities within the State, including—

(i) Current and anticipated personnel vacancies and shortages; and

(ii) The number of preservice and inservice programs;

(c) Is integrated and aligned, to the maximum extent possible, with State plans and activities under the Elementary and Secondary Education Act of 1965, as amended (ESEA), the Rehabilitation Act of 1973, as amended, and the Higher Education Act of 1965, as amended (HEA);

(d) Describes a partnership agreement that is in effect for the period of the grant, which agreement shall specify—

(i) The nature and extent of the partnership described in accordance with section 652(b) of IDEA and the respective roles of each member of the partnership, including, if applicable, an individual, entity, or agency other than the SEA that has the responsibility under State law for teacher preparation and certification; and

(ii) How the SEA will work with other persons and organizations involved in, and concerned with, the education of children with disabilities, including the respective roles of each of the persons and organizations;

(e) Describes how the strategies and activities the SEA uses to address identified professional development and personnel needs will be coordinated with activities supported with other public resources (including funds provided under Part B and Part C of IDEA and retained for use at the State level for personnel and professional development purposes) and private resources;

(f) Describes how the SEA will align its personnel development plan with the plan and application submitted under sections 1111 and 2112, respectively, of the ESEA;

(g) Describes those strategies the SEA will use to address the identified professional development and personnel needs and how such strategies will be implemented, including—

(i) A description of the programs and activities that will provide personnel with the knowledge and skills to meet the needs of, and improve the performance and achievement of, infants, toddlers, preschoolers, and children with disabilities; and

(ii) How such strategies will be integrated, to the maximum extent possible, with other activities supported by grants funded under section 662 of IDEA;

(h) Provides an assurance that the SEA will provide technical assistance to local educational agencies (LEAs) to improve the quality of professional development available to meet the needs of personnel who serve children with disabilities;

(i) Provides an assurance that the SEA will provide technical assistance to entities that provide services to infants and toddlers with disabilities to improve the quality of professional development available to meet the needs of personnel serving those children;

(j) Describes how the SEA will recruit and retain highly qualified teachers and other qualified personnel in geographic areas of greatest need;

(k) Describes the steps the SEA will take to ensure that economically disadvantaged and minority children are not taught at higher rates by teachers who are not highly qualified; and

(l) Describes how the SEA will assess, on a regular basis, the extent to which the strategies implemented have been effective in meeting the performance goals described in section 612(a)(15) of IDEA.

Partnerships

Required Partners

Applicants shall establish a partnership with LEAs and other State agencies involved in, or concerned with, the education of children with disabilities, including—

(a) Not less than one institution of higher education; and

(b) The State agencies responsible for administering Part C of IDEA, early education, child care, and vocational rehabilitation programs.

Other Partners

An SEA shall work in partnership with other persons and organizations involved in, and concerned with, the education of children with disabilities, which may include—

(a) The Governor;

(b) Parents of children with disabilities ages birth through 26;

(c) Parents of nondisabled children ages birth through 26;

(d) Individuals with disabilities;

(e) Parent training and information centers or community parent resource centers funded under sections 671 and 672 of IDEA, respectively;

(f) Community-based and other nonprofit organizations involved in the education and employment of individuals with disabilities;

(g) Personnel as defined in section 651(b) of IDEA;

(h) The State advisory panel established under Part B of IDEA;

(i) The State interagency coordinating council established under Part C of IDEA;

(j) Individuals knowledgeable about vocational education;

(k) The State agency for higher education;

(l) Noneducational public agencies with jurisdiction in the areas of health, mental health, social services, and juvenile justice;

(m) Other providers of professional development who work with infants, toddlers, preschoolers, and children with disabilities;

(n) Other individuals; and

(o) In cases where the SEA is not responsible for teacher certification, an individual, entity, or agency responsible for teacher certification as defined in section 652(b)(3) of IDEA.

Use of Funds

(a) *Professional Development Activities*—Consistent with the absolute priority announced in this notice, each SEA that receives a State Personnel Development Grant under this program shall use the grant funds to support activities in accordance with the State's Personnel Development Plan, including one or more of the following:

(1) Carrying out programs that provide support to both special education and regular education teachers of children with disabilities and principals, such as programs that—

(i) Provide teacher mentoring, team teaching, reduced class schedules and case loads, and intensive professional development;

(ii) Use standards or assessments for guiding beginning teachers that are consistent with challenging State student academic achievement and functional standards and with the requirements for professional development, as defined in section 9101 of the ESEA; and

(iii) Encourage collaborative and consultative models of providing early intervention, special education, and related services.

(2) Encouraging and supporting the training of special education and regular education teachers and administrators to effectively use and integrate technology—

(i) Into curricula and instruction, including training to improve the ability to collect, manage, and analyze data to improve teaching, decision-making, school improvement efforts, and accountability;

(ii) To enhance learning by children with disabilities; and

(iii) To effectively communicate with parents.

(3) Providing professional development activities that—

(i) Improve the knowledge of special education and regular education teachers concerning—

(A) The academic and developmental or functional needs of students with disabilities; or

(B) Effective instructional strategies, methods, and skills, and the use of State academic content standards and student academic achievement and functional standards, and State assessments, to improve teaching practices and student academic achievement;

(ii) Improve the knowledge of special education and regular education teachers and principals and, in appropriate cases, paraprofessionals, concerning effective instructional practices, that—

(A) Provide training in how to teach and address the needs of children with different learning styles and children who are limited English proficient;

(B) Involve collaborative groups of teachers, administrators, and, in appropriate cases, related services personnel;

(C) Provide training in methods of—

(I) Positive behavioral interventions and supports to improve student behavior in the classroom;

(II) Scientifically based reading instruction, including early literacy instruction;

(III) Early and appropriate interventions to identify and help children with disabilities;

(IV) Effective instruction for children with low incidence disabilities;

(V) Successful transitioning to postsecondary opportunities; and

(VI) Classroom-based techniques to assist children prior to referral for special education;

(D) Provide training to enable personnel to work with and involve parents in their child's education, including parents of low income and limited English proficient children with disabilities;

(E) Provide training for special education personnel and regular education personnel in planning, developing, and implementing effective and appropriate individualized education programs (IEPs); and

(F) Provide training to meet the needs of students with significant health, mobility, or behavioral needs prior to serving those students;

(iii) Train administrators, principals, and other relevant school personnel in conducting effective IEP meetings; and

(iv) Train early intervention, preschool, and related services providers, and other relevant school personnel, in conducting effective individualized family service plan (IFSP) meetings.

(4) Developing and implementing initiatives to promote the recruitment and retention of highly qualified special education teachers, particularly initiatives that have been proven effective in recruiting and retaining highly qualified teachers, including programs that provide—

(i) Teacher mentoring from exemplary special education teachers, principals, or superintendents;

(ii) Induction and support for special education teachers during their first three years of employment as teachers; or

(iii) Incentives, including financial incentives, to retain special education

teachers who have a record of success in helping students with disabilities.

(5) Carrying out programs and activities that are designed to improve the quality of personnel who serve children with disabilities, such as—

(i) Innovative professional development programs (which may be provided through partnerships that include institutions of higher education), including programs that train teachers and principals to integrate technology into curricula and instruction to improve teaching, learning, and technology literacy, which professional development shall be consistent with the definition of professional development in section 9101 of the ESEA; and

(ii) The development and use of proven, cost effective strategies for the implementation of professional development activities, such as through the use of technology and distance learning.

(6) Carrying out programs and activities that are designed to improve the quality of early intervention personnel, including paraprofessionals and primary referral sources, such as—

(i) Professional development programs to improve the delivery of early intervention services;

(ii) Initiatives to promote the recruitment and retention of early intervention personnel; and

(iii) Interagency activities to ensure that early intervention personnel are adequately prepared and trained.

(b) *Other Activities*—Consistent with the absolute priority announced in this notice, each SEA that receives a State Personnel Development Grant under this program shall use the grant funds to support activities in accordance with the State's Personnel Development Plan, including one or more of the following:

(1) Reforming special education and regular education teacher certification (including recertification) or licensing requirements to ensure that—

(i) Special education and regular education teachers have—

(A) The training and information necessary to address the full range of needs of children with disabilities across disability categories; and

(B) The necessary subject matter knowledge and teaching skills in the academic subjects that the teachers teach;

(ii) Special education and regular education teacher certification (including recertification) or licensing requirements are aligned with challenging State academic content standards; and

(iii) Special education and regular education teachers have the subject matter knowledge and teaching skills, including technology literacy, necessary to help students with disabilities meet challenging State student academic achievement and functional standards.

(2) Programs that establish, expand, or improve alternative routes for State certification of special education teachers for highly qualified individuals with a baccalaureate or master's degree, including mid-career professionals from other occupations, paraprofessionals, and recent college or university graduates with records of academic distinction who demonstrate the potential to become highly effective special education teachers.

(3) Teacher advancement initiatives for special education teachers that promote professional growth and emphasize multiple career paths (such as paths to becoming a career teacher, mentor teacher, or exemplary teacher) and pay differentiation.

(4) Developing and implementing mechanisms to assist LEAs and schools in effectively recruiting and retaining highly qualified special education teachers.

(5) Reforming tenure systems, implementing teacher testing for subject matter knowledge, and implementing teacher testing for State certification or licensing, consistent with Title II of the HEA.

(6) Funding projects to promote reciprocity of teacher certification or licensing between or among States for special education teachers, except that no reciprocity agreement developed under this priority may lead to the weakening of any State teacher certification or licensing requirement.

(7) Assisting LEAs to serve children with disabilities through the development and use of proven, innovative strategies to deliver intensive professional development programs that are both cost effective and easily accessible, such as strategies that involve delivery through the use of technology, peer networks, and distance learning.

(8) Developing, or assisting LEAs in developing, merit based performance systems, and strategies that provide differential and bonus pay for special education teachers.

(9) Supporting activities that ensure that teachers are able to use challenging State academic content standards and student academic achievement and functional standards, and State assessments for all children with disabilities, to improve instructional practices and improve the academic achievement of children with disabilities.

(10) When applicable, coordinating with, and expanding centers established under, section 2113(c)(18) of the ESEA to benefit special education teachers.

(c) *Contracts and Subgrants*—An SEA that receives a grant under this program—

(1) Shall award contracts or subgrants to LEAs, institutions of higher education, parent training and information centers, or community parent resource centers, as appropriate, to carry out the State plan; and

(2) May award contracts and subgrants to other public and private entities, including the lead agency under Part C of IDEA, to carry out the State plan.

(d) *Use of Funds for Professional Development*—An SEA that receives a grant under this program shall use—

(1) Not less than 90 percent of the funds the SEA receives under the grant for any fiscal year for the Professional Development Activities described in paragraph (a); and

(2) Not more than 10 percent of the funds the SEA receives under the grant for any fiscal year for the Other Activities described in paragraph (b).

(e) *Grants to Outlying Areas*—Public Law 95–134, permitting the consolidation of grants to the outlying areas, shall not apply to funds received under this program authority.

Program Authority: 20 U.S.C. 1451 through 1455.

Applicable Regulations: (a) EDGAR in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 85, 97, 98, and 99. (b) The notice of final priority for this program published in the **Federal Register** on June 9, 2006 (71 FR 33578).

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration's budget request for FY 2008 does not include funds for this program. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2009 from the list of unfunded applicants from this competition.

Estimated Range of Awards: $500,000—$4,000,000 (for the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico. In the case of an outlying area awards will be not less than $80,000.

Maximum Award: We will reject any application that proposes a budget

exceeding $4,000,000 for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

Note: We will set the amount of each award after considering—

(1) The amount of funds available for making the grants;

(2) The relative population of the State or outlying area;

(3) The types of activities proposed by the State or outlying area;

(4) The alignment of proposed activities with section 612(a)(14) of IDEA;

(5) The alignment of proposed activities with State plans and applications submitted under sections 1111 and 2112, respectively, of the ESEA; and

(6) The use, as appropriate, of scientifically-based research and instruction.

Estimated Average Size of Awards: $959,400, excluding outlying areas.

Estimated Number of Awards: 5.

Note: The Department is not bound by any estimates in this notice.

Project Period: Not less than one year and not more than five years.

III. Eligibility Information

1. *Eligible Applicants:* An SEA of one of the 50 States, the District of Columbia, or the Commonwealth of Puerto Rico or an outlying area (United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands). Current State Program Improvement Grant grantees with multi-year awards who wish to apply for a grant under the State Personnel Development Grants Program may do so, subject to section 651(e) of IDEA, which prohibits a State requesting a continuation award under the State Improvement Grant Program, as in effect prior to December 3, 2004, from receiving any other award under this program authority for that fiscal year.

2. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

3. *Other: General Requirements*—The projects funded under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

IV. Application and Submission Information

1. *Address to Request Application Package:* Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794–1398. Telephone, toll free: 1–877–433–7827. FAX: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *http://www.ed.gov/pubs/edpubs.html* or at its e-mail address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA Number 84.323A.

Individuals with disabilities can obtain a copy of the application package in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) by contacting the person or team listed under *Alternate Format* in section VIII in this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to the equivalent of no more than 100 pages, using the following standards:

• A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.

• Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.

• Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the two-page abstract, the resumes, the bibliography, the references, or the letters of support. However, you must include all of the application narrative in Part III.

We will reject your application if—

• You apply these standards and exceed the page limit; or

• You apply other standards and exceed the equivalent of the page limit.

3. *Submission Dates and Times:*

Applications Available: September 5, 2007. Deadline for Transmittal of Applications: January 3, 2008.

Applications for grants under this competition may be submitted electronically using the Grants.gov Apply site (Grants.gov), or in paper format by mail or hand delivery. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery, please refer to section IV. 6. *Other Submission Requirements* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: March 3, 2008.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section in this notice.

6. *Other Submission Requirements:* Applications for grants under this competition may be submitted electronically or in paper format by mail or hand delivery.

a. Electronic Submission of Applications

To comply with the President's Management Agenda, we are participating as a partner in the Governmentwide Grants.gov Apply site. The State Personnel Development Grants Program—CFDA Number 84.323A is included in this project. We request your participation in Grants.gov.

If you choose to submit your application electronically, you must use the Governmentwide Grants.gov Apply site at *http://www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

You may access the electronic grant application for the State Personnel Development Grants Program—CFDA Number 84.323A at: *http://www.Grants.gov.* You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.323, not 84.323A).

Please note the following:

• Your participation in Grants.gov is voluntary.

• When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

• Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted, and must be date and time stamped by the Grants.gov system no later than 4:30 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not consider your application if it is date and time stamped by the Grants.gov system later than 4:30 p.m., Washington, DC time, on the application deadline date. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30 p.m., Washington, DC time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

• You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov at *http://e-Grants.ed.gov/help/GrantsgovSubmissionProcedures.pdf.*

• To submit your application via Grants.gov, you must complete all steps in the Grants.gov registration process (see *http://www.grants.gov/applicants/get_registered.jsp*). These steps include (1) registering your organization, a multi-part process that includes registration with the Central Contractor Registry (CCR); (2) registering yourself as an Authorized Organization Representative (AOR); and (3) getting authorized as an AOR by your organization. Details on these steps are outlined in the Grants.gov 3-Step Registration Guide (see *http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf*). You also must provide on your application the same D–U–N–S Number used with this registration. Please note that the registration process may take five or more business days to complete, and you must have completed all registration steps to allow you to submit successfully an application via Grants.gov. In addition you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you submit your application in paper format.

• If you submit your application electronically, you must submit all documents electronically, including all information you typically provide on the following forms: Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. Please note that two of these forms—the SF 424 and the Department of Education Supplemental Information for SF 424—have replaced the ED 424 (Application for Federal Education Assistance).

• If you submit your application electronically, you must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified in this paragraph or submit a password-protected file, we will not review that material.

• Your electronic application must comply with any page-limit requirements described in this notice.

• After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues With the Grants.Gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

b. Submission of Paper Applications by Mail

If you submit your application in paper format by mail (through the U.S. Postal Service or a commercial carrier), you must mail the original and two copies of your application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.323A), 400 Maryland Avenue, SW., Washington, DC 20202–4260;

or

By mail through a commercial carrier: U.S. Department of Education, Application Control Center, Stop 4260, Attention: (CFDA Number 84.323A), 7100 Old Landover Road, Landover, MD 20785–1506.

Regardless of which address you use, you must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

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

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. Submission of Paper Applications by Hand Delivery

If you submit your application in paper format by hand delivery, you (or a courier service) must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.323A), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are listed in the application package.

2. *Peer Review:* In the past, there have been problems in finding peer reviewers without conflicts of interest for competitions in which many entities throughout the country submit applications. The Standing Panel requirements under IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that, for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within the specific group. This procedure will ensure the availability of a much larger group of reviewers without conflicts of interest. It also will increase the quality, independence and fairness of the review process and permit panel members to review applications under discretionary grant competitions for which they have also submitted applications. However, if the Department decides to select for funding an equal number of applications in each group, this may result in different cut-off points for fundable applications in each group.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notice (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section in this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section in this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary in 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *http://www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* The goal of the State Personnel Development Grants (SPDG) Program is to reform and improve State systems for personnel preparation and professional development in early intervention, educational, and transition services in order to improve results for children with disabilities. Under the Government Performance and Results Act of 1993 (GPRA), the Department has developed performance measures to assess the success of the program in meeting these goals. These measures are: (1) The percent of personnel receiving professional development through the SPDG program based on scientific or evidence-based instructional practices; (2) the percentage of SPDG projects that have implemented personnel development/training activities that are aligned with improvement strategies identified in their State Performance Plan (SPP); (3) the percentage of professional development/training activities provided through the SPDG program based on scientific or evidence-based instructional/behavioral practices; (4) the percentage of professional development/training activities based on scientific or evidence-based instructional/behavioral practices, provided through the SPDG program, that are sustained through ongoing and comprehensive practices (e.g., mentoring, coaching, structured guidance, modeling, continuous inquiry, etc.); and (5) in States with SPDG projects that have special education teacher retention as a goal, the Statewide percentage of highly qualified special education teachers in State-identified professional disciplines (e.g., teachers of children with emotional disturbance, deafness, etc.) consistent with sections 602(a)(10) and 612(a)(14) of IDEA, who remain teaching after the first three years of employment.

Each grantee must annually report its performance on these measures in the project's annual performance report to the Department in accordance with section 653(d) of IDEA and 34 CFR 75.590.

VII. Agency Contact

For Further Information Contact:

Larry Wexler, U.S. Department of Education, 400 Maryland Avenue, SW., Room 4019, Potomac Center Plaza, Washington, DC 20202–2550. Telephone: (202) 245–7571.

If you use a TDD, call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

VIII. Other Information

Alternative Format: Individuals with disabilities can obtain this document and a copy of the application package in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 5075, Potomac Center Plaza, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: August 29, 2007.

William W. Knudsen,

Acting Deputy Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. E7–17524 Filed 9–4–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River Site

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site. The Federal Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Monday, September 24, 2007, 1 p.m.–5 p.m. Tuesday, September 25, 2007, 8:30 a.m.–4 p.m.

ADDRESSES: Sheraton North Charleston Hotel, 4770 Goer Drive, North Charleston, SC 29406.

FOR FURTHER INFORMATION CONTACT: Gerri Flemming, Office of External Affairs, Department of Energy Savannah River Operations Office, P.O. Box A, Aiken, SC, 29802; Phone: (803) 952–7886.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

Monday, September 24, 2007

1 p.m. Combined Committee Session.
5 p.m. Adjourn.

Tuesday, September 25, 2007

8:30 a.m. Approval of Minutes, Agency Updates.
9:15 a.m. Public Comment Session.
9:30 a.m. Chair and Facilitator Update.
10 a.m. Administrative Committee Report.
11 a.m. Strategic and Legacy Management Committee Report.
11:45 a.m. Public Comment Session.
12 p.m. Lunch Break.
1 p.m. Nuclear Materials Committee Report.
2 p.m. Waste Management Committee Report.
3 p.m. Facility Disposition and Site Remediation Committee Report.
3:45 p.m. Public Comment Session.
4 p.m. Adjourn.

If needed, time will be allotted after public comments for items added to the agenda and administrative details. A final agenda will be available at the meeting Monday, September 24, 2007.

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Gerri Flemming's office at the address or telephone listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Gerri Flemming at the address or phone number listed above. Minutes will also be available at the following Web site *http://www.srs.gov/general/outreach/srs-cab/srs-cab.html.*

Issued at Washington, DC on August 30, 2007.

Rachel Samuel,

Deputy Committee Management Officer.

[FR Doc. E7–17495 Filed 9–4–07; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings # 1

August 28, 2007.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC07–116–001.

Applicants: KGen Acquisition I, LLC; KGEN Power Corporation; KGen Partners, LLC; LSP Energy Limited Partnership; La Paloma Generating Company, LLC.

Description: KGen Power Corp et al. submit an amendment to the 7/13/07 filing of a joint application for authorization and the acquisition of La Paloma Generating Co, LLC.

Filed Date: 08/21/2007.

Accession Number: 20070824–0119.

Comment Date: 5 p.m. Eastern Time on Tuesday, September 4, 2007.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER07–940–001.

Applicants: Midwest Independent Transmission System Operator, Inc.; PJM Interconnection, LLC.

Description: Midwest Independent System Operator Inc and submit PJM Interconnection LLC submit its proposed revisions to section 4 of the Congestion Management Process of their Joint Operating Agreement.

Filed Date: 08/23/2007.

Accession Number: 20070827–0031.

Comment Date: 5 p.m. Eastern Time on Thursday, September 13, 2007.

Docket Numbers: ER07–1099–001.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool Inc submits as Exhibit I a clean copy of the 6/29/07 filing with the proper designations.

Filed Date: 08/23/2007.

Accession Number: 20070827–0028.

Comment Date: 5 p.m. Eastern Time on Thursday, September 13, 2007.

Docket Numbers: ER07–1300–000.

Applicants: Reliant Energy Solutions Northeast, LLC.

Description: Reliant Energy Solutions Northeast LLC submits an application for an order accepting rates for filing and for certain waivers and blanket approvals.

Filed Date: 08/23/2007.

Accession Number: 20070827–0029.

Comment Date: 5 p.m. Eastern Time on Thursday, September 13, 2007.

Docket Numbers: ER07–1301–000.

Applicants: Elwood Energy, LLC.

Description: Elwood Energy LLC submits its Rate Schedule FERC 2, its revenue requirement for Reactive Supply and Voltage Control from Generation Sources Service supplied by its generation facilities.

Filed Date: 08/24/2007.

Accession Number: 20070827–0030.

Comment Date: 5 p.m. Eastern Time on Friday, September 14, 2007.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR07–15–000.

Applicants: North American Electric Reliability Corp.

Description: Request of The North American Electric Reliability Corporation for Approval of Amended and Restated Bylaws Of Northeast Power Coordinating Council, Inc., and for substitution of Northeast Power Coordinating Council, Inc. as a regional entity.

Filed Date: 08/21/2007.

Accession Number: 20070821–5032.

Comment Date: 5 p.m. Eastern Time on Thursday, September 20, 2007.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Acting Deputy Secretary.

[FR Doc. E7–17443 Filed 9–4–07; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8463–4]

Clean Air Act Advisory Committee (CAAAC): Notice of Meeting

AGENCY: Environmental Protection Agency.

ACTION: Notice of Meeting and Conference Call.

SUMMARY: The Environmental Protection Agency (EPA) established the Clean Air Act Advisory Committee (CAAAC) on November 19, 1990, to provide independent advice and counsel to EPA on policy issues associated with implementation of the Clean Air Act of 1990. The Committee advises on economic, environmental, technical scientific, and enforcement policy issues.

Dates & Addresses: Open meeting notice; Pursuant to 5 U.S.C. App. 2 section 10(a)(2), notice is hereby given that the Clean Air Act Advisory Committee will hold its next open meeting on Thursday September, 20, 2007 from 8:30 a.m. to 4 p.m. at the Double Tree Hotel at 300 Army Navy Drive, in Arlington, Virginia. Seating will be available on a first come, first served basis. The Economic Incentives and Regulatory Innovations subcommittee will meet on September 19, 2007 from 8:30 a.m. to 12 p.m. The Permits, New Source Review and Toxics subcommittee will meet on September 19, 2007 from approximately 12:45 p.m. to 3:30 p.m. The Mobile Source Technical Review subcommittee will meet on September 19, 2007 from 8:30 a.m. to 5 p.m. These meetings will also be at the Double Tree Hotel. There will also be a teleconference call of the full Clean Air Act Advisory Committee on September 24, 2007 from approximately 1–3 p.m. The agenda for the CAAAC full committee meeting on September 20, 2007 and the teleconference contact information for the September 24, 2007 will be posted on the Clean Air Act Advisory Committee Web site at *http://www.epa.gov/oar/caaac/*.

Inspection of Committee Documents: The Committee agenda and any documents prepared for the meeting will be publicly available at the meeting. Thereafter, these documents, together with CAAAC meeting minutes, will be available by contacting the Office of Air and Radiation Docket and requesting information under docket OAR–2004–0075. The Docket office can be reached by telephoning 202–260–7548; FAX 202–260–4400.

FOR FURTHER INFORMATION CONTACT: Concerning the CAAAC, please contact Pat Childers, Office of Air and Radiation, U.S. EPA (202) 564–1082, FAX (202) 564–1352 or by mail at U.S. EPA, Office of Air and Radiation (Mail code 6102 A), 1200 Pennsylvania Avenue, NW., Washington, DC 20004. For information on the Subcommittees, please contact the following individuals: (1) Permits/NSR/Toxics Integration—Debbie Stackhouse, (919) 541–5354; and (2) Air Quality Management—Jeff Whitlow, (919) 541–5523 (3) Economic Incentives and Regulatory Innovations—Carey Fitzmaurice, (202)564–1667 (4) Mobile Source Technical Review—John Guy, (202) 343–9276 Additional Information on these meetings, CAAAC, and its Subcommittees can be found on the CAAAC Web site: *http://www.epa.gov/oar/caaac/*.

For information on access or services for individuals with disabilities, please contact Mr. Pat Childers at (202) 564–1082 or *childers.pat@epa.gov*. To request accommodation of a disability, please contact Mr. Childers, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: August 29, 2007.

Pat Childers,

Designated Federal Official, Clean Air Act Advisory Committee, Office of Air and Radiation.

[FR Doc. E7–17513 Filed 9–4–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8463–7; Docket ID No. EPA–HQ–ORD–2006–0812]

Child-Specific Exposure Factors Handbook

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of peer-review panel workshop.

SUMMARY: The Environmental Protection Agency (EPA) is announcing that Eastern Research Group, Inc. (ERG), an EPA contractor for external scientific review, will convene an independent panel of experts and organize and conduct a peer-review workshop, to review the external review draft document titled, ''Child-Specific Exposure Factors Handbook'' (EPA/600/R–06/096A). EPA provided an opportunity for public comment on the draft document from October 2006 to January 2007. The draft document was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development. The ''Child-Specific Exposure Factors Handbook'' provides a summary of statistical data on various exposure factors used in assessing children's exposures, including: Drinking water consumption; soil ingestion and mouthing behavior; inhalation rates; dermal factors including skin surface area and soil adherence factors; consumption of retail and home-grown foods; breast milk intake; and human activity pattern data. Once completed, this report will serve as a resource for exposure assessors for estimating children's exposures. An interim final version of this handbook was published in 2002. This updated version provides analysis of exposure factors data using the age groups for children recommended in the EPA document entitled, ''Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants'' (EPA/630/P–03/003F) (Available on line at *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=146583).*

EPA released this draft document in October 2006, solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. This document has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency policy or determination.

In preparing a final report, EPA will consider the public comments submitted to EPA's docket during the public comment period, and the contractor's report of the external peer-review workshop, including any oral public comments received at the workshop.

DATES: The peer-review panel workshop will begin on September 19, 2007, at approximately 8 a.m. and end at 4 p.m. on September 20, 2007. Members of the public may attend the peer-review panel workshop. Time will be set aside on the morning of September 19, 2007, for registered attendees who wish to make brief oral comments (for more information refer to the instructions for registration below).

ADDRESSES: Eastern Research Group, Inc. (ERG), an EPA contractor for external scientific review, will convene an independent panel of experts and organize and conduct a peer-review panel workshop to review this draft document. The peer-review panel workshop will be held at The Navy League Building, located at 2300 Wilson Boulevard, Arlington, VA. Observers may attend the peer-review panel workshop through a registration process by calling ERG's conference line between the hours of 9 a.m. and 5:30 p.m.EDT at (781) 674–7374 or toll free at (800) 803–2833, or by faxing a registration request to (781) 674–2906 (please reference the CSEFH Peer-Review Panel Workshop and include full address and contact information) , or by sending an e-mail to *meetings@erg.com* (subject line: CSEFH Peer-Review Panel Workshop; body: Include full address and contact information). Pre-registration is strongly recommended as space is limited, and registrations will be accepted on a first-come, first-served basis. The deadline for pre-registration is September 12, 2007. If space allows, registrations will continue to be accepted after this date, including on-site registration. Time will be set aside during the morning of the first day of the meeting to hear comments from observers, and individuals will be limited to a maximum of five minutes. Please inform ERG when registering if you wish to make a comment at the workshop.

The draft document, ''Child-Specific Exposure Factors Handbook,'' is available primarily via the Internet on the National Center for Environmental Assessment's home page under the Recent Additions and the Data and Publications menus at *http://www.epa.gov/ncea.* A limited number of paper copies are available from the Technical Information Staff, NCEA–W; telephone: (202) 564–3261; facsimile: (202) 565–0050. If you are requesting a paper copy, please provide your name, mailing address, and the document title, ''Child-Specific Exposure Factors Handbook''. Copies are not available from ERG and copies will not be available onsite.

FOR FURTHER INFORMATION CONTACT: Questions regarding registration and logistics for the external peer-review panel workshop should be directed to ERG, 110 Hartwell Avenue, Lexington, MA 02421–3136; telephone: (781) 674–7374 or toll free at (800) 803–2833; facsimile: (781) 674–2906; e-mail: *meetings@erg.com.*

If you need technical information about the draft document, please contact Jacqueline Moya, National Center for Environmental Assessment (NCEA); telephone: (202) 564–3245; facsimile: (202) 565–0079; e-mail *moya.jacqueline@epa.gov.*

Dated: August 29, 2007.

Rebecca Clark,

Acting Director, National Center for Environmental Assessment.

[FR Doc. E7–17540 Filed 9–4–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2007–0490; FRL–8146–2]

TSCA Section 21 Petition on Nonylphenol and Nonylphenol Ethoxylates; Response to Citizens' Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On June 6, 2007, the Sierra Club, the Environmental Law and Policy Center, the Pacific Coast Federation of Fishermen's Associations, the Washington Toxics Coalition, Physicians for Social Responsibility, and UNITE HERE petitioned EPA under section 21 of the Toxic Substances Control Act (TSCA) to initiate rulemaking proceedings under sections 4 and 6 of TSCA. Specifically, petitioners requested that EPA require manufacturers and importers to conduct certain health and safety studies under TSCA section 4; and also require, under TSCA section 6(a), labeling on all products containing nonylphenol (NP) and nonylphenol ethoxylates (NPEs), and limit the use of NP and NPEs where the use of these substances presents an unreasonable risk to public health and the environment. For the reasons set forth in this notice, EPA is granting the petitioners' request to initiate a proceeding for chronic aquatic toxicity testing under TSCA section 4 and will

also request comment on potential additional testing related to certain of the petitioners' requests, but is denying the petition in regard to TSCA section 6 and to the remaining specific TSCA section 4 requests.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Lintner, 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 Dominiak or John Schaeffer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8104 or (202) 564–8173; e-mail address: *dominiak.mary@epa.gov* or *schaeffer.john@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, or distribute in commerce NP or NPEs. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers (including importers) (NAICS codes 325, 32411, e.g., chemical manufacturing and petroleum refineries) of one or more of the subject chemicals.
- Surface active agent manufacturers (NAICS code 325613).
- Industrial launderers (NAICS code 81233).

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 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 identification (ID) number EPA–HQ–OPPT–2007–0490. 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

A. What is a TSCA Section 21 Petition?

Section 21 of TSCA allows citizens 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 facts that the petitioner believes establish the need 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**. The petitioners 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. *TSCA section 21.* TSCA section 21, itself, does not expressly identify the basis under which EPA should decide whether to grant or deny a citizens' petition. Rather, TSCA section 21(b)(1) requires that the petition set forth the facts that it is claimed establish it is ''necessary'' to issue a rule or order that is the subject of the petition. In addition, TSCA section 21 establishes standards the 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)). Further, TSCA section 21 implicitly incorporates the statutory standards under TSCA sections 4 and 6 for issuing regulations, requiring petitioners to ''set forth the facts which it is claimed establish that it is necessary to issue...a rule under section [4 or 6].'' (15 U.S.C. 2620(b)(1) (emphasis added)). Accordingly, EPA has relied on the standards in TSCA section 21 and in TSCA sections 4 and 6 as the basis for evaluating and deciding on the NP/NPE petition.

2. *Legal standards regarding TSCA section 4 test rules.* Under TSCA section 4, EPA must make a number of findings in order to issue a rule to require testing. In all cases, EPA must find that data on a chemical are insufficient to evaluate its effects and that testing of the chemical is necessary to develop the missing data. (15 U.S.C. 2603(a)(1)(A) and (B)). In addition, EPA must either find that:

i. The chemical may present an unreasonable risk of injury or

ii. The chemical is:

a. Produced in substantial quantities, and

b. May either:

A. Result in significant or substantial human exposure, or

B. Result in substantial environmental release.

TSCA section 21 allows a court to order EPA to initiate rulemaking if the court makes essentially the same determination after a *de novo* review of the petition. However, TSCA section 21 omits the third finding required under TSCA section 4 from the findings that a court must make in order to require EPA to initiate TSCA section 4 rulemaking—i.e., the finding that ''testing is necessary to develop the data.'' (15 U.S.C. 2620(b)(4)(B)(i)). Nonetheless, EPA believes TSCA section 21(b)(4) is best interpreted as incorporating all of the TSCA section 4 findings. The alternative would be to read the statute as empowering a court

to require EPA to initiate a rule even where the Agency could not make proposed findings consistent with TSCA section 4 or take final action on the rule. EPA's interpretation is supported by legislative history. (House conference report (H. Conf. Rept.) 94–1679 at 97–99 (1976)).

3. *Legal standards regarding TSCA section 6 control rules*. In evaluating the request for rules under TSCA section 6 to control chemicals, EPA assessed whether such rules are necessary to protect against unreasonable risk. This is the same test the court would apply under TSCA section 21.

The finding of unreasonable risk is a judgment under which the decisionmaker determines that the risk of health or environmental injury from a chemical outweighs the burden to society of potential regulations. An unreasonable risk decision cannot be made considering risk alone. Rather, the probability of harm must be considered against the impacts of regulation. In promulgating any rule under TSCA section 6, the statute requires that the Administrator consider:

- The effects of the substance or mixture on health and the environment and the magnitude of the exposure of human beings and the environment to the substance or mixture.
- The benefits of the 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)).

C. What Action is Requested Under this TSCA Section 21 Petition?

On June 6, 2007, the Sierra Club, the Environmental Law and Policy Center, the Pacific Coast Federation of Fishermen's Associations, the Washington Toxics Coalition, Physicians for Social Responsibility, and UNITE HERE petitioned EPA to take action under TSCA section 4 for seven categories of tests and under TSCA section 6 for four categories of restrictions.

The requested actions under TSCA section 4 are:

1. Require testing to ''fill the gaps'' for chronic toxicity of NPE oligomers (oligomers are the 1–2 mole ethoxylate of NP, also known as ''short-chain'' NPEs) to aquatic organisms.

2. Require the testing of mixtures to ''fill the gaps'' regarding the additive toxicity of NP and NPE oligomers to aquatic organisms.

3. Require testing on the estrogenic disruption impact, including multi-generational and population level impact, of NP and NPEs to aquatic organisms.

4. Require testing of NP and NPEs for vitellogenin gene expression.

5. Require testing to ascertain certain aspects of NP and NPE toxicity to humans, including general population exposure, metabolism, dermal absorption, and placental development.

6. Require epidemiology testing for industrial laundry workers exposed to NPEs.

7. Require testing to determine exposure to NPEs in residential indoor air.

The requested actions under TSCA section 6 are:

1. Require labeling on all products containing NP and NPEs.

2. Restrict the use of NPEs where the user cannot verify that the chemicals will receive proper wastewater treatment.

3. Ban the use of NP and NPEs in industrial and consumer detergents.

4. Require pollution prevention planning by facilities that use 2,000 kilograms (kg) or more of NP or NPEs.

III. Disposition of Petition

Using the criteria in Unit II.B. to assess the NP/NPE petition, EPA has concluded that, with respect to petitioners' first request for chronic toxicity testing of ''short-chain'' NPEs, the petitioners have provided facts demonstrating that existing data may be insufficient to permit a reasoned evaluation of the effects of the chemicals, and that the chemicals are produced in substantial quantities and either may result in significant or substantial human exposure, or may result in substantial environmental release. Accordingly, EPA grants the petitioners' request that EPA initiate a proceeding for the issuance of a rule under TSCA section 4 regarding chronic aquatic toxicity testing on certain NPEs. However, EPA has determined that petitioners have not provided facts to support the conclusion that the other tests they requested are necessary to permit a reasoned evaluation of the chemicals and EPA is, accordingly, denying the petitioners' remaining specific TSCA section 4 testing requests. Further, EPA has determined that petitioners failed to provide sufficient justification for any of the requested control actions under TSCA section 6 and, therefore, EPA is denying these requests. Each of the petitioners' requests is addressed specifically in the following discussion.

A. Grant of Request to Initiate a Section 4 Test Rule

Petitioners' first request was that EPA initiate testing to determine the chronic toxicity of NPEs, especially ''short-chain'' NPEs, ''for development of protective water quality criteria and standards that account for the full range of negative impacts from NP and NPEs.'' EPA agrees that data concerning the chronic effects of ''short-chain'' NPEs appear to be limited (Refs. 1 and 2) and may be insufficient to adequately evaluate the risk of chronic exposures to aquatic organisms from ''short-chain'' NPEs. However, to develop a properly tailored test requirement that would provide EPA with sufficient data, EPA believes it would be most productive to examine a number of additional considerations prior to the issuance of a proposed rule. These considerations include determining which NPEs might be studied to adequately characterize the potential risk presented by chronic exposures to these chemicals, based on such factors as the potential for aquatic organisms to be exposed to them. For example, NP1EO and NP2EO have been detected in the environment and may be the candidates for further testing, but other NPEs, including various derivatives and degradation products, may not need to be considered. EPA further notes that, if adequate acute aquatic toxicity testing data are not already available on specific NPEs in the same species appropriate for chronic testing, those acute data may need to be developed in order to set appropriate concentration levels for chronic testing and for calculating acute-to-chronic ratios. Additional considerations may include determining how many taxa are needed, and which species in those taxa would be most appropriate in order to properly characterize the potential aquatic toxicity of the chemicals present in freshwater and saltwater systems. EPA may also consider whether chronic aquatic toxicity testing for NP in saltwater fish species may be warranted, and whether testing to assess the toxicity and fate of sediment-bound NP in both freshwater and marine/estuarine habitats should be considered, since these data are limited (Refs. 2, 3, and 4). Finally, EPA notes that the apparent focus of the petition is the development of water quality criteria (WQC). Although petitioners have referenced testing designed to satisfy the requirements imposed by States and EPA for data sufficient for setting WQC values, EPA notes that the standards for setting WQC are different than the standard for requiring testing under TSCA section 4, and a reasoned

evaluation of the chemicals under TSCA may require different tests than the full battery of studies necessary to issue such criteria. Accordingly, rather than initially proposing a rule pursuant to TSCA section 4, where the Agency would present its preliminary conclusions on these points, EPA will publish an Advanced Notice of Proposed Rulemaking (ANPRM) initiating proceedings under TSCA section 4. The ANPRM will identify these issues for public comment. The information received from this process would guide EPA in developing a proposed testing program under TSCA section 4.

B. Denials of Requests to Initiate TSCA Section 4 Test Rules

Petitioners' second request was that EPA ''fill the data gaps regarding the additive toxicity of NP and NPE oligomers to species.'' Petitioners requested testing of unspecified mixtures of NP and NPEs in acute and chronic assays to address this perceived gap. The petitioners noted that, given their similar structure and mode of action, the toxicity of NP and NPEs may be additive. EPA currently believes that the question of additive toxicity of various NPEs would not be addressed effectively by requiring the testing of unspecified mixtures of them. Additive toxicity is often more pragmatically addressed by using methods to combine the results of testing the individual components of mixtures. Petitioners provided no rationale to explain why this more pragmatic approach of testing individual chemicals would be inadequate in this instance. Therefore, EPA does not believe it has the basis at this time to support the finding required under TSCA section 4(a)(2) for ordering the testing of mixtures: That the effects of the mixture ''may not be reasonably and more efficiently determined...by testing the chemical substances which comprise the mixture.'' EPA considers that obtaining certain acute and chronic aquatic toxicity data on the appropriate individual NPE, as described in this unit in the response to petitioners' first request, could provide useful information addressing the additive toxicity question raised by petitioners. EPA thus denies the specific request that EPA order the testing of mixtures, but EPA may consider multiple approaches to addressing the questions concerning possible additive toxicity in the ANPRM.

Petitioners' third request was that EPA conduct research on individual endocrine disruption impacts and on the relationship between individual endocrine disruption impacts and population-level impacts, including multi-generation effects. In general, EPA questions whether such mechanism-specific testing is needed to permit a reasoned evaluation of these chemicals given other data that exist and the additional data that EPA would consider in the ANPRM. Available studies already evaluate effects on the test organisms' mortality, growth, and reproduction, which are apical to any endocrine disruption that may occur. As summarized in EPA's Office of Water Ambient Water Quality Criteria (WQC) Document for NP, the ability of nonylphenol to induce estrogenic effects has seldom been reported at concentrations below the freshwater final chronic value of 6.6 micrograms/Liter (µg/L) (Ref. 3). EPA considers at this time that the existing data, particularly combined with the acute and chronic aquatic toxicity data that EPA proposes to discuss in its ANPRM, would be sufficient to evaluate effects on individuals and populations (Refs. 3, 5, and 6). In addition, test methods to assess multi-generational impacts are not currently available, and it is not yet certain that such methods would provide data that would significantly advance understanding beyond existing chronic study data with regard to NP, given that NP demonstrates estrogenic effects at concentrations at or above which chronic effects are also seen. The Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Endocrine Disruptor Screening Program (EDSP) is currently developing and validating freshwater and saltwater fish 2-generation test methods and also a crustacean (mysid) 2-generation test method. However, those methods are not expected to be fully validated before 2010, and additional work with the test method will be required to demonstrate the benefit of performing these studies. As noted in the WQC document, when the appropriate EDSP testing protocols have been developed and validated, EPA may consider whether additional testing of NP and NPE might be warranted (Ref. 3). For these reasons, EPA cannot conclude that the available information relevant to this requested testing is insufficient to permit a reasoned evaluation of the health or environmental effects of these chemicals or that the requested testing is necessary, and EPA, therefore, denies this request.

Petitioners' fourth request was that EPA apply a specific vitellogenin gene expression assay to NP and each individual NPE. In general, EPA questions whether such mechanism-specific testing is needed to permit a reasoned evaluation of these chemicals given other data that exist. Several different vitellogenin gene expression tests exist (Refs. 7, 8, and 9), but each serves the same purpose of demonstrating the potential of a chemical for estrogenic expression. The Agency considers that available information on NP and various NPEs is sufficient to adequately demonstrate and evaluate the estrogenic expression of NP and also to provide enough of a basis on which to project the lesser contribution of various NPEs, making further vitellogenin assays unnecessary (Refs. 5, 6, 10, and 11). Accordingly, EPA cannot conclude that the available information relevant to this requested testing is insufficient to permit a reasoned evaluation of the health or environmental effects of these chemicals or that the requested testing is necessary, and EPA, therefore, denies the request for a TSCA section 4 test rule requiring the vitellogenin gene expression assay.

Petitioners' fifth request encompasses a diverse cluster of testing, including dermal absorption, oxidative metabolism, the effects of NP on human placental development, and NP and NPE exposure to the general population of the United States. Data to evaluate these effects either already exist or are being generated under other programs and need not be duplicated. For example, a combination of existing human and animal studies provides a reasonable understanding of the metabolism of NP in humans. The data available indicate a metabolic profile common to phenols (Refs. 12, 13, and 14). In addition, studies on dermal absorption of NP and NPEs have already been conducted and have concluded that dermal absorption of NP is negligible, and that dermal absorption of NPEs through human and animal skin is less than 1% (Ref. 15). The petitioners cited a study done on human placental tissue suggesting that NP may have some effect on trophoblastic cells of the placenta, and specifically requested that a similar study be repeated. EPA does not believe that repeating this non-standard study or attempting to design a similar one would add to the understanding of these chemicals, because existing studies on whole organisms have already more fully addressed reproductive and other health effects (Ref. 16). Reproductive studies of NP in mammals have been conducted (Refs. 17 and 18), as well as other studies which have examined the estrogenic effects of NP in mammals (e.g., uterotrophic assay) (Refs. 19, 20, and 21), and, on the basis of these data,

EPA believes it has sufficient information to evaluate NP's reproductive risks to human health without conducting a non-standard placental study of the type requested by petitioners. With regard to assessing NP and NPE exposure to the general U.S. population, EPA notes that the Centers for Disease Control and Prevention (CDC) indicated through a notice published in 2003 that NP has already been slated for inclusion in the *National Report on Human Exposure to Environmental Chemicals*, and there is thus no need for EPA to duplicate that activity (Ref. 22). For these reasons, EPA cannot conclude that the available information relevant to this requested testing is insufficient to permit a reasoned evaluation of the health or environmental effects of these chemicals or that the requested testing is necessary, and EPA, therefore, denies these requests for testing under TSCA section 4.

Petitioners' sixth request was that EPA conduct an epidemiology study of industrial laundry workers who may be exposed to NP and NPEs in detergents. Before an epidemiology study can be effectively designed or conducted, however, there needs to be evidence that there are sufficient exposures to a substance to warrant a study of human health effects potentially attributable to those exposures. As noted in the comments submitted by the Uniform and Textile Service Association (UTSA) and the Textile Rental Services Association (TRSA), approximately 90% of industrial laundries use injected liquid detergent (Ref. 23). Given the low volatility (Ref. 24) and the negligible dermal absorption of NP and NPE (Ref. 15), these industrial laundry operations would not present significant exposure potential. Accordingly, there is no evidence to support a conclusion that significant exposures exist that would warrant an epidemiological study in this overall industry. However, for the approximate 10% of industrial laundry operations and an unknown number of institutional laundry operations that may use powdered detergent, EPA considers that there is potential for inhalation exposure to dust containing NP and NPE by workers and that the number of potentially exposed workers involved could be substantial (Ref. 25). As these concerns are based on estimates and not actual exposure monitoring data, they would not support a conclusion that there are sufficient exposures to warrant an epidemiology study. However, EPA considers that obtaining additional exposure information may be warranted to reasonably assess the potential for risk associated with this one exposure scenario. Accordingly, EPA denies the petitioners' specific request for an epidemiology study, but plans to include in the ANPRM a discussion of the need for data concerning NP and NPE exposures of laundry workers where powdered detergents are used, and to solicit comment on the best means to obtain that information (e.g., whether through requiring an exposure study, workplace exposure monitoring, the voluntary submission of existing monitoring data, or other means).

Finally, the petitioners' seventh request concerned ordering a nationwide study of residential exposures based on one study which found levels of NP and NPEs in dust and indoor air in all homes in the study. However, in both the study cited by petitioners and in a second study that found NP or NPEs in only 10% of the homes studied (Refs. 26 and 27), the levels of NP found were far below any level of concern suggested in reviews (e.g., Ref. 16). Neither study could be assumed to be representative of households across the United States, but both studies would suggest that residential indoor air and dust do not contribute significantly to household exposure. Therefore, EPA cannot conclude that the available information relevant to this requested testing is insufficient to permit a reasoned evaluation of the health effects of these chemicals. Similarly, EPA believes there is no evidence indicating that exposures of the general population to NP and NPEs are of concern at the present, and notes that the CDC human biomonitoring work will provide nationally representative data on the levels of general population exposures to NP irrespective of exposure source. Accordingly, EPA denies the request for a nationwide residential exposure study under TSCA section 4.

C. Denial of Requests to Issue TSCA Section 6 Control Rules

EPA has concluded that the petitioners have not set forth the facts establishing the need for the control actions requested under TSCA section 6. Although the petition asserts that an unreasonable risk exists, the petition does not present a reasonable basis to conclude both that the chemicals present or will present an unreasonable risk and that the specific actions requested by petitioners would be necessary to protect adequately against such risk using the least burdensome requirements. Accordingly, EPA denies the petitioners' requests for control actions under TSCA section 6.

The petitioners requested that EPA issue TSCA section 6 actions to require labeling, not just Material Safety Data Sheets (MSDSs), on all products containing NP and NPE; to restrict the use of NP and NPE where the user (including the 25% of U.S. households that rely on septic systems) cannot verify that the chemical will receive proper/effective treatment at a well-managed sewage treatment plant from an activated sludge treatment process designed to nitrify; to ban the use of the chemicals in industrial and consumer detergents in favor of existing, less toxic alternatives; and, similar to Canada, to require facilities that use 2,000 kg or more of NP or NPEs to develop formal pollution prevention plans, and to consider safer substitutes consistent with OPPT's Safer Detergents Stewardship Initiative (SDSI).

As noted in Unit III.B., in order to issue a rule under TSCA section 6, EPA must affirmatively find that the risks are unreasonable, and in making that determination, must consider a number of specified issues. These relate not merely to the effects of the chemical(s), but also to:

1. The benefits of the substance(s) for various uses and the availability of substitutes for such uses.

2. The reasonably ascertainable economic consequences of the control mechanisms proposed to control the risk, including the effect on the national economy and small business and technical innovation.

These considerations are integral to the determination that a substance presents an unreasonable risk, and the petitioners have not presented sufficient facts to allow EPA to evaluate the issues. It is not sufficient in a petition under TSCA section 21 to assert that an unreasonable risk exists without providing the facts that would support that assertion.

For example, in presenting their argument for actions under TSCA section 6, the petitioners failed to provide information that would permit consideration of the effect of their requested controls on the national economy, small business and technological innovation, the environment, and public health. Petitioners asserted that the costs of their requested controls would be small and that the benefits of their controls would reduce risk, but provided no data to substantiate either their estimates of cost or of the efficacy of their proposed control actions.

In addition, petitioners did not address the extent to which actions taken under other statutes or voluntary programs may already be addressing the

risk that may be presented by these chemicals, and whether those other statutes or voluntary programs may provide more appropriate tools than TSCA section 6 action to control risk to the extent necessary as additional data are generated on chemical effects and exposure. EPA has addressed NP and, to some extent, NPE in recent regulatory actions with respect to water quality criteria (Refs. 3 and 28) and to the reassessment of tolerances for pesticide inerts on food (Ref. 29). EPA also sought public comment in May 2007 on SDSI (Ref. 30). SDSI is intended to complement the water quality criteria for NP by promoting the voluntary conversion by the detergent industry to alternative surfactants that break down quickly to less toxic compounds. EPA must assess those public comments and the potential of SDSI to impact the need for any further regulatory controls.

The data and information supplied in the petition and the information provided in public comments do not provide a reasonable basis to conclude that NP or NPE pose an unreasonable risk to health or the environment. Consequently, EPA has determined that petitioners have failed to provide sufficient justification for any of their requests for control actions under TSCA section 6 of TSCA, and EPA is denying the request that EPA initiate actions under TSCA section 6.

IV. Comments Received

EPA published a notice in the **Federal Register** issue of July 10, 2007, announcing receipt of the petition and inviting public comment on or before July 25, 2007 (Ref. 31). EPA received ten timely comments from one individual, one petitioner, one State agency, and seven nonprofit trade or professional associations, and about 1,900 mass-mailed comments from private citizens through a mass comment campaign evidently sponsored by one or more of the petitioners. EPA also received a request for an extension of the comment period on July 25, 2007, submitted by UNITE HERE and the Sierra Club, two of the petitioners. The request for extension was denied because of the schedule for response mandated by TSCA section 21, although EPA indicated that late comments would be considered to the extent possible. One late comment was submitted on August 1, 2007, by another trade association. One State agency submitted a late letter addressed to the Administrator which was received on August 6, 2007, and was directed to the docket as a late comment.

The petitioner (the Environmental Law and Policy Center), the individual, the two State agencies (the New York State Department of Environmental Conservation and the Illinois Environmental Protection Agency), and the mass mailing campaign supported the petition, without presenting additional significant substantive data apart from an additional reference provided by the petitioner. This reference concerned data already in EPA's possession.

All but one of the trade or professional organizations opposed the petition on the grounds that existing data were already sufficient to assess the chemicals and that no unreasonable risk was demonstrated in the petition. Five of the organizations (the UTSA, the TRSA, the Soap and Detergent Association, the Consumer Specialty Products Association, and the Alkylphenols and Ethoxylates Research Council) submitted detailed comments with references to data. These data were already in EPA's possession. The remaining opposing organization (CropLife America) and the association submitting late comments (the Chemical Producers and Distributors Association) supported the position expressed by the Alkylphenols and Ethoxylates Research Council.

The National Association of Clean Water Agencies (NAWCA) did not comment on the substance of the petition, but indicated that any action taken by EPA in response to the petition should not place the burden for response on the nation's wastewater treatment utilities.

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24. EPA. E-mail communication from Greg Fritz to John Schaeffer and Mary Dominiak. Subject: Vapor Pressure estimates for NP and NPEs (NP1EO and NP2EO) (with two attachments: Huntsman Corporation Technical Bulletin: SURFONIC® N-31.5 Surfactant (2005) and EPIWIN [SRC CORP.] Program Estimates (EPI_est.doc)). August 14, 2007.

25. EPA. Draft Engineering Report of Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs) In Response to Section 21 Petition. EPA, OPPT, Economics, Exposure and Technology Division, Chemical Engineering Branch. July 18, 2007. 15 pp.

26. Rudel, R.A.; Camann, D.E.; Spengler, J.D.; Korn, L.R.; and Brody, J.G. 2003. Phthalates, Alkylphenols, Pesticides, Polybrominated Diphenyl Ethers, and Other Endocrine-Disrupting Compounds in Indoor Air and Dust. *Environmental Science and Technology*. 37 (20):4543–4553.

27. Morgan, M.K.; Sheldon, L.S.; and Croghan, C.W. 2004. A Pilot Study of Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP). Volume I: Final Report to U.S. Environmental Protection Agency, Contract Number 68–D–99–011, Task Order 0002.

28. EPA. Notice of Availability of Final Aquatic Life Ambient Water Quality Criteria for Nonylphenol. Notice. **Federal Register** (71 FR 9337, February 23, 2006) (FRL–OW–8035–8). Available on-line at *http://www.epa.gov/fedrgstr*.

29. EPA. Memorandum from Kerry Leifer, Inert Ingredient Assessment Branch, Registration Division and Pauline Wagner, Chief, Inert Ingredient Assessment Branch, Registration Division to Lois Rossi, Director, Registration Division. Subject: Reassessment of Four Exemptions from the Requirement of a Tolerance for Nonylphenol Ethoxylates (with attached Action Memorandum: Inert Reassessments: Four Exemptions from the Requirement of a Tolerance for Nonylphenol Ethoxylates, dated July 31, 2006).

30. EPA. Safer Detergents Stewardship Initiative (SDSI). Available on-line at *http://www.epa.gov/dfe/pubs/projects/formulat/sdsi.htm*. Agency Information Collection Activities; Proposed Collection; Comment Request; Safer Detergent Stewardship Initiative (SDSI) Program; EPA ICR No 2261.01, OMB Control No. 2070-new. Notice. **Federal Register** (72 FR 26357, May 9, 2007) (FRL–8125–4). Available on-line at *http://www.epa.gov/fedrgstr*.

31. EPA. TSCA Section 21 Petition on Nonylphenol and Nonylphenol Ethoxylates; Notice of Receipt. Notice. **Federal Register** (72 FR 37530, July 10, 2007) (FRL–8139–7). Available on-line at *http://www.epa.gov/fedrgstr*.

List of Subjects

Environmental protection, Hazardous substances, Nonylphenol, Nonylphenol Ethoxylates.

Dated: August 29, 2007.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. E7–17542 Filed 9–4–07; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted to the Office of Management and Budget, Comment Requested

August 28, 2007.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of

information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before November 5, 2007. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, (202) 395–5887, or via fax at 202–395–5167 or via Internet at *Nicholas_A._Fraser@omb.eop.gov* and to *Judith-B.Herman@fcc.gov,* Federal Communications Commission, Room 1–B441, 445 12th Street, SW., Washington, DC 20554 or an e-mail to *PRA@fcc.gov.* If you would like to obtain or view a copy of this information collection after the 60 day comment period, you may do so by visiting the FCC PRA Web page at: *http://www.fcc.gov/omd/pra.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith B. Herman at 202–418–0214 or via the Internet at *Judith-B.Herman@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0798.

Title: FCC Application for Radio Service Authorization: WTB and PSHS.

Form No.: FCC Form 601.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households, business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 252,720 respondents; 252,720 responses.

Estimated Time per Response: 1.25 hours.

Frequency of Response: On occasion reporting requirement, third party disclosure requirement, recordkeeping requirement and every 10 year reporting requirement.

Obligation To Respond: Required to obtain or retain benefits.

Total Annual Burden: 221,130 hours.

Total Annual Cost: $50,584,000.

Privacy Act Impact Assessment: Yes.

Nature and Extent of Confidentiality: In general there is no need for confidentiality. On a case-by-case basis, the Commission may be required to withhold from disclosure certain information about the location, character, or ownership of a historic property, including traditional religious sites.

Needs and Uses: The Commission will submit this revision to the OMB after this 60 day comment period to obtain the full three-year clearance from them.

The FCC Form 601 is a consolidated, multi-part application form, or ''long-form'', that is used for general market-based licensing and site-by-site licensing for wireless telecommunications and public safety services filed through the Commission's Universal Licensing System (ULS). FCC Form 601 is composed of a main form that contains the administrative information and a series of schedules used for filing technical and other information. Respondents are encouraged to submit FCC Form 601 electronically and are required to do so when submitting FCC Form 601 to apply for an authorization for which the applicant was the winning bidder in a spectrum auction.

The data collected on the FCC Form 601 include the FCC Registration Number (FRN), which serves as a ''common link'' for all filings an entity has with the FCC. The Debt Collection Improvement Act of 1996 requires that those entities filing with the Commission to use an FRN. FCC Form 601 is also being used for auctionable services as they are implemented; to apply for a new authorization; or to amend a pending application for an authorization to operate a license for wireless radio services. This includes Public Mobile Services, Personal Communications Services, General Wireless Communications Services, Private Land Mobile Radio Services, Broadcast Auxiliary Services, Fixed Microwave Services, Instructional Television Fixed Service (ITFS) and the Multipoint Distribution Service (MDS), Maritime Services (excluding ships), and Aviation Services (excluding aircraft). It may also be used to modify or renew an existing license, cancel a license, withdraw a pending application, obtain a duplicate license, submit required notifications, request an extension of time to satisfy construction requirements, or request an administrative update to an existing license (such as a mailing address change), request a Special Temporary Authorization (STA), or a Developmental License. The Commission is now seeking OMB approval because we are increasing the number of respondents by 2,200 and the annual cost burden; and add new radio service codes and instructional changes to Schedules B and D due to Auction 73 of the 700 MHz band licenses (see Second Report and Order in FCC 07–132, WT Docket No. 06–150) scheduled for January 16, 2008.

OMB Control Number: 3060–0799.

Title: FCC Ownership Disclosure Information for the Wireless Telecommunications Services.

Form No.: FCC Form 602.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 550 respondents; 5,216 responses.

Estimated Time Per Response: 1.50 hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits.

Total Annual Burden: 5,216 hours.

Total Annual Cost: $508,200.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: In general, there is no need for confidentiality. On a case by case basis, the Commission may be required to withhold from disclosure certain information about the location, character, or ownership of a historic property, including traditional religious sites.

Needs and Uses: The Commission will submit this revision to the OMB after this 60-day comment period to obtain the full three-year clearance from them.

The purpose of the FCC Form 602 is to obtain the identity of the filer and to elicit information required by 47 CFR 1.2112 of the Commission's rules regarding: (1) Persons or entities holding a 10 percent or greater direct or indirect ownership interest or any general partners in a general partnership holding a direct or indirect ownership interest in the applicant (''Disclosable Interest Holders''); and (2) all FCC-regulated entities in which the filer or any of its Disclosable Interest Holders owns a 10 percent or greater interest.

The data collected on the FCC Form 602 includes the FCC Registration Number (FRN), which serves as a ''common link'' for all filings an entity has with the FCC. The Debt Collection Improvement Act of 1996 requires that entities filing with the Commission use a FRN. The FCC Form 602 was designed for, and must be filed electronically in the Universal Licensing System (ULS) by all licensees that hold licenses in auctionable services.

The Commission is now seeking OMB approval because we are increasing the number of respondents by 50 and the annual cost burden due to Auction 73 of the 700 MHz band licenses (see Second Report and Order in FCC 07–132, WT Docket No. 06–150) scheduled for January 16, 2008.

OMB Control Number: 3060–0800.

Title: FCC Application for Assignments of Authorization and Transfers of Control; WTB and PSHS.

Form No.: FCC Form 603.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households, business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 32,751 respondents; 32,751 responses.

Estimated Time Per Response: 1.75 hours.

Frequency of Response: On occasion reporting requirement, recordkeeping requirement.

Obligation to Respond: Mandatory.

Total Annual Burden: 36,846 hours.

Total Annual Cost: $3,111,295.

Privacy Act Impact Assessment: Yes.

Nature and Extent of Confidentiality: In general, there is no need for confidentiality. On a case by case basis, the Commission may be required to withhold from disclosure certain information about the location, character, or ownership of a historic property, including traditional religious sites.

Needs and Uses: The Commission will submit this revision to the OMB after this 60-day comment period to obtain the full three-year clearance from them.

FCC Form 603 is a multi-purpose form used to apply for approval of assignment or transfer of control of licenses in the wireless services. The data collected on this form is used by the FCC to determine whether the public interest would be served by approval of the requested assignment or transfer. This form is also used to notify the Commission of consummated assignments and transfers of wireless and/or public safety licenses that have previously been consented to by the Commission or for which notification but not prior consent is required. This form is used by applicants/licensees in the Public Mobile Services, Personal Communications Services, General Wireless Communications Services, Private Land Mobile Radio Services, Broadcast Auxiliary Services, Broadband Radio Services, Educational Radio Services, Fixed Microwave Services, Maritime Services (excluding ships), and Aviation Services (excluding aircraft).

The purpose of this form is to obtain information sufficient to identify the parties to the proposed assignment or transfer, establish the parties basic eligibility and qualifications, classify the filing, and determine the nature of the proposed service. Various technical schedules are required along with the main form applicable to Auctioned Services, Partitioning and Disaggregation, Undefined Geographical Area Partitioning, Notification of Consummation or Request for Extension of Time for Consummation.

The Commission is now seeking OMB approval because we are increasing the number of respondents by 200 and the annual cost burden and add an additional option for coverage requirements on Schedule B due to Auction 73 of the 700 MHz band licenses (see Second Report and Order in FCC 07–132, WT Docket No. 06–150) scheduled for January 16, 2008.

OMB Control Number: 3060–1058.

Title: FCC Application or Notification for Spectrum Leasing Arrangement: WTB and PSHS.

Form No.: FCC Form 608.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 1,623 respondents; 1,623 responses.

Estimated Time Per Response: 5 hours.

Frequency of Response: On occasion reporting requirement and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits.

Total Annual Burden: 8,115 hours.

Total Annual Cost: $1,334,106.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: In general there is no need for confidentiality. On a case by case basis, the Commission may be required to withhold from disclosure certain information about the location, character, or ownership of a historic property, including traditional religious sites.

Needs and Uses: The Commission will submit this revision to the OMB after this 60-day comment period to obtain the full three-year clearance from them. FCC Form 608 is a multi-purpose form used to provide notification or request approval for any spectrum leasing arrangement ('Leases') entered into between an existing licensee ('Licensee') in certain wireless services and a spectrum lessee ('Lessee'). This form is also required to notify or request approval for any spectrum subleasing arrangement ('Sublease'). The form is also used to provide notification for any Private Commons Arrangement entered into between a Licensee, Lessee, or Sublessee and a class of third-party users (as defined in 47 CFR 1.9080 of the Commission's Rules.) The data collected on the form is used by the FCC to determine whether the public interest would be served by the Lease or Sublease. The Commission is now seeking OMB approval because we are increasing the number of respondents by 30 as a result of the Second Report and Order in FCC 07–132, WT Docket No. 06–150.

OMB Control Number: 3060–1092.

Title: Interim Procedures for Filing Applications Seeking Approval for Designated Entity Reportable Eligibility Events and Annual Reports.

Form Nos.: FCC Forms 609–T and 611–T.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents: 1,100 respondents; 2,750 responses.

Estimated Time Per Response: .50–6 hours.

Frequency of Response: On occasion and annual reporting requirements.

Obligation to Respond: Required to obtain or retain benefits.

Total Annual Burden: 7,288 hours.

Total Annual Cost: $1,494,625.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: In general there is no need for confidentiality. On a case by case basis, the Commission may be required to withhold from disclosure certain information about the location, character, or ownership of a historic property, including traditional religious sites.

Needs and Uses: The Commission will submit this revision to the OMB after this 60-day comment period to obtain the full three-year clearance from them.

FCC Form 609–T is used by Designated Entities (DEs) to request prior Commission approval pursuant to 47 CFR 1.2114 of the Commission's Rules for any reportable eligibility event. The FCC Form 611–T is used by Designated Entity licensees to file an annual report, pursuant to 47 CFR 1.2110(n) of the Commission's Rules, related to eligibility for designated entity benefits. The data collected on the form is used by the FCC to determine whether the public interest would be served by the approval of the reportable eligibility event.

The Commission is now seeking OMB approval because we are increasing the number of respondents by 100 as a result of the Second Report and Order in FCC 07–132, WT Docket No. 06–150.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. E7–17503 Filed 9–4–07; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to OMB for Review and Approval

August 28, 2007.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before October 5, 2007. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser of Office of Management and Budget (OMB), via Internet at *Nicholas_A._Fraser@omb.eop.gov* or via fax at (202) 395–5167 and to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC.

If you would like to obtain or view a copy of this information collection, you may do so by visiting the FCC PRA Web page at: http://www.fcc.gov/omd/pra.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at (202) 418–2918 or via the Internet at *PRA@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0250.

Title: Sections 73.1207, 74.784 and 74.1284, Rebroadcasts.

Form Number: Not applicable.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, local or tribal government.

Number of Respondents: 6,062.

Estimated Time per Response: 30 minutes.

Frequency of Response: Recordkeeping requirement; On occasion reporting requirement; Semi-annual reporting requirement; Third party requirement.

Total Annual Burden: 5,306 hours.

Total Annual Cost: None.

Nature of Response: Required to obtain or retain benefits.

Confidentiality: No need for confidentiality required.

Privacy Impact Assessment: No impact(s).

Needs and Uses: 47 CFR 73.1207 requires that licensees of broadcast stations obtain written permission from an originating station prior to retransmitting any program or any part thereof. A copy of the written consent must be kept in the station's files and made available to the FCC upon request. Section 73.1207 also specifies procedures that broadcast stations must follow when rebroadcasting time signals, weather bulletins, or other material from non-broadcast services.

47 CFR 74.784 requires licensees of low power television and TV translator stations to notify the FCC when rebroadcasting programs or signals of another station occurs. They are also required to certify that written consent has been obtained from originating station. FCC staff uses the data to ensure compliance with Section 325(a) of the Communications Act, as amended.

47 CFR 74.1284 requires that the licensee of a FM translator station obtain prior consent to rebroadcast programs of any FM broadcast station or other FM translator. The licensee must notify the Commission of the call letters of each station rebroadcast and must certify that written consent has been received from the licensee of that station.

The Commission is revising this information collection to consolidate rule Section 47 CFR 73.1207 into OMB control number 3060–0250. The rule section is currently approved under OMB control number 3060–0173.

OMB Control Number: 3060–0633.

Title: Sections 73.1230, 74.165, 74.432, 74.564, 74.664, 74.765, 74.832, 74.1265, Posting or Filing of Station Licenses.

Form Number: Not applicable.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities, Not-for-profit institutions.

Number of Respondents: 2,584.

Estimated Hours per Response: 0.083 hours.

Frequency of Response: Recordkeeping requirement; On occasion reporting requirement; Third party disclosure requirement.

Total Annual Burden: 214 hours.

Total Annual Cost: $24,860.

Nature of Response: Required to obtain or retain benefits.

Confidentiality: No need for confidentiality required.

Privacy Impact Assessment: No impact(s).

Needs and Uses: 47 CFR 73.1230 requires that the station license and any other instrument of station authorization for an AM, FM or TV station be posted in a conspicuous place where the licensee considers to be the principal control point of the transmitter.

47 CFR 74.165 requires that the instrument of authorization for an experimental broadcast station be available at the transmitter site.

47 CFR 74.432(j) (remote pickup broadcast station) and 74.832(j) (low power auxiliary station) requires that the license of a remote pickup broadcast/low power auxiliary station shall be retained in the licensee's files, posted at the transmitter, or posted at the control point of the station. These sections also require the licensee to forward the station license to the FCC in the case of permanent discontinuance of the station.

47 CFR 74.564 (aural broadcast auxiliary stations) requires that the station license and any other instrument of authorization be posted in the room where the transmitter is located, or if operated by remote control, at the operating position.

47 CFR 74.664 (television broadcast auxiliary stations) requires that the station license and any other instrument of authorization be posted in the room where the transmitter is located. Sections 74.765 (low power TV, TV translator and TV booster) and 74.1265 (FM translator stations and FM booster

stations), require that the station license and any other instrument of authorization be retained in the station's files. In addition, the call sign of the station, together with the name, address and telephone number of the licensee or the local representative of the licensee, and the name and address of the person and place where the station records are maintained, shall be displayed at the transmitter site on the structure supporting the transmitting antenna.

The Commission is revising this information collection to remove 47 CFR 74.965 from the information collection. The rule section was removed from the CFR. It is no longer in existence.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E7–17505 Filed 9–4–07; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to OMB for Emergency Review and Approval

August 30, 2007.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before September 12, 2007. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via e-mail to *nfraser@omb.eop.gov* or via fax at 202–395–5167, and to the Federal Communications Commission via e-mail to *PRA@fcc.gov* or by U.S. mail to Jerry Cowden, Federal Communications Commission, Room 1–B135, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: For additional information contact Jerry Cowden via e-mail at *PRA@fcc.gov* or at 202–418–0447. If you would like to obtain or view a copy of this information collection you may do so by visiting the FCC PRA Web page at: *http://www.fcc.gov/omd/pra.*

SUPPLEMENTARY INFORMATION: The Commission is requesting emergency OMB processing of this information collection and has requested OMB approval by September 19, 2007.

OMB Control Number: None.

Title: Information collection for Emergency Communications Back-Up System Report to Congress.

Form No.: Not applicable.

Type of Review: New collection.

Respondents: Businesses or other for-profit; not-for-profit institutions; and state, local or tribal governments.

Number of Respondents: 45 respondents; 45 responses.

Estimated Time per Response: 40 hours.

Frequency of Response: One-time reporting.

Obligation to Respond: Voluntary.

Total Annual Burden: 1,800 hours.

Total Annual Cost: $33,000. This is based on an estimate that half the respondents (22) will fly a representative (or representatives) the equivalent of a coast-to-coast round trip to Washington, DC and will have lodging for one night. The average cost of a single round trip fare and one night lodging is estimated to be $1500.

Nature and Extent of Confidentiality: The Commission will work with respondents to ensure that their concerns regarding the confidentiality of any proprietary or business-sensitive information are resolved in a manner consistent with the Commission's rules.

Privacy Act Impact Assessment: This information collection does not affect individuals or households, and therefore a privacy impact assessment is not required.

Needs and Uses: The information collection sought will enable the Commission to fulfill its obligation under the Implementing Recommendations of the 9/11 Commission Act of 2007 (Act), Public Law 110–53. The purpose of the Act is to ''provide for the implementation of the recommendations of the National Commission on Terrorist Attacks Upon the United States.'' Towards this end, the Act mandates that the Commission ''shall conduct a vulnerability assessment of the Nation's critical communications and information systems infrastructure and shall evaluate the technical feasibility of creating a back-up emergency communications system that complements existing communications resources and takes into account next generation and advanced communications technologies.'' The Commission must submit a report to Congress that details the findings of this evaluation not later than 180 days after the date of enactment of the Act (since the Act was enacted on August 3, 2007, the report will be due to Congress on January 30, 2008).

To complete this report, the Commission seeks to collect information primarily through face-to-face meetings, phone calls (including conference calls), and e-mail correspondence with commercial service and network operators (*i.e.*, private satellite, wireline, and wireless operators, circuit and packet network operators), users (or owners) of emergency communication systems and networks, (*e.g.*, emergency responders including first responders, 9–1–1 system and dispatch operators, federal, state and local emergency agencies), and their associations, manufacturers of public safety equipment and emergency communications networks and systems, operators of networks for emergency responders, and standards organizations and industry groups working on public safety equipment and emergency communications networks and systems and standards. Information will be sought concerning emergency communications networks, including user devices, network equipment, operations processes and operations systems, and concerning the feasibility of commercial service providers to support the needs of public safety, including: (1) Technical capabilities and characteristics of equipment (*e.g.*, analog/digital, power, range, access protocol, broadband/wideband/narrowband, etc.), (2) technical capabilities and characteristics of commercial services to support the needs of public safety, (3) cost and deployment of commercial services for

use by public safety, (4) cost of user devices and network equipment of emergency communications networks (*e.g.*, unit cost, maintenance/upgrade cost, etc.), and the cost of operations and operations systems (including feature upgrades) for emergency communications networks and services, (5) deployment of user devices, network equipment, and operations processes and equipment of emergency communications systems (*e.g.*, type of systems deployed or to be deployed), number of units deployed/sold, etc.), (6) standardization of user devices, network equipment, and operations interfaces of emergency communications systems (*e.g.*, standard/proprietary, standard activities, etc.), (7) interoperability (*i.e.*, the ability of communications among different systems, devices and groups) of user groups, user devices, network equipment, and operations processes and equipment of emergency communications systems (*e.g.*, interoperability among first responders within a jurisdiction, among jurisdictions using the same and different network technologies), (8) spectrum usage of user devices and network equipment of emergency communications systems (*e.g.*, frequencies of operation, shared/dedicated spectrum, etc.), (9) applications and application requirements for end users and the technical requirements for such applications including bandwidth needs, (10) operations systems features and operations processes supporting emergency network operation during an emergency, (11) service capabilities (*e.g.*, voice, data, video, mobile to mobile communications, etc.), (12) evolutionary trend of user devices, network equipment, and operations of emergency communications systems (*e.g.*, next generation, migration path, etc.), (13) backhaul connectivity of network equipment and facilities (*e.g.*, commercial/private, wired/wireless, capacity, etc.), (14) description of network technology and architecture (*e.g.*, whether the network design accommodates access to emergency responders from other jurisdictions, capability of architecture to support resiliency in disaster situations, etc.), (15) operations budget for the network, (16) responsibilities of the organizations operating the networks, including service provisioning, traffic management and network maintenance, especially during an emergency, (17) plans, if any, for restoring emergency communication services or reverting to backup networks in the event that a primary emergency communications network is damaged or destroyed, (18) ability of existing emergency communications networks to back up or complement the communication resources of other emergency communications networks, (19) ability to rapidly increase emergency communication network capacity in the event that the capacity limits of the network are exceeded in a major disaster, (20) a description of the role of ''core services'' such as authentication and agency locator services, whether and how they are implemented in existing and planned networks, and their costs, (21) a description of the processes and systems used or planned to connect emergency responders to a back-up network in an emergency, and (22) plans to restore emergency communications services if the network over which they are provided is damaged, destroyed, or sufficiently congested to be impaired or unusable (*e.g.*, changes in operations staffing in emergency conditions, dynamic bandwidth allocation to users or networks, back-up communications for other emergency communications services or networks), other administrative or planning issues associated with the deployment and maintenance of such backup national emergency communications capabilities.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. E7–17507 Filed 9–4–07; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 28, 2007.

1. Federal Reserve Bank of Atlanta (David Tatum, Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30309:

1. Community First, Inc., Columbia, Tennessee; to acquire 100 percent of the voting shares of First National Bank of Centerville, Centerville, Tennessee.

Board of Governors of the Federal Reserve System, August 30, 2007.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E7–17489 Filed 9–4–07; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act; Notice of Meeting

TIME AND DATE: 9 a.m. (Eastern Time), September 17, 2007.

PLACE: 4th Floor Conference Room, 1250 H Street, NW., Washington, DC 20005.

STATUS: Parts will be open to the public and parts closed to the public.

Matters To Be Considered

Parts Open to the Public

1. Approval of the minutes of the August 20, 2007 Board member meeting.
2. Thrift Savings Plan activity report by the Executive Director.
   a. Monthly Participant Activity Report.
   b. Monthly Investment Performance Report.
   c. Legislative Report.
3. Increasing Decimal Places in Fund Prices.
4. Business Assurance and IT Infrastructure.
5. Annual Budget Report.

a. Fiscal Year 2007 Results.
b. Fiscal Year 2008 Budget.
c. Fiscal Year 2009 Estimate.

Parts Closed to the Public

6. Personnel.

CONTACT PERSON FOR MORE INFORMATION: Thomas J. Trabucco, Director, Office of External Affairs, (202) 942–1640.

Dated: August 31, 2007.

Thomas K. Emswiler,

Secretary to the Board, Federal Retirement Thrift Investment Board.

[FR Doc. 07–4350 Filed 8–31–07; 11:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information and Comments on Research That Involves Adult Individuals With Impaired Decision-making Capacity

AGENCY: Office for Human Research Protections, Office of Public Health and Science, Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science is seeking information and comments about whether guidance or additional regulations are needed to adequately protect adult individuals with impaired decision-making capacity who are potential subjects in research. This request for information and comments stems from the recommendation of an HHS working group, generated in response to the report published by the National Bioethics Advisory Commission (NBAC) entitled ''Research Involving Persons With Mental Disorders That May Affect Decision-making Capacity'' (December 1998), and from subsequent recommendations by the National Human Research Protections Advisory Committee (NHRPAC).[a]

In addition, as part of its charge to provide expert advice and recommendations to the Secretary of Health and Human Services (the Secretary) and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human subjects, the Secretary's Advisory Committee on Human Research Protections (SACHRP) has formed a Subcommittee on Inclusion of Individuals with Impaired Decision-Making in Research. This SACHRP subcommittee is currently considering whether guidance or additional regulations are needed for research involving individuals with impaired decision-making capacity. The information and comments submitted in response to this notice will be shared with SACHRP to inform the Committee's recommendations to the Secretary and Assistant Secretary for Health.

DATES: Submit written or electronic information and comments by December 4, 2007.

ADDRESSES: Submit written comments to REQUEST FOR INFORMATION ON RESEARCH THAT INVOLVES ADULT INDIVIDUALS WITH IMPAIRED DECISION-MAKING CAPACITY, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to *impairedcapacityohrp@hhs.gov,* or via facsimile at 301–402–2071. Comments received within the comment period, including any personal information provided, will be made available to the public upon request.

FOR FURTHER INFORMATION CONTACT: Julie Kaneshiro, Office for Human Research Protections, Department of Health and Human Services, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; 240–453–6900; e-mail *julie.kaneshiro@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Health and Human Services (HHS) regulates research involving human subjects conducted or supported by HHS through regulations codified at 45 CFR part 46 which are administered by OHRP. The HHS regulations stipulate that in order to approve research covered by the regulations, an institutional review board (IRB) shall determine that when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. 45 CFR 46.111(b). Apart from this broad requirement regarding vulnerable populations, the HHS regulations do not contain specific additional standards for the participation of adults with impaired decision-making capacity in research, nor do they define who should be considered as part of this population. In response to the recommendations by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) that pertained to research involving individuals who are institutionalized as mentally infirm, in 1978, the Department of Health, Education, and Welfare (now HHS), issued proposed regulations on research involving those institutionalized as mentally disabled. However, these proposed regulations were never finalized or adopted due to a lack of consensus on the proposed regulatory provisions, and a judgment that the general HHS regulations governing human subjects' participation in research were sufficient to address the National Commission's recommendations.

The impetus for this request for information and comments stems from a number of different sources. HHS is aware that some research currently conducted or supported by HHS involves adults with impaired decision-making capacity. HHS believes that research involving adults with impaired decision-making capacity is important and necessary in order to improve the health and well-being of such individuals. HHS and others have long recognized the potential vulnerability of these subjects, and that research involving this population needs to be conducted with adequate safeguards. At this time HHS believes it is appropriate to solicit the views of the public on whether the current human subject protection regulations are adequate in safeguarding these individuals. This request for information and comments also stems from recommendations of an HHS working group (HHS WG), generated in response to the report published by the former NBAC entitled ''Research Involving Persons with Mental Disorders That May Affect Decision-making Capacity'' (December 1998), and from subsequent recommendations by the former NHRPAC.

A. NBAC Report

In its December 1998 report, the full text of which can be found on the Internet at *http://bioethics.georgetown.edu/nbac,* NBAC defined decisional impairment as a limitation or incapacity that is not part of normal growth and development. NBAC's report contained recommendations for helping to ensure adequate protections for people with decisional impairment who participate in research, but referred only to research involving persons with mental disorders

[a] The National Human Research Protections Advisory Committee has been disbanded and replaced by the Secretary's Advisory Committee on Human Research Protections.

that may affect decision-making capacity.

NBAC's recommendations called for a new regulatory framework requiring IRBs to classify into one of three categories all proposed research that involves people with impaired decision-making capacity due to mental disorders, based on the level of risk and potential for direct medical benefit to the research subject. NBAC identified three categories of research that pose: (1) Minimal risk to subjects; (2) greater than minimal risk to subjects and having the prospect of direct medical benefit; and (3) greater than minimal risk to subjects but having no prospect of direct medical benefit. NBAC recommended that the legally authorized representative of a subject with impaired decision-making capacity be able to give permission for the subject's participation in research protocols that fall into either of the first two categories. However, NBAC recommended that research in the third category could not proceed unless one of two conditions occurred: Either (1) the research subject would have had to give Prospective Authorization for the particular class of research when competent, or (2) a Special Standing Panel (SSP), convened by the Secretary of HHS, would need to review the research and find it approvable or have issued guidelines about the class of research indicating that it was approvable. In NBAC's recommendations, Prospective Authorization would provide individuals, when competent, with an opportunity to express their preferences (if they have them) regarding future research participation, within certain limits. NBAC recommended that a Prospective Authorization should specify the ''particular class of research,'' and the degree of specificity in the Prospective Authorization should be correlated with the level of risk posed by the research. For example, a person with a diagnosis of early stage Alzheimer's Disease who is still competent to make decisions could express his or her preference to participate in greater than minimal risk clinical trials testing interventions for moderate or severe Alzheimer's Disease in the future, when he or she may not be competent to make decisions.

B. HHS Working Group

The Office of Science Policy, Office of the Assistant Secretary for Planning and Evaluation, convened an HHS WG to analyze NBAC's recommendations and to develop a proposed HHS response to the NBAC report. The HHS WG's report can be found on the Internet at *http://aspe.hhs.gov/sp/human.shtml.* The HHS WG considered, among other things, NBAC's recommended framework described above. The HHS WG was concerned that this framework was not practical because it would lead to the use of either a Prospective Authorization or a SSP for a large number of research protocols involving subjects with impaired decision-making capacity. The HHS WG concluded that the widespread use of Prospective Authorizations is unlikely. Thus, unless the research involved the prospect of direct medical benefit to the participants, an SSP would need to review all research involving greater than minimal risk.

The HHS WG compared NBAC's proposed regulatory framework to the HHS regulations governing the participation of children in research (45 CFR part 46 subpart D [hereafter referred to as ''subpart D regulations'']). The subpart D regulations allow an IRB to consider a broad range of different types of direct benefits to the subject, not just direct medical benefits, when weighing the risks posed by research involving greater than minimal risk that presents the prospect of direct benefit to the individual child. NBAC, on the other hand, recommended that benefits be limited to direct medical benefits only for research involving subjects with impaired decision-making capacity. The subpart D regulations also create an intermediate risk category, not included in NBAC's framework, called a ''minor increase over minimal risk.'' The HHS WG noted that an alternative regulatory framework modeled on subpart D could provide appropriate protection and also decrease the number of studies needing SSP review and thus may increase the feasibility of such reviews.

The HHS WG decided that NBAC's recommended framework would limit an IRB's authority to approve research involving an adult with impaired decision-making capacity more than it would an IRB's authority to approve a child's participation in the same type of research. The HHS WG further noted that NBAC's framework would alter IRB authority in ways that could produce different results. For example, the subpart D regulations permit a child's parent or guardian to enroll the child in research that has no prospect of direct benefit and that poses a minor increase over minimal risk if an IRB determines the research, among other things, is ''likely to yield generalizable knowledge * * * of vital importance'' about the child's disorder or condition (45 CFR 46.406). However, under NBAC's recommendations, the legally authorized representative of an adult with impaired decision-making capacity could not enroll the adult in the same type of research, unless the adult had signed a Prospective Authorization or the SSP approved or issued guidelines about the research. The HHS WG recognized that safeguards for children and adults with impaired decision-making capacity need not necessarily be identical, but noted that two different standards might be confusing to investigators and IRBs.

In addition, in its 1998 report, NBAC considered how ethically acceptable research could be conducted with human subjects who suffer from mental disorders that may affect their decision-making capacity. The HHS WG interpreted the intended scope of NBAC's recommendations as applying to research involving ''persons with mental disorders that may affect decision making capacity,'' but determined that the scope of NBAC's recommendations seem appropriately applicable to research involving adults with decisional impairment, irrespective of the cause. The HHS WG noted that some physical disorders or conditions (e.g., cancer, sepsis, head injury) also might result in impaired capacity to make decisions, and therefore, an inability to give voluntary informed consent to participate in research. In addition, the HHS WG was concerned that limiting the scope of protections to research subjects whose decision-making capacity is impaired because of a mental disorder may be perceived to be stigmatizing to such individuals. Thus, the HHS WG concluded that adults with an impaired capacity to make a decision as a result of any disease or condition should receive the same protections as those individuals with an impaired decision-making capacity from a mental disorder.

The HHS WG proposed that OHRP request public comment on the issues raised by the NBAC framework and the HHS WG's analysis of those issues. This request for information and comments is designed to accomplish that goal.

C. NHRPAC Report

In response to NBAC's recommendations and the HHS WG's report, at OHRP's request, NHRPAC drafted a report entitled ''Informed Consent and the Decisionally Impaired.'' NHRPAC was an advisory committee to the Secretary of HHS, the Assistant Secretary for Health, the Director of OHRP, and other Departmental officials on a broad range of issues and topics pertaining to or associated with the protection of human research subjects. NHRPAC's draft report is available on the Internet at

http://www.hhs.gov/ohrp/nhrpac/documents/nhrpac10.pdf. NHRPAC's report applies to ''all potential subjects in biomedical and social/behavioral research who lack decisional capacity for any reason and is not limited to persons with mental disorders.'' In its report, NHRPAC recommended specific protections at different levels of risk and potential benefit for research with the decisionally impaired population. These risk-benefit categories included:

(1) Research that involves no more than minimal risk,

(2) Research that involves greater than minimal risk but presents the prospect of direct benefit to the subjects,

(3) Research that involves a minor increase over minimal risk that does not present the prospect of direct benefit but is likely to yield generalizable knowledge about the subject's condition or disorder, and

(4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of persons with impaired decision-making capacity, provided the Secretary of HHS makes specified determinations after consulting with a panel of experts and providing the opportunity for public review and comment.

These risk categories are similar to those contained in the subpart D regulations governing research with children.

D. SACHRP Activities

In October 2002, SACHRP was created by the Secretary to replace NHRPAC. SACHRP is charged to advise, consult with, and make recommendations to the Secretary and Assistant Secretary for Health on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. In carrying out its charge, SACHRP formed a Subcommittee on Inclusion of Individuals with Impaired Decision-Making Capacity in Research. Specifically, this SACHRP subcommittee will develop recommendations for consideration by SACHRP about whether guidance or additional regulations are needed for research involving individuals with impaired decision-making capacity. In making its assessment, the Subcommittee will review the relevant provisions of subpart A, 45 CFR part 46, including the provisions at 45 CFR 46.111(b), and will seek additional information to formulate its decision as it deems necessary.

The information and comments submitted in response to this notice will be shared with SACHRP to inform the Committee's recommendations to the Secretary and Assistant Secretary for Health.

The reports of the National Commission, NBAC, and NHRPAC specifically address and endorse the inclusion of decisionally incapacitated subjects in clinical research with the provision of adequate protections for these subjects. Based on these recommendations and reports over the years, and SACHRP's current work on this issue, OHRP is seeking comment on whether it is necessary to develop additional safeguards to protect adult individuals with impaired decision-making capacity because these individuals may have diminished or no capacity to provide informed consent to their participation in research. The next section contains the specific questions of interest to HHS.

II. Request for Information and Comments

OHRP is seeking information and comments from the public about whether guidance or additional regulations are needed to adequately protect adult individuals with impaired decision-making capacity who are potential subjects in research. The scope of this request for information and comments is limited to research involving adult subjects because additional protections for children involved as subjects in research already exists under the subpart D regulations. In addition, this notice is not directed toward consideration of emergency research involving the decisionally impaired that would be covered under the HHS's Secretarial waiver under 45 CFR 46.101(i) on the exception from informed consent requirements for emergency research (published in the **Federal Register** in 1996 at 61 FR 51531). OHRP believes that this existing provision already addresses the conduct of emergency research without informed consent that involves individuals with impaired decision-making capacity.

OHRP specifically seeks information and comments on the following issues. Comments should also include a reference to the specific numbered question being addressed:

1. What are investigators' and IRBs' current practices in regard to the conduct, review, and approval of research involving decisionally impaired adult individuals?

1a. Have investigators' or IRBs' practices changed as a result of NBAC's or NHRPAC's recommendations? If not, why not?

1b. If an IRB regularly reviews research proposals involving adult individuals with impaired decision-making capacity, do such IRBs include one or more members or consultants who are familiar with conditions that may affect decision-making capacity and with the concerns of the population being studied?

1c. Are investigators proposing research targeting adult individuals with impaired decision-making capacity as subjects providing IRBs with a thorough justification for their proposed research design, including a description of the procedures that are designed to minimize risks to subjects?

1d. If research protocols targeting adult individuals with impaired decision-making capacity as subjects are being approved by IRBs when the research could be done with other subjects, what are the reasons for IRBs approving such studies?

1e. Are investigators proposing research targeting adult individuals with impaired decision-making capacity as subjects providing IRBs with a thorough evaluation of the risks and potential benefits to the subjects involved in the proposed research study?

1f. For research involving adult individuals with impaired decision-making capacity as subjects, how are subjects' potential or actual objections to enrollment or continued participation in research being addressed by investigators and IRBs?

1g. Are IRBs requiring investigators to have an assessment of a potential subject's capacity to consent, and if so, under what circumstances? If IRBs are requiring capacity assessments for some research, is the degree of risk presented by the research pertinent to the IRB's decision to require such assessments? What concerns have arisen in regard to capacity assessments?

1h. For studies that have included an assessment of potential subjects' capacity to consent, how has this assessment been used in the informed consent process? Are subjects notified when they have been found to lack capacity to consent? When informed consent is sought from such a subject's legally authorized representative, are potential subjects provided an opportunity to assent or object to their participation in the research?

1i. For research involving subjects who are able to provide informed consent, but are expected to have fluctuating, limited, or diminishing decision-making capacity during the course of the research study, what processes or procedures have investigators implemented, or have IRBs

required, in order to ensure that the rights and welfare of such subjects remains adequately protected?

2. What problems or concerns have arisen for investigators, IRBs, or research subjects in the conduct or review of research involving decisionally impaired individuals as subjects?

2a. To what extent, if any, has the absence of OHRP guidance or additional regulatory requirements given rise to unacceptable practices by IRBs or investigators reviewing or conducting research targeting adult individuals with impaired decision-making capacity as subjects, or created inappropriate barriers to the conduct of research involving individuals with impaired decision-making capacity as subjects?

2b. Please describe the process used when a legally authorized representative is asked to consent on behalf of a prospective research subject for research involving adult individuals with impaired decision-making capacity as subjects. Do the legally authorized representatives use substituted judgment (decisions that reflect the views of the individual expressed while decisionally capable) or the best interest standard? Which seems more ethically justified?

2c. How are advance directives for health care and for research used when a legally authorized representative is available?

2d. Have any problems or concerns arisen in regard to seeking consent from a legally authorized representative on behalf of a prospective research subject for research involving adult individuals with impaired decision-making capacity as subjects? If so, please describe the issues that have arisen.

3. The current requirement for IRB approval under the HHS regulations at 45 CFR 46.111(b), states:

> When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Please describe the additional safeguards you have included in studies to protect the rights and welfare of subjects with impaired decision-making capacity.

3a. Does the regulatory provision cited above provide sufficient protections for adult subjects with impaired decision-making capacity or are additional regulatory safeguards needed? If additional safeguards are needed, what should these additional protections be? Below please find a compendium of possible additional protections for subjects with impaired decision-making capacity. Please feel free to comment on any or all of them, and to suggest others. In your comments, please indicate if your comments are directed towards the issuance of either guidance or additional regulations:

- Consent auditor/independent consent monitor.
- Sliding scale of capacity, (i.e., protections should be proportional to the severity of capacity impairment, or to the magnitude of experimental risk, or both).
- Description of specific tasks to assess capacity (these may be study-specific).
- Independent assessment of decision-making capacity.
- Enhancement of IRB expertise such that the IRB includes members or consultants familiar with conditions that may affect decision-making capacity and with the concerns of the population being studied.
- Obtaining consent from legally authorized representative.
- Obtaining assent from subjects with impaired decision-making capacity (may be limited to objecting to inclusion in the research study). This would be in addition to consent from the legally authorized representative.
- Use of advance directive for research where permitted by state/local law.
- Use of appropriate waiting periods (after research presented to the subject) before obtaining assent or consent as possible.
- Consent enhancements: Interventions to increase the subject's decision-making capacity.
- Other suggestions.

3b. If the regulations at 45 CFR part 46 are sufficient, should OHRP issue additional guidance on how the regulations should be applied to protect adult subjects with impaired decision-making capacity?

3c. If additional regulations are needed would a risk-based model, such as a model based on the subpart D regulations be appropriate? If not, what type of regulatory model would be appropriate?

3d. If additional regulations are needed, would it be appropriate to develop additional regulations that would only apply to a subset of the population of adult subjects with impaired decision-making capacity? For example, would it be appropriate to develop additional regulations that would apply only to adult individuals who have no capacity to provide legally effective informed consent (e.g. comatose individuals or individuals in a persistent vegetative state)?

4. How should the population of adults with impaired decision-making be defined for the purposes of guidance or regulation? Note that the subpart D regulations contain a definition of the term ''children,'' who are defined as '' * * * persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.'' See 45 CFR 46.402(a). Does the definition of the term ''children'' in the subpart D regulations provide a helpful model for developing a definition of ''adults with impaired decision-making capacity,'' or would a definition modeled on the definition of ''children'' inappropriately exclude adult individuals who are at risk of decisional impairment, and those who suffer from some form of persistent, fluctuating, or progressive decisional impairment, but who nevertheless retain the capacity to give legally effective informed consent under the applicable law of the jurisdiction in which the research will be conducted? If a comparable definition of adults with impaired decision-making capacity was to be developed, such a definition could read: ''Adults with impaired decision-making capacity are persons who do not have the capacity to give legally effective informed consent to treatments or procedures involved in research/clinical investigation, under the applicable law of the jurisdiction in which the research/clinical investigation will be conducted.''

5. In some circumstances, certain adult subjects may develop impaired decision-making capacity (e.g. persistent, fluctuating, or progressive decisional impairment) after consenting and enrolling in research. In such cases, is guidance needed, or are additional regulations necessary, in order to adequately protect adult subjects who become decisionally impaired during their participation in research? For example, should guidance or additional regulations address when it would be appropriate for investigators to seek the consent of the subject's legally authorized representative to enable the subject's continued participation?

6. If guidance or additional regulations are needed to adequately protect the rights and welfare of subjects with impaired decision-making capacity, should such guidance or regulations address the issue of assent? Note that the subpart D regulations generally require that IRBs determine that adequate provisions are made for soliciting the assent of children when in

the judgment of the IRB the children are capable of providing assent. (See 45 CFR 46.408.)

6a. If an adult with impaired decision-making capacity is capable of providing assent to participation in research, should the guidance or regulation indicate that the adult subject's assent should always be a condition for proceeding with the research? If there are circumstances when an adult subject's assent should not be necessary, what are those circumstances?

Melody Lin,

Deputy Director, Office for Human Research Protections.

[FR Doc. E7–17490 Filed 9–4–07; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): National HIV Behavioral Surveillance System, Funding Opportunity Announcement (FOA) Number PS 08–001

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:

8:30 a.m.–5 p.m., October 22, 2007 (Closed).

8 a.m.–2 p.m., October 23, 2007 (Closed).

Place: Sheraton Gateway Atlanta Airport Hotel, 1900 Sullivan Road, Atlanta, Georgia 30337, Telephone (770) 997–1100.

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 ''National HIV Behavioral Surveillance System,'' FOA Number PS 07–001.

Contact Person for More Information: Shoukat Qari, D.V.M., Ph.D., Scientific Review Administrator, Strategic Science and Program Unit, Office of the Director, Coordinating Center for Infectious Diseases, CDC, 1600 Clifton Road, NE., MS E05, Atlanta, GA 30333, Telephone (404) 639–6101.

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: August 29, 2007.

Diane C. Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–17519 Filed 9–4–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Environmental Health/Agency for Toxic Substances and Disease Registry; the Program Peer Review Subcommittee (PPRS) of the Board of Scientific Counselors (BSC), Centers for Disease Control and Prevention (CDC), National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR): Teleconference

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC, NCEH/ATSDR announces the aforementioned subcommittee meeting:

Time and Date: 3 p.m.–5 p.m., September 24, 2007.

Place: The teleconference will originate at NCEH/ATSDR in Atlanta, Georgia. To participate, dial (877)315–6535 and enter conference code 383520.

Purpose: Under the charge of the BSC, NCEH/ATSDR, the PPRS will provide the BSC, NCEH/ATSDR with advice and recommendations on NCEH/ATSDR program peer review. They will serve the function of organizing, facilitating, and providing a long-term perspective to the conduct of NCEH/ATSDR program peer review.

Matters To Be Discussed: A discussion of Preparedness and Emergency Response Peer Review, and review and approve previous meeting minutes.

Agenda items are subject to change as priorities dictate.

Supplementary Information: This meeting is scheduled to begin at 3 p.m. Eastern Time. To participate, please dial (877)315–6535 and enter conference code 383520. Public comment period is scheduled for 4–4:15 p.m.

Contact Person for More Information: Sandra Malcom, Committee Management Specialist, Office of Science, NCEH/ATSDR, M/S E–28, 1600 Clifton Road, NE., Atlanta, Georgia 30333, Telephone (404)498–0622.

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 NCEH/ATSDR.

Dated: August 29, 2007.

Diane C. Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–17522 Filed 9–4–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request; Proposed Projects

Title: Child Care and Development Fund Tribal Annual Report (ACF–700 Report).

OMB No.: 0980–0241.

Description: The Child Care and Development Fund (CCDF) report requests annual Tribal aggregate information on services provided through the CCDF, which is required by the CCDF Final Rule (45 CFR parts 98 and 99). Tribal Lead Agencies (TLAs) are required to submit annual aggregate data appropriate to Tribal programs on children and families receiving CCDF-funded child care services.

The CCDF statute and regulations also require TLAs to submit a supplemental narrative as part of the ACF–700 report. This narrative describes general child care activities and actions in the TLA's service area and is not restricted to CCDF-funded child care activities. Instead, this description is intended to address all child care available in the TLA's service area. The ACF–700 and supplemental narrative report will be included in the Secretary's report to Congress, as appropriate, and will be shared with all TLA's to inform them of CCDF-funded activities in other Tribal programs.

Respondents: Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–700 Report	260	1	38	9,880

Estimated Total Annual Burden Hours: 9,880.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 28, 2007.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. 07–4310 Filed 9–4–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Title V section 510 Abstinence Education Grant Program—Annual Program Application and Annual Performance Progress Report.

OMB No.: 0970–0271.

Description: The Title V section 510 Abstinence Education Grant Program (section 510 program) is a formula block grant program, authorized through September 30, 2007, by S. 1701, a bill to provide for the extension of transitional medical assistance (TMA) and the abstinence education program through the end of fiscal year 2007, and for other purposes.

The section 510 *Annual Program Application* requires basic application information that will be used by the Administration for Children and Families (ACF) to establish applicant eligibility, determine each applicant's compliance with Federal law, review and evaluate each applicant's proposed plans, and to develop any conditions to be placed on grant awards. Projects must meet the legislative priorities as described in section 510 of Title V of the Social Security Act.

The section 510 *Annual Performance Progress Report* includes four forms through which grantees report basic performance information, which is used by ACF to determine each grantee's compliance with Federal law and to review and evaluate each applicant's progress toward achieving its goals. Basic performance information includes the unduplicated count of clients served, hours of service received by clients, program completion data, and communities served.

Respondents: The 50 States, the District of Columbia, and the following 8 Territories: American Samoa, Guam, Republic of the Marshall Islands, Federated States of Micronesia, Commonwealth of the Northern Mariana Islands, Republic of Palau, Commonwealth of Puerto Rico, and the U.S. Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Response per respondent	Average burden hours per response	Total burden hours
Annual Program Application	59	1	36	2,124
Annual Performance Progress Report	59	1	122	7,198

Estimated Total Annual Burden Hours: 9,322.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974. Attn: Desk Officer for the Administration for Children and Families.

Dated: August 29, 2007.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. 07–4311 Filed 9–4–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first

published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://www.workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov*.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Mandatory Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016 (Formerly: Bayshore Clinical Laboratory).

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264.

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770/888–290–1150.

Aegis Sciences Corporation, 345 Hill Ave., Nashville, TN 37210, 615–255–2400 (Formerly: Aegis Analytical Laboratories, Inc.).

Baptist Medical Center-Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917.

Diagnostic Services, Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913, 239–561–8200/800–735–5416.

Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602, 229–671–2281.

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215–674–9310.

Dynacare Kasper Medical Laboratories,* 10150–102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780–451–3702 / 800–661–9876.

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609.

Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630.

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504–361–8989 / 800–433–3823 (Formerly: Laboratory Specialists, Inc.).

Kroll Laboratory Specialists, Inc., 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130 (Formerly: Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.).

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288 / 800–800–2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400 / 800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900 / 800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

Laboratory Corporation of America Holdings, 13112 Evening Creek Drive, Suite 100, San Diego, CA 92128, 858–668–3710 / 800–882–7272 (Formerly: Poisonlab, Inc.).

Laboratory Corporation of America Holdings, 550 17th Ave., Suite 300, Seattle, WA 98122, 206–923–7020 / 800–898–0180 (Formerly: DrugProof, Division of Dynacare/Laboratory of Pathology, LLC; Laboratory of Pathology of Seattle, Inc.; DrugProof, Division of Laboratory of Pathology of Seattle, Inc.).

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042 / 800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927 / 800–873–8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.).

Marshfield Laboratories, Forensic Toxicology Laboratory, 1000 North Oak Ave., Marshfield, WI 54449, 715–389–3734 / 800–331–3734.

MAXXAM Analytics Inc.*, 6740 Campobello Road, Mississauga, ON, Canada L5N 2L8, 905–817–5700 (Formerly: NOVAMANN (Ontario), Inc.).

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466 / 800–832–3244.

Meriter Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6225, (Formerly: General Medical Laboratories).

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295 / 800–950–5295.

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088.

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250 / 800–350–3515.

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory).

Oregon Medical Laboratories, 123 International Way, Springfield, OR 97477, 541–341–8092.
Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory).
Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991 / 800–541–7891x7.
Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858–643–5555.
Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913–339–0372 / 800–821–3627.
Quest Diagnostics Incorporated, 3175 Presidential Dr., Atlanta, GA 30340, 770–452–1590 / 800–729–6432 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).
Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600 / 877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories).
Quest Diagnostics Incorporated, 7600 Tyrone Ave., Van Nuys, CA 91405, 866–370–6699/818–989–2521 (Formerly: SmithKline Beecham Clinical Laboratories).
S.E.D. Medical Laboratories, 5601 Office Blvd., Albuquerque, NM 87109, 505–727–6300/800–999–5227.
South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 574–234–4176 x276.
Southwest Laboratories, 4645 E. Cotton Center Boulevard, Suite 177, Phoenix, AZ 85040, 602–438–8507/800–279–0027.
Sparrow Health System, Toxicology Testing Center, St. Lawrence Campus, 1210 W. Saginaw, Lansing, MI 48915, 517–364–7400 (Formerly: St. Lawrence Hospital & Healthcare System).
St. Anthony Hospital Toxicology Laboratory, 1000 N. Lee St., Oklahoma City, OK 73101, 405–272–7052.
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, Suite 208, Columbia, MO 65203, 573–882–1273.
Toxicology Testing Service, Inc., 5426 NW. 79th Ave., Miami, FL 33166, 305–593–2260.
U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085.

*The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 13, 2004 (69 FR 19644). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Elaine Parry,

Acting Director, Office of Program Services, SAMHSA.

[FR Doc. E7–17511 Filed 9–4–07; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5121–N–27]

Notice of Proposed Information Collection: Comment Request; Continuation of Interest Reduction Payments After Refinancing Section 236 Projects

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* November 5, 2007.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Lillian Dietzer, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8001, Washington, DC 20410 or *Lillian_L_Dietzer@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Kimberly R. Munson, Housing Program Manager, Office of Asset Management, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone (202) 708–1320 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Continuation of Interest Reduction Payments after Refinancing Section 236 Projects.

OMB Control Number, if applicable: 2502–NEW.

Description of the need for the information and proposed use: The purpose of this information collection is to preserve low-income housing units. HUD uses the information to ensure that owners and mortgagees/public entities enter into binding agreements for continuation of Interest Reduction Payments (IRP) after refinancing certain Section 236 projects.

Agency form numbers, if applicable: None.

Estimation of the total numbers of hours needed to prepare the information collection including number of

respondents, frequency of response, and hours of response: The number of burden hours is estimated to be 1,343. The number of respondents is 2,267, the frequency of response is based on the owner's request to refinance (averaged to date at 125 per year), the number of responses is 125, and the burden hour per response is 10.75.

Status of the proposed information collection: This is a new collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: August 29, 2007.

Frank L. Davis,

General Deputy Assistant Secretary for Housing-Deputy Federal Housing Commissioner.

[FR Doc. E7–17487 Filed 9–4–07; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5121–N–29]

Notice of Proposed Information Collection: Comment Request; Housing Counseling Program—Biennial Agency Performance Review

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* November 5, 2007.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Lillian L. Deitzer, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8003, Washington, DC 20410 or *Lillian_L._deitzer@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Margaret Burns, Director, Office of Single Family Program Development, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410, telephone (202) 708–2121 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Housing Counseling Program—Biennial Agency Performance Review.

OMB Control Number, if applicable: 2502–NEW.

The information collection is essential to the Department's mission to expand homeownership opportunities and improve access to affordable housing. The Housing Counseling Program supports the delivery of a wide variety of housing counseling services to homebuyers, homeowners, low- to moderate-income renters, and the homeless. Counselors provide guidance and advice to help families and individuals improve their housing conditions and meet the responsibilities of tenancy and homeownership. Counselors also help borrowers avoid predatory lending practices, such as inflated appraisals, unreasonably high interest rates, unaffordable repayment terms, and other conditions that can result in a loss of equity, increased debt, default, and foreclosure. Housing Counseling Agencies are viewed as significant partners in helping HUD expand opportunities for individuals to receive adequate, professional housing counseling services.

In order to maintain their status as a HUD-approved agency, housing counseling agencies must remain in compliance with program policies and regulations. HUD determines during the course of perform reviews if an agency has remained in compliance with the program regulations. Findings from performance reviews are used to approve or disapprove the status of housing counseling agencies to participate in the program. The form HUD–9910, is the performance review checklist used by HUD employees to the biennial reviews. The information collected during the review is used to assist HUD in evaluating the managerial and financial capacity of organizations to sustain operations sufficient to implement HUD approved housing counseling programs. If agencies are found to be non-compliant HUD may revoke an agency's approval status and prohibit their participation in the Housing Counseling Program.

Agency form numbers, if applicable: HUD–9910.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The number of respondents are estimated to be 583 generating approximately 583 annual responses; the frequency of response is biennially, the estimated time needed to respond is 2.5 hours; and the total estimated annual burden hours are 1,457.

Status of the proposed information collection: This is a new information collection request. Portions of this request were formerly approved under OMB Control Number 2502–0261.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: August 24, 2007.

Frank L. Davis,

General Deputy Assistant Secretary for Housing-Deputy Federal Housing Commissioner.

[FR Doc. E7–17488 Filed 9–4–07; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: The public is invited to comment on the following applications to conduct certain activities with endangered species.

DATES: Written data, comments or requests must be received by October 5, 2007.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents

within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION:

Endangered Species

The public is invited to comment on the following applications for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*). Written data, comments, or requests for copies of these complete applications should be submitted to the Director (address above).

Applicant: Peregrine Fund, Boise, ID, PRT–819573.

The applicant requests renewal and amendment of a permit to import live harpy eagles (*Harpia harpyja*) and samples from worldwide locations and to export/re-export live birds and samples as part of an ongoing conservation project which enhances the survival of the species/scientific research. This notification covers activities to be conducted by the applicant over a five-year period.

Applicant: Gail W. Hearn, Arcadia University/Drexel University, Philadelphia, PA, PRT–161812.

The applicant requests a permit to import biological samples from Bioko drill monkey (*Mandrillus leucophaeus poensis*), Black colobus monkey (*Colobus satanas satanas*), and Bioko red-eared monkey (*Cercopithecus erythrotis erythrotis*) for the purpose of enhancement of the species through scientific research. This notification covers activities conducted by the applicant for a five-year period.

Applicant: Hayden H. Thompson, Denver, CO, PRT–161012.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Leonard G. Sunram, Detroit Lakes, MN, PRT–161194.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Dated: August 10, 2007.

Michael L. Carpenter,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. E7–17504 Filed 9–4–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice: Receipt of Application for an Incidental Take Permit; Request for Comments

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The City of Adrian (Applicant) has applied to the U.S. Fish and Wildlife Service (Service) for an incidental take permit (ITP) pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (Act). The proposed duration of the permit is 30 years. The Applicant has prepared a Habitat Conservation Plan (HCP) to address potential impacts to the federally endangered Topeka shiner (*Notropis topeka*).

This notice, provided pursuant to section 10(a)(1)(B) of the Act, advises the public and other agencies of the availability of the HCP for review and comment.

The Service has made a preliminary determination that the HCP and permit application are eligible for categorical exclusion under the National Environmental Policy Act of 1969 (NEPA). The basis for this determination is contained in an Environmental Action Statement and low-effect screening form, which are also available for public review.

DATES: Written data or comments must be received on or before October 5, 2007.

ADDRESSES: Send written comments to Tony Sullins, Field Supervisor, U.S. Fish and Wildlife Service, Twin Cities Field Office, 4101 East 80th Street, Bloomington, MN 55425. Fax number: 612–725–3609.

FOR FURTHER INFORMATION CONTACT: Mr. Phil Delphey (612) 725–3548, extension 206.

SUPPLEMENTARY INFORMATION:

Availability of Documents

Individuals requesting copies of the applications and proposed HCP should contact the U.S. Fish and Wildlife Service by telephone at (612) 725–3548 or by letter (see **ADDRESSES**). Copies of the proposed HCP also are available for public inspection during regular business hours at the U.S. Fish and Wildlife Service, Bloomington Field Office, 4101 East 80th Street, Bloomington, MN, or at the Service's Regional Web site at: *http://www.fws.gov/midwest/Endangered/permits/hcp/index.html.* All comments received become part of the official public record. Requests for such comments will be handled in accordance with the Freedom of Information Act and the Council on Environmental Quality's NEPA regulations [40 CFR 1506.6(f)]. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. If a respondent wishes us to withhold his/her name and/or address, this must be stated prominently at the beginning of the comment.

Background

Section 9 of the Act and its implementing Federal regulations prohibit the take of animal species listed as endangered or threatened. The definition of take under the Act includes the following activities: To harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in such conduct (16 U.S.C. 1538). The Service has principal trust responsibility for the conservation and protection of threatened and endangered species under the ESA. Section 10 of the ESA, 16 U.S.C. 1539, establishes a program whereby persons seeking to pursue activities that otherwise could give rise to liability for unlawful ''take'' of federally-protected species may receive an ITP, which protects them from such liability. To obtain an ITP, the applicant must submit an HCP and the taking must be incidental to, and not the purpose of, an otherwise lawful activity. *Id.* §§ 1539(a)(1)(B), 1539(a)(2)(A). Once the Service has determined that the applicant has satisfied these and other statutory criteria, it may issue the ITP.

The Applicant operates a municipal well field and is proposing to increase the annual consumption of groundwater at the well field from 50 million to 60.5 million gallons per year. The increase in the annual consumption of groundwater at the Adrian well field has the potential to impact water levels and stream flow in an unnamed stream that borders the well field to the south. The Topeka

shiner (*Notropis topeka*), which is listed as endangered under the Endangered Species Act, inhabits the tributary stream. Proposed operations of the well field may cause take of Topeka shiners in the stream. The maximum pumping rate for the well field will remain unchanged. Therefore, anticipated impacts to stream flow and water levels in the tributary are expected to be minor.

The purposes of the HCP are to minimize incidental take, to mitigate the effects of any such take to the maximum extent practicable, and to avoid any appreciable reduction in the likelihood of the survival and recovery of this species in the wild. Topeka shiners rely on pools in the main channel of streams and off channel pools (e.g., oxbows). Therefore, the proposed mitigation strategy for the project is creation of new pool habitat in a stream reach inhabited by Topeka shiners. The Applicant proposes to follow the general design of similar pools constructed by the Service in Iowa at one of two proposed mitigation sites and to monitor the constructed habitat to ensure that it contains the physical habitat features essential to the conservation of Topeka shiners. The creation of new pool habitat, along with the proposed monitoring program, is intended to accomplish the following biological goals of the HCP: (1) Ensure that the current range of Topeka shiners in Minnesota is not diminished; and, (2) facilitate the ability of the existing Topeka shiners to increase their population stability and/or abundance within its current range.

Decisions

The Service will evaluate the permit application, the HCP, and the comments submitted thereon to determine whether the application meets the requirements of section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended. If the requirements are met, the Service will issue an incidental take permit to the Applicant for take of Topeka shiners incidental to the otherwise lawful activities of the project. The Service will not make a final decision until after the end of the 30-day comment period and will fully consider all comments received during the comment period.

Authority

This document is published under the authority of the Endangered Species Act (16 U.S.C. 1531 *et seq.*).

Dated: August 29, 2007.

Tony Sullins,

Field Supervisor.

[FR Doc. E7–17520 Filed 9–4–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Proposed Safe Harbor Agreement for the Oregon Chub, Lane County, OR

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; receipt of application.

SUMMARY: Marilyn and Randy Sprick have applied to the U.S. Fish and Wildlife Service (Service) for an enhancement of survival permit pursuant to section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (Act). The permit application includes a proposed Safe Harbor Agreement (Agreement) between Mr. and Mrs. Sprick, the Oregon Department of Fish and Wildlife, and the Service. The proposed term of the Agreement is 10 years and the term of the permit is 30 years. The requested permit would authorize Mr. and Mrs. Sprick to carry out habitat management measures that would benefit the federally-listed as endangered Oregon chub (*Oregonichthys crameri*). The covered area or geographic scope of this Agreement includes an artificial pond surrounded by a 100-foot buffer. We request comments from the public on the permit application, proposed Agreement, and related documents, which are available for review.

DATES: Comments must be received from interested parties on or before October 5, 2007. The final permit decision will be made no sooner than October 5, 2007.

ADDRESSES: You may obtain copies of the documents for review by contacting Richard Szlemp, U.S. Fish and Wildlife Service, 2600 SE. 98th Ave., Suite 100, Portland, Oregon 97266; facsimile (503) 231–6195; or by making an appointment to view the documents at the above address during normal business hours. You may also view the documents on the Internet through *http://www.fws.gov/oregonfwo/species/*. You may submit your written comments to Kemper M. McMaster, State Supervisor, Fish and Wildlife Service, 2600 SE. 98th Ave., Suite 100, Portland, Oregon 97266, or facsimile (503) 231–6195. Include your name and address in your comments and refer to the 'Sprick SHA'.

FOR FURTHER INFORMATION CONTACT: Richard Szlemp (*see* **ADDRESSES**) (503) 231–6179.

SUPPLEMENTARY INFORMATION: Under a Safe Harbor Agreement, participating landowners voluntarily undertake management activities on their property to enhance, restore, or maintain habitat benefiting species listed under the Act (16 U.S.C. 1531 *et seq.*). Safe Harbor Agreements, and the subsequent enhancement of survival permits that are issued pursuant to section 10(a)(1)(A) of the Act, encourage private and other non-federal property owners to implement conservation efforts for listed species by assuring the landowners that they will not be subjected to increased property use restrictions as a result of their efforts to attract listed species to their property, or to increase the numbers or distribution of listed species already on their property. Application requirements and issuance criteria for enhancement of survival permits through Safe Harbor Agreements are found in 50 CFR 17.22(c). These permits allow any necessary future incidental take of any covered species above the mutually agreed upon baseline conditions for those species in accordance with the terms of the permit and accompanying agreement.

We have worked with Mr. and Mrs. Sprick and the Oregon Department of Fish and Wildlife to develop the proposed Agreement for the conservation of the Oregon chub. The area covered by this Agreement is composed of an artificial pond with an approximate area of 0.65 acre, and a 100-foot buffer surrounding the pond. The total area covered by this Agreement is approximately 1.7 acres. Environmental baseline conditions have been established as zero Oregon chub being present in the pond. The purpose of this Agreement is to establish a new population of Oregon chub as refugia for the natural population. Under this Agreement, a minimum of 500 Oregon chub will be introduced from an existing wild population by the Oregon Department of Fish and Wildlife. The estimated carrying capacity of the Sprick's pond is approximately 1,000 individuals. The Oregon Department of Fish and Wildlife will monitor the Oregon chub population and habitat conditions at least once a year. Upon reaching this threshold, this population may be used as a source for translocations by the Oregon Department of Fish and Wildlife, but would not be lowered beyond 500 individuals at the time of removal.

The Spricks will avoid conducting activities that could adversely affect the Oregon chub's habitat within 100 feet of the pond's perimeter during the 10-year term of the Agreement. The permit duration is 30 years, which would allow up to an additional 20 years for the terms of the Agreement to remain in effect before a return to baseline conditions may occur.

Without the regulatory assurances provided through the Agreement and permit, landowners may otherwise be unwilling or reluctant to engage in activities that would place federally-listed species such as the Oregon chub onto their properties. The proposed Agreement is expected to provide a net conservation benefit to the Oregon chub by creating a protected refugia, increasing the population, and translocating individuals, beyond those needed to maintain the refugia population, to other suitable locations.

The Oregon chub was listed as an endangered species by the Service in 1993 (58 FR 53800). At the time of listing, their were only five known populations and they were restricted to an 18.6 mile stretch of the Middle Fork Willamette River drainage, representing approximately two percent of the species' historic range. In 2006, there were 18 populations totaling 500 or more individuals. Oregon chub remain at risk due to the loss of suitable habitat and the continued threats posed by the proliferation of non-native fishes, water withdrawals, accelerated sedimentation due to land management activities, and potential chemical spills or careless pesticide applications. Their status has improved in recent years, resulting primarily from successful introductions and the discovery of previously undocumented populations.

The Service has made a preliminary determination that the proposed Agreement and permit application are eligible for a categorical exclusion under the National Environmental Policy Act of 1969 (NEPA). We explain the basis for this determination in an Environmental Action Statement that is also available for public review (*see* **ADDRESSES**).

The Service will evaluate the permit application, associated documents, and comments submitted thereon to determine whether the permit application meets the requirements of section 10(a) of the Act and NEPA regulations. All comments received, including names and addresses, will become part of the administrative record and will be available for review pursuant to section 10(c) of the Act. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. Anonymous comments will not be considered. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, are available for public inspection in their entirety.

If we determine that all requirements are met, we will sign the Agreement and issue an enhancement of survival permit under section 10(a)(1)(A) of the Act to Mr. and Mrs. Sprick for the take of Oregon chub, incidental to otherwise lawful activities in accordance with the terms of the Agreement. This notice is provided pursuant to section 10(c) of the Act and NEPA regulations (40 CFR 1506.6).

Dated: August 29, 2007.

Kemper M. McMaster,

State Supervisor, Fish and Wildlife Service, Oregon Fish and Wildlife Office, Portland, Oregon.

[FR Doc. 07–4316 Filed 9–4–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permit for marine mammals.

SUMMARY: The following permit was issued.

ADDRESSES: Documents and other information submitted with this application are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358–2281.

FOR FURTHER INFORMATION CONTACT: Division of Management Authority, telephone 703/358–2104.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on the dates below, as authorized by the provisions of the Fish and Wildlife Service issued the requested permits subject to certain conditions set forth therein.

Marine Mammals

Permit number	Applicant	Receipt of application Federal Register notice	Permit issuance date
154919	Scott A. Hanan	72 FR 33242; June 15, 2007 July 16, 2007.	

Dated: August 10, 2007.

Michael L. Carpenter,

Senior Permit Biologist, Branch of Permits, Division of Management Authority.

[FR Doc. E7–17502 Filed 9–4–07; 8:45 am]

BILLING CODE 4310–55–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–550]

In the Matter of Certain Modified Vaccinia Ankara (''MVA'') Viruses and Vaccines and Pharmaceutical Compositions Based Thereon; Notice of a Commission Determination Not To Review an Initial Determination Terminating the Investigation in Its Entirety Based on a Consent Order; Issuance of Consent Order

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 54) of the presiding administrative law judge (''ALJ'') in the above-captioned investigation terminating the investigation in its entirety on the basis of a consent order.

FOR FURTHER INFORMATION CONTACT: Clint A. Gerdine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–2310. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on September 23, 2005, based on a complaint filed by Bavarian Nordic A/S of Denmark (''Bavarian Nordic''). The complaint alleged violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) (''section 337'') in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain Modified Vaccinia Ankara (''MVA'') viruses and vaccines and pharmaceutical compositions based thereon by reason of infringement of various claims of United States Patent Nos. 6,761,893 and 6,913,752. The complaint also alleged violations of section 337 in the importation of certain MVA viruses and vaccines and pharmaceutical compositions based thereon or in the sale of such articles by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States. The complaint named a single respondent, Acambis PLC of the United Kingdom (''Acambis''). Only the patent allegations remain in this investigation.

After a hearing and post-hearing briefing, the then-presiding ALJ issued a final initial determination (''final ID'') on September 6, 2006, finding no violation of section 337. The ALJ held that the patents were infringed but invalid.

Bavarian Nordic, Acambis, and the Commission investigative attorney filed petitions for review of the final ID. On November 22, 2006, the Commission determined to review the final ID in its entirety, and to ask the parties for briefing on the issues on review and on remedy, the public interest, and bonding. On February 21, 2007, the Commission determined to remand the final ID to the ALJ and to extend the target date for completion of the investigation to October 19, 2007. The target date was subsequently extended to February 20, 2008.

On July 27, 2007, complainant and respondent filed a joint motion to terminate the investigation on the basis of a consent order. The Commission investigative attorney filed a response in support of the motion. The consent order includes a provision vacating the final ID of September 6, 2006.

The ALJ issued the subject ID on August 9, 2007, granting the motion for termination. He found that the consent order stipulation satisfies Commission rule 210.21(c)(3)(i), and that the termination of the investigation by consent order is not contrary to the public interest. No party petitioned for review of the ID. The Commission has determined not to review the ID. The investigation is terminated in its entirety and the final ID of September 6, 2006, is vacated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in sections 210.21(c) and 210.42(h) of the Commission's Rules of Practice and Procedure (19 CFR 210.21(c), 210.42(h)).

Issued: August 29, 2007.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E7–17465 Filed 9–4–07; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–577]

In the Matter of Certain Wireless Communications Equipment, Articles Therein, and Products Containing the Same; Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation Based on Settlement

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 59) issued by the presiding administrative law judge (''ALJ'') terminating the above-captioned investigation based on a settlement agreement.

FOR FURTHER INFORMATION CONTACT: Paul M. Bartkowski, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–5432. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on June 29, 2006, based on a complaint filed by Samsung Telecommunications America, LLP and Samsung Electronics Co., Ltd. (''Complainants''). The complaint alleged violations of section 337 of the

Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States and the sale of certain wireless communications equipment, articles therein, and products containing the same by reason of infringement of certain claims of U.S. Patent Nos. 6,598,202; 6,882,636; 6,154,652; 6,920,331; 6,421,353; 6,920,602; and 6,928,604. The complaint named four respondents: Ericsson, Inc.; Telefonaktiebolaget LM Ericsson; Sony Ericsson Mobile Communications AB; and Sony Ericsson Mobile Communications (USA) Inc. (''Respondents'').

On August 9, 2007, the presiding administrative law judge issued the subject ID (Order No. 59) granting a joint motion by Complainants and Respondents to terminate the investigation based upon a signed patent license agreement between the private parties. No petitions for review of the ID were filed. The Commission has determined not to review the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 CFR 210.42).

Issued: August 29, 2007.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E7–17464 Filed 9–4–07; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Emergency Review; Comment Request

August 29, 2007.

The Department of Labor hereby announces the submission of the following information collection request (ICR), utilizing emergency review procedures specified in 5 CFR 1320.13, for the Office of Management and Budget (OMB) review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). OMB approval has been requested by September 17, 2007. A copy of this ICR, with applicable supporting documentation; including among other things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or by contacting Darrin King on 202–693–4129 (this is not toll-free number) / e-mail: *king.darrin@dol.gov.*

Interested parties are encouraged to send comments within 5 days from the date of this publication in the **Federal Register**. Comments should be sent to the Office of Information and Regulatory Affairs, Attn: Katherine Astrich, OMB Desk Officer for the Employment and Training Administration, Room 10235, Washington, DC 20503 (Telephone: 202–395–7316 / Fax: 202–395–6974, these are not toll-free numbers). Comments may be submitted by E-mail to *OIRA_submission@omb.eop.gov*. In order to ensure the appropriate consideration, comments should reference the OMB Control Number (see below).

The Office of Management and Budget 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.

Agency: Employment and Training Administration.

Title: Work Opportunity Tax Credit (WOTC) and Welfare-to-Work (WtW) Tax Credit.

OMB Control Number: 1205–0371.

Form Numbers: ETA–9062; ETA–9058; ETA–9057; ETA–9059; ETA–9063; ETA–9061; and ETA–9065.

Affected Public: State Workforce Agencies; participating agencies; business sector; and disadvantaged jobseekers.

Estimated Number of Annual Respondents: 990,000.

Estimated Total Annual Burden Hours: 848,325.

Total Estimated Annual Cost Burden: $0.

Description: On May 25, 2007 the President signed into law the *Small Business and Work Opportunity Tax Act of 2007* (Pub. L. 110–28). Section 8211 of this Act extended and modified the WOTC Program for a continuing 44-month period through August 31, 2011. The new provisions and amendments to certain target groups apply to new hires that begin to work for an employer after May 25. Another recent legislation, the *Tax Relief and Health Care Act of 2006* (Pub. L. 109–432) signed into law on December 20, 2006 extended the WOTC for two additional years through December 31, 2007 and consolidated the program by merging the Welfare-to-Work Tax Credit into the WOTC. This Act also made various amendments and introduced new provisions that streamline the program and make it easier for the business sector to participate. The statutory changes and new provisions required that the following program report, processing and administrative forms, and materials be revised and updated to reflect the new changes and provisions:

To request a certification from a state workforce agency (SWA), employers or their representatives must submit not only IRS Form 8850 but also either ETA Form 9061 or 9062. SWAs cannot process timely filed but incomplete requests. Through a special arrangement with OMB, IRS Form 8850 was cleared by OMB May 26, 2007. Therefore, ETA is requesting this emergency ICR approval of the listed forms and program materials so that the SWAs can start processing all the new certification requests with the changes that became effective May 26, 2007. This emergency approval will help prevent the accumulation of unprocessed timely filed certification requests, which will result in significant backlogs for the states and the timely issuance to employers of certifications for all the new eligible hires in accordance with Congressional intent.

Darrin King,

Acting Departmental Clearance Officer.

[FR Doc. E7–17483 Filed 9–4–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–59,641]

Arizona Textile, a Division of Charming Shoppers, Inc., also known as Fenise Apparel, Phoenix, AZ; 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 21, 2006, applicable to workers of Arizona Textile, a division of Charming Shoppers, Inc., Phoenix, Arizona. The notice was published in the **Federal Register** on August 4, 2006 (71 FR 44320).

At the request of the petitioners, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of ladies apparel (i.e., tops, pants, shorts, culottes, dresses, jackets, and skirts).

New information provided by the company shows that Arizona Textile became known as Fenise Apparel on July 14, 2006 after a change in ownership. Some workers separated from employment at the subject firm had their wages reported under a separate unemployment insurance (UI) tax accounts for Fenise Apparel.

Accordingly, the Department is amending this certification to show a change in ownership.

The intent of the Department's certification is to include all workers of Arizona Textile, a division of Charming Shoppers, Inc., Phoenix, Arizona who were adversely affected by a shift in production of ladies apparel to China, Vietnam and the Dominican Republic.

The amended notice applicable to TA–W–59,641 is hereby issued as follows:

Workers producing ladies apparel at Arizona Textile, a division of Charming Shoppers, Inc., also known as Fenise Apparel, Phoenix, Arizona, who became totally or partially separated from employment on or after June 27, 2005, through July 21, 2008, 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 28th day of August 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–17472 Filed 9–4–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–58,910; TA–W–58,910A]

Joan Fabrics Corporation Mastercraft Sales and Design, Fall River, MA; Including Employees of Joan Fabrics Corporation Mastercraft and Sales and Design, Fall River, MA, Located In New York, NY; 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 Regarding Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on March 17, 2006, applicable to workers of Joan Fabrics Corporation, Mastercraft Sales and Design, Fall River, Massachusetts. The notice was published in the **Federal Register** on April 13, 2006 (71 FR 19209).

At the request of the State agency and company officials, the Department reviewed the certification for workers of the subject firm. New information shows that worker separations have occurred involving employees of the Fall River, Massachusetts facility of Joan Fabrics Corporation, Mastercraft Sales and Design who are located in New York, New York.

Ms. Jeanne Chun, Ms. Kerry Burke and Ms. Alicia Harvin provided sales and designing function services for the Mastercraft Sales and Design of the Fall River, Massachusetts location of the subject firm.

Based on these findings, the Department is amending this certification to include employees of the Fall River, Massachusetts facility of Joan Fabrics, Mastercraft Sales and Design who are located in New York, New York.

The intent of the Department's certification is to include all workers of Joan Fabrics Corporation, Mastercraft Sales and Design, Fall River, Massachusetts who were adversely affected by shift in production to Mexico by Joan Fabrics Corporation.

The amended notice applicable to TA–W–58,910 is hereby issued as follows:

All workers of Joan Fabrics Corporation, Mastercraft Sales and Design (TA–W–58,910), including employees in support of Joan Fabrics Corporation, Mastercraft Sales and Design, Fall River, Massachusetts located in New York, New York (TA–W–58,910A), who became totally or partially separated from employment on or after February 21, 2005, through March 17, 2008, 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 27th day of August 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–17471 Filed 9–4–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,550]

Linq Industrial Fabrics, Inc. Including Workers Whose Wages Were Paid by Thrace-Linq, Inc. and Texene LLC, Summerville, SC; 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 1074 (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 August 13, 2007, applicable to workers of LINQ Industrial Fabrics, Inc., Summerville, South Carolina. The notice will be published soon in the **Federal Register**.

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of woven and nonwoven industrial textile fabrics.

New information shows that when LINQ Industrial Fabrics, Inc., closed April 30, 2007, Thrace-LINQ, Inc. and Texene LLC purchased the assets of the subject firm. Workers of the subject firm then became employees of Thrace-LINQ, Inc. and Texene LLC, and their wages were reported under two separate

unemployment insurance (UI) tax accounts: Thrace-LINQ, Inc. and Texene LLC.

Accordingly, the Department is amending the certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of LINQ Industrial Fabrics, Inc. who were adversely affected by increased customer imports.

The amended notice applicable to TA–W–61,550 is hereby issued as follows:

All workers of LINQ Industrial Fabrics, Inc., including workers whose wages were paid by Thrace–LINQ, Inc. and Texene LLC, Summerville, South Carolina, who became totally or partially separated from employment on or after April 30, 2006, through August 13, 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 28th day of August 2007.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–17477 Filed 9–4–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than September 17, 2007.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than September 17, 2007.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 28th day of August 2007.

Ralph Dibattista,

Director, Division of Trade Adjustment Assistance.

Appendix

TAA PETITIONS INSTITUTED BETWEEN 8/20/07 AND 8/24/07

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
62005	Novacel, Inc. (Comp)	Newton, MA	08/20/07	08/17/07
62006	Albany International Corp. (UFCWIU)	Mennands, NY	08/20/07	08/16/07
62007	VanSeal (frmly John Crane, Inc.) (State)	Vandalia, IL	08/20/07	08/17/07
62008	Encompass Group, LLC (Comp)	McDonough, GA	08/20/07	08/17/07
62009	Global Motorsport GPR Inc. (State)	Valencia, CA	08/20/07	08/03/07
62010	Cargill (Wkrs)	Sidney, OH	08/20/07	08/17/07
62011	Art Leather Manufacturing Company (Wkrs)	Hicksville, NY	08/21/07	08/20/07
62012	Clayson Knitting Company, Inc. (Comp)	Red Springs, NC	08/21/07	08/20/07
62013	Columbia Lighting (Comp)	Spokane, WA	08/21/07	08/16/07
62014	Finotex (State)	Hialeah, FL	08/21/07	08/12/07
62015	Kester (State)	Des Plaines, IL	08/21/07	08/15/07
62016	Karastan Rug Plant (Union)	Eden, NC	08/21/07	08/20/07
62017	Fargo Electronics (State)	Eden Prarie, MN	08/21/07	08/20/07
62018	Hi Rel Systems (Comp)	Hillsboro, OR	08/21/07	08/21/07
62019	Brandon International (Comp)	Baldwin Park, CA	08/21/07	08/15/07
62020	Denton Hosiery Mills Inc. (Comp)	Denton, NC	08/22/07	08/23/07
62021	Emcore Corporation (Wkrs)	Albuquerque, NM	08/22/07	08/21/07
62022	Irwin Industrial Tool (State)	DeWitt, NE	08/22/07	08/21/07
62023	Selectrucks Refurbishing Center (Comp)	Tooele, UT	08/22/07	08/24/07
62024	CDS /Ensembles, Inc. (Comp)	Greer, SC	08/23/07	08/01/07
62025	Seminole Tubular Products—Wheatland Tube Company (State).	Houston, TX	08/23/07	08/20/07
62026	TI Automotive (Comp)	Normal, IL	08/23/07	08/21/07
62027	General Products Corporation (Wkrs)	Jackson, MI	08/23/07	08/16/07
62028	Deluxe Tool and Engineering, Inc. (Comp)	Wyoming, MN	08/23/07	08/22/07
62029	Foxcroft Sportswears (Comp)	Fall River, MA	08/23/07	08/21/07
62030	Alcan (State)	City of Commerce, CA	08/23/07	08/10/07
62031	Laird Technologies (Wkrs)	St. Louis, MO	08/23/07	08/20/07
62032	DGS Stamping (UAW)	Cleveland, OH	08/23/07	08/15/07
62033	Textile Arts and Film, Inc. (Wkrs)	Chester, SC	08/23/07	08/15/07
62034	Wavesplitter Tech Inc. (Wkrs)	Santa Clara, CA	08/23/07	08/13/07
62035	Kadant Web Systems (Comp)	Auburn, MA	08/24/07	08/22/07
62036	Clover Technologies Group, LLC (Comp)	Mesa, AZ	08/24/07	08/20/07
62037	Avon Automotive (Comp)	Cadillac, MI	08/24/07	08/20/07
62038	Albany International Corp. (Union)	Rensselaer, NY	08/24/07	08/16/07

TAA PETITIONS INSTITUTED BETWEEN 8/20/07 AND 8/24/07—Continued

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
62039	Hole In None Hosiery (Comp)	Burlington, NC	08/24/07	08/22/07
62040	The Colibri Group (Comp)	Providence, RI	08/24/07	08/23/07
62041	Johnson Controls (State)	Santa Fe Springs, CA	08/24/07	08/09/07
62042	Tecumseh Power Company (IAM)	Grafton, WI	08/24/07	08/22/07
62043	Synergis Technologies (Wkrs)	Grand Rapids, MI	08/24/07	08/24/07

[FR Doc. E7–17470 Filed 9–4–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,958]

Sekely Industries, Inc. Including On-Site Workers of Staffright, Bartech, and Alliance Staffing, Salem, OH; Notice of Revised Determination on Reconsideration

On May 14, 2007, the Department of Labor (Department) issued a Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance for the workers and former workers of Sekely Industries, Inc., Salem, Ohio (subject firm). The Department's Notice of Negative Determination was published in the **Federal Register** on June 6, 2007 (72 FR 31346). Workers produced automotive dies until the subject firm ceased operation in January 2007. The subject firm used temporary workers supplied by Staffright, Bartech, and Alliance Staffing agencies.

The investigation revealed that section 222(a)(2)(A)(I)(C) and section (a)(2)(B)(II)(B) of the Trade Act of 1974, as amended, were not met.

The investigation revealed that the subject firm did not increase its imports of dies or successfully shift its production of automotive dies abroad during the relevant period. The investigation also revealed no increased imports by the subject firm's major declining customers of like or directly competitive dies accompanied by decreased subject firm purchases.

By application dated June 11, 2007, a worker requested administrative reconsideration of the negative determination. The request alleged that the subject firm shifted production to an affiliated facility in China.

During the reconsideration investigation, the Department confirmed that the subject firm did not shift production abroad. The Department also received new information that revealed that, during the relevant period, a major declining customer of the subject firm replaced subject firm purchases with imported dies that are like or directly competitive with those produced by the subject firm.

In accordance with section 246 the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department herein presents the results of its investigation regarding certification of eligibility to apply for ATAA. The Department has determined in this case that the group eligibility requirements of section 246 have been met.

A significant number of workers at the firm are age 50 or over and possess skills that are not easily transferable. Competitive conditions within the industry are adverse.

Conclusion

After careful review of the new information obtained in the reconsideration investigation, I determine that workers and former workers of Sekely Industries, Inc., Salem, Ohio are negatively impacted by increased imports of automotive dies like or directly competitive with those produced by the subject firm.

In accordance with the provisions of the Act, I make the following certification:

All workers of Sekely Industries, Inc., including on-site temporary workers of Staffright, Bartech, and Alliance Staffing, Salem, Ohio who became totally or partially separated from employment on or after February 9, 2006, through two years from the date of this certification, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974, and are eligible to apply for alternative trade adjustment assistance under section 246 of the Trade Act of 1974.

Signed at Washington, DC this 28th day of August 2007.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–17473 Filed 9–4–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,541]

South Indiana Lumber Company, Inc., Liberty, KY; Notice of Negative Determination on Reconsideration

On August 3, 2007, the Department issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of the subject firm. The notice was published in the **Federal Register** on August 14, 2007 (72 FR 45450).

The petition for the workers of South Indiana Lumber Company, Inc., Liberty, Kentucky engaged in production of furniture blanks, stair balusters, and handle blanks was denied because the ''contributed importantly'' group eligibility requirement of Section 222 of the Trade Act of 1974, as amended, was not met. The subject firm did not import furniture blanks, stair balusters, and handle blanks nor did it shift production to a foreign country during the relevant period. The ''contributed importantly'' test is generally demonstrated through a survey of the workers' firm's customers. The survey revealed no imports of furniture blanks, stair balusters, and handle blanks during the relevant period.

The petitioners filed a request for reconsideration and requested that workers of South Indiana Lumber Company, Inc., Liberty, Kentucky be considered eligible for TAA as a secondary affected company. The petitioner provided the names of two TAA certified companies to which the subject firm allegedly supplied products during the relevant time period.

A company official was contacted to verify whether the subject firm supplied furniture blanks, stair balusters, and handle blanks to the companies provided by the petitioner. The company official stated that South Indiana Lumber Company, Inc., Liberty, Kentucky did not sell to these TAA certified facilities and that these specific facilities were not customers of the

subject firm during the relevant time period. The Department conducted a further investigation and determined that none of the direct customers of the subject firm were certified eligible for TAA during the relevant time period.

Furthermore, the Department requested an additional list of customers from the subject firm and conducted a new customer survey regarding their purchases of furniture blanks, stair balusters, and handle blanks in 2005, 2006 and January through May of 2007 over the corresponding 2006 period. This survey revealed no imports of furniture blanks, stair balusters, and handle blanks during the relevant time period.

Conclusion

After reconsideration, I affirm the original notice of negative determination of eligibility to apply for worker adjustment assistance for workers and former workers of South Indiana Lumber Company, Inc., Liberty, Kentucky.

Signed at Washington, DC this 29th day of August, 2007.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–17476 Filed 9–4–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,522]

Unifi, Inc.—Dillon Plant Formerly Known as Dillon Yarn, Dillon, SC; 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 Regarding Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on August 15, 2007, applicable to workers of Unifi, Inc.,—Dillon Plant, Dillon, South Carolina. The notice will be published soon in the **Federal Register**.

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of textured polyester yarns and twisted sewing threads.

The subject firm originally named Dillon Yarn, was renamed Unifi, Inc.—Dillon Plant on January 1, 2007. The State agency reports that some workers wages at the subject firm are being reported under the Unemployment Insurance (UI) tax account for Dillon Yarn, Dillon, South Carolina.

Accordingly, the Department is amending this certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Unifi, Inc.—Dillon Plant, formerly known as Dillon Yarn, who were adversely affected by increased customer imports.

The amended notice applicable to TA–W–61,522 is hereby issued as follows:

All workers of Unifi, Inc.—Dillon Plant, formerly known as Dillon Yarn, Dillon, South Carolina, who became totally or partially separated from employment on or after May 10, 2006, through August 15, 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 28th day of August 2007.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–17475 Filed 9–4–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,961; TA–W–60,961A]

Vytech Industries, Inc., Anderson, SC; Including An Employee Of Vytech Industries, Inc., Anderson SC, Located in Salisbury, MD; 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 Regarding Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on March 26, 2007, applicable to workers of VyTech Industries, Inc., Anderson, South Carolina. The notice was published in the **Federal Register** on April 10, 2007 (72 FR 17936).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. New information shows that a worker separation occurred involving an employee of the Anderson, South Carolina facility of VyTech Industries, Inc. who is located in Salisbury, Maryland.

Mr. Barry Seldomridge provided sales and engineering function services for the Anderson, South Carolina location of the subject firm.

Based on these findings, the Department is amending this certification to include an employee of the Anderson, South Carolina facility of VyTech Industries, Inc. who is located in Salisbury, Maryland.

The intent of the Department's certification is to include all workers of VyTech Industries, Inc., Anderson, South Carolina who were adversely affected by increased customer imports.

The amended notice applicable to TA–W–60,961 is hereby issued as follows:

All workers of VyTech Industries, Inc., Anderson, South Carolina (TA–W–60,961), including an employee in support of VyTech Industries, Inc., Anderson, South Carolina located in Salisbury, Maryland (TA–W–60,961A), who became totally or partially separated from employment on or after February 9, 2006, through March 26, 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 28th day of August 2007.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–17474 Filed 9–4–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Proposed Information Collection Request for National Agricultural Workers Survey; Comment Request

AGENCY: Employment and Training Administration.

ACTION: Notice.

SUMMARY: The Department of Labor, 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 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)(2)(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 Employment and Training Administration is soliciting comments concerning the proposed three-year continuation of the National Agricultural Workers Survey with revisions.

A copy of the proposed information collection request can be obtained by contacting the office listed below in the addressee section of this notice or by accessing: *http://www.doleta.gov/OMBCN/1205–0453.cfm*.

DATES: Written comments must be submitted to the office listed in the addressee's section below on or before November 5, 2007.

ADDRESSES: Submit written comments to the Employment and Training Administration, Office of Policy Development and Research, 200 Constitution Avenue, NW., Room N5641, Washington, DC 20210, Attention: Mr. Daniel Carroll. Telephone number: 202–693–2795 (this is not a toll-free number). Fax: 202–693–2766. E-mail: *carroll.daniel.j@dol.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor has been continually surveying hired farm workers since 1988 via the National Agricultural Workers Survey (NAWS). The survey's primary focus is to describe the employment, demographic, and health characteristics of hired crop farm workers. It is the only national-level data source for this information.

The NAWS provides an understanding of the manpower resources available to U.S. agriculture, and both public and private service programs use the data for planning, implementing, and evaluating farm worker programs.

The NAWS samples hired crop farm workers in three cycles each year to capture the seasonality of agricultural employment. Workers are randomly sampled at their work sites. During the initial contact, arrangements are made to interview the respondent at home or at another location of convenience to the respondent. Depending on the information needs and resources of the various federal agencies that use NAWS data, between 1,500 and 4,000 workers are interviewed each year.

The primary NAWS questionnaire routinely provides a standard set of information on the employment, demographic, and health characteristics of hired crop workers. When new information is required, Federal agencies add supplemental collection instruments to the NAWS.

Beginning with the October 2007 interview cycle, the Employment and Training Administration, in partnership with the Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, proposes to collect additional information on the occupational health of hired crop workers via the NAWS. The new information would come from administering new questions on occupational mental health.

The purpose of this notice is to solicit comments regarding: (1) The currently approved versions of the primary questionnaire and the agricultural occupational injury supplement; and (2) the addition of the occupational mental health questions. The primary questionnaire, injury supplement, and proposed occupational mental health questions are discussed below.

Primary NAWS Questionnaire

The questionnaire is administered to hired crop agricultural workers 14 years old and older. It contains a household grid, where the education level and migration history of the respondent and each member of the respondent's household are recorded, and an employment grid, where a full year of respondent's employment is detailed. Information on income, assets, legal status, and use of contribution- and needs-based programs is also elicited.

In the employment grid, interviewers record the task and crop for agricultural jobs, type and amount of non-agricultural employment, periods of unemployment, and time spent outside the United States. For the respondent's current agricultural job, information on how the job was obtained, wages and payment method (piece or hourly), employment type (direct hire or labor-contracted) and duration (year-round or seasonal), benefits, availability of water and sanitation, pesticide training, transportation, and housing arrangements is recorded.

Demographic and health information collected via the primary questionnaire includes age, gender, place of birth, marital status, languages spoken, English language ability, participation in education and employment training programs, health history (lifetime), musculoskeletal problems (last 12 months), and quality of and access to health care.

The Agricultural Occupational Injury Supplement

This CDC/NIOSH-sponsored supplement is administered to all NAWS respondents who had a qualifying agricultural occupational injury in the United States in the 12-month period before the date of interview. For each qualifying injury, the respondent is asked how, when and where the injury occurred, the body part(s) injured, where medical treatment was received, how the treatment was paid for, and the number of days the respondent couldn't work or worked at a reduced activity level.

Proposed Occupational Mental Health Supplement

CDC/NIOSH is proposing to add, for one year only, an occupational mental health supplement. The supplement will include four questions each concerning decisions latitude and work limitations, two questions each concerning job demands and job insecurity, and one question each concerning perceived general health and family concerns. In addition, the Center for Epidemiologic Studies Depression Scale (CES–D) Short Form 10 (SF–10), which contains 10 items, would be administered.

II. Review Focus

The Department of Labor 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 appropriated automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions

Type of Review: Revision of Approved Collection.

Agency: Employment and Training Administration.

Title: National Agricultural Workers Survey.

OMB Number: 1205–0453.
Affected Public: Individuals, Farms.
Total Respondents: 5,344.
Frequency: Annual.

Total Responses: 5,344.

Average Time per Response: 48.1 minutes.

Estimated Total Burden Hours: 4,288 (*see* Table 1, below).

TABLE 1.—ESTIMATED BURDEN HOURS ASSOCIATED WITH THE FY 2008 NAWS

Who will be interviewed?	Survey instrument	Respondents per year	Average time per respondent	Total hours
Farm Workers	Primary Questionnaire, including occupational mental health questions.	4,000	57 minutes	3,800
Farm Workers with a qualifying injury.	Occupational Injury Supplement	160*	15 minutes	40
Employers	Point of Contact Only	1,344	20 minutes	448
Total		5,344		4,288

*Not included in total respondents; they are a subset of the Primary Questionnaire respondents.

Total Burden Cost (operating/maintaining): $0.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: August 29, 2007.

Emily Stover DeRocco,

Assistant Secretary, Employment and Training Administration.

[FR Doc. E7–17498 Filed 9–4–07; 8:45 am]

BILLING CODE 4510–FM–P

LEGAL SERVICES CORPORATION

Sunshine Act Meetings of the Board of Directors and One of the Board's Committees

TIMES AND DATES: The Legal Services Corporation (''LSC'') Board of Directors (''Board'') and the Board's Operations & Regulations Committee will meet by conference call on September 11, 2007, in the order set forth in the following schedule. (The Board Meeting will commence immediately upon adjournment of the committee meeting.)

PUBLIC OBSERVATION BY TELEPHONE: Members of the public that wish to listen to the meetings live may do so at LSC Headquarters (333 K. Street, NW., Washington, DC—3rd Floor Conference Center) or by following the telephone call-in directions provided below. Those members of the public that join the call are asked to keep their telephones muted in order to eliminate background noises. Comments from the public may from time to time be solicited by the presiding Chairman.

Call-In Directions for Both Meetings:

- Call toll-free number 1–800–857–7178;
- When prompted, enter the following numeric pass code: 28764;
- When connected to the call, please ''MUTE'' your telephone immediately. You may do so by dialing ''*6.''

MEETING SCHEDULE

Tuesday, September 11, 2007	Time
1. Operations & Regulations Committee.	11 a.m.
2. Board of Directors	Immediately upon conclusion of the Operations & Regulations Committee Meeting.

LOCATION: LSC staff joining the call will be doing so from the LSC Conference Center, on the 3rd Floor of 333 K Street, NW., Washington, DC, and may be joined by members of the public.

STATUS OF MEETINGS: Open.

Tuesday, September 11, 2007

Operations & Regulations Committee

Agenda

Open Session

1. Approval of agenda.
2. Consider and act on rulemaking to revise Part 1626 relative to eligibility of citizens of the Republic of the Marshall Islands, the Federated States of Micronesia and the Republic of Palau.
3. Public comment.
4. Consider and act on other business.
5. Consider and act on adjournment of meeting.

Board of Directors

Agenda

Open Session

1. Approval of agenda.
2. Consider and act the recommendation of the Operations and Regulations Committee regarding proposed rulemaking to revise Part 1626 relative to eligibility of citizens of the Republic of the Marshall Islands, the Federated States of Micronesia and the Republic of Paulau.
3. Public comment.
4. Consider and act on other business.
5. Consider and act on motion to adjourn meeting.

CONTACT PERSON FOR INFORMATION: Patricia D. Batie, Manager of Board Operations, at (202) 295–1500.

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Patricia D. Batie, at (202) 295–1500.

Dated: August 31, 2007.

Victor M. Fortuno,

Vice President for Legal Affairs, General Counsel & Corporate Secretary.

[FR Doc. 07–4348 Filed 8–31–07; 11:18 am]

BILLING CODE 7050–01–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (07–062)]

NASA International Space Station Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces an open meeting of the NASA International Space Station Advisory Committee.

DATES: October 1, 2007, 1 p.m.–2 p.m. Eastern Daylight Time.

ADDRESSES: National Aeronautics and Space Administration Headquarters, 300 E Street, SW., Room 6H45, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Dr. Glen R. Asner, Office of External Relations, (202) 358–0903, National Aeronautics and Space Administration, Washington, DC 20546–0001.

SUPPLEMENTARY INFORMATION: This meeting will be open to the public up to the seating capacity of the room. Five seats will be reserved for members of the press. The agenda for the meeting is as follows:

—To assess the operational readiness of the International Space Station to support a new crew.
—To assess the Russian and American flight teams' preparedness to accomplish the Expedition Sixteen mission.
—To assess the health and flight readiness of the Expedition Sixteen crew.

Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide the following information: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, phone); title/position of attendee. To expedite admittance, attendees should provide identifying information in advance by contacting Glen Asner via e-mail at *glen.asner@nasa.gov* or by telephone at (202) 358–0903 by September 21, 2007. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Dated: August 24, 2007.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. E7–17468 Filed 9–4–07; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL TRANSPORTATION SAFETY BOARD

Agenda; Sunshine Act Meeting

TIME AND DATE: 9:30 a.m., Tuesday, September 11, 2007.

PLACE: NTSB Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.

STATUS: The two items are open to the public.

MATTER TO BE CONSIDERED: 1124C, Motorcycle Safety Recommendation Letters.

7833a, *Railroad Accident Report*—Derailment of Chicago Transit Authority Train Number 220 Between Clark/Lake and Grand/Milwaukee Stations, Chicago, Illinois, July 11, 2006.

NEWS MEDIA CONTACT: Telephone: (202) 314–6100.

Individuals requesting specific accommodations should contact Chris Bisett at (202) 314–6305 by Friday, September 7, 2007.

The public may view the meeting via alive or archived webcast by accessing a link under ''News & Events'' on the NTSB home page at *http://www.ntsb.gov*.

FOR MORE INFORMATION CONTACT: Vicky D'Onofrio, (202) 314–6410.

Dated: August 31, 2007.

Vicky D'Onofrio,

Federal Register Liaison Officer.

[FR Doc. 07–4352 Filed 8–31–07; 12:52 pm]

BILLING CODE 7533–01–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–237 and 50–249]

Exelon Generation Company, LLC; Notice of Consideration of Issuance of Amendment to Renewed Facility Operating License No. DPR–19 and Renewed Facility Operating License No. DPR–25; Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Renewed Facility Operating License No. DPR–19 and Renewed Facility Operating License No. DPR–25 issued to Exelon Generation Company, LLC, (the licensee) for operation of the Dresden Nuclear Power Station, Units 2 and 3 (DNPS), located in Grundy County, Illinois.

The proposed amendment would revise the values of the safety limit minimum critical power ratio (SLMCPR) in Technical Specification Section 2.1.1, ''Reactor Core SLs.'' The amendment request is being re-noticed because the Nuclear Regulatory Commission staff determined during the review of the licensee's request that the change affected the licenses for both units at the DNPS. This notice supersedes the notice that appeared on July 31, 2007 (72 FR 41783).

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in Title 10 of the Code of Federal Regulations (10 CFR), Section 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The probability of an evaluated accident is derived from the probabilities of the individual precursors to that accident. The consequences of an evaluated accident are determined by the operability of plant systems designed to mitigate those consequences. Limits have been established consistent with NRC approved methods to ensure that fuel performance during normal, transient, and accident conditions is acceptable. The proposed change conservatively establishes the SLMCPR for DNPS Unit 2, Cycle 21 such that the fuel is protected during normal operation and during plant transients or anticipated operational occurrences (AOOs).

Changing the SLMCPR does not increase the probability of an evaluated accident. The change does not require any physical plant modifications, physically affect any plant components, or entail changes in plant operation. Therefore, no individual precursors of an accident are affected.

The proposed change revises the SLMCPR to protect the fuel during normal operation as well as during plant transients or AOOs. Operational limits will be established based on the proposed SLMCPR to ensure that the SLMCPR is not violated. This will ensure that the fuel design safety criterion (i.e., that at least 99.9% of the fuel rods do not experience transition boiling during normal operation and AOOs) is met. Since the proposed change does not affect operability of plant systems designed to mitigate any consequences of accidents, the consequences of an accident previously evaluated are not expected to increase.

Therefore, the proposed change does not involve a significant increase in the

probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Creation of the possibility of a new or different kind of accident requires creating one or more new accident precursors. New accident precursors may be created by modifications of plant configuration, including changes in allowable modes of operation. The proposed change does not involve any plant configuration modifications or changes to allowable modes of operation. The proposed change to the SLMCPR assures that safety criteria are maintained for DNPS, Unit 2, Cycle 21.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The SLMCPR provides a margin of safety by ensuring that at least 99.9% of the fuel rods do not experience transition boiling during normal operation and AOOs if the MCPR limit is not violated. The proposed change will ensure the current level of fuel protection is maintained by continuing to ensure that at least 99.9% of the fuel rods do not experience transition boiling during normal operation and AOOs if the MCPR limit is not violated. The proposed SLMCPR values were developed using NRC-approved methods. Additionally, operational limits will be established based on the proposed SLMCPR to ensure that the SLMCPR is not violated. This will ensure that the fuel design safety criterion (i.e., that no more than 0.1% of the rods are expected to be in boiling transition if the MCPR limit is not violated) is met.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of either facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D59, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner/requestor must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner/requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to

intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Nontimely requests and/or petitions and contentions will not be entertained absent a determination by the Commission or the presiding officer of the Atomic Safety and Licensing Board that the petition, request and/or the contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii).

A request for a hearing or a petition for leave to intervene must be filed by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; (2) courier, express mail, and expedited delivery services: Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff; (3) e-mail addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, *HEARINGDOCKET@NRC.GOV*; or (4) facsimile transmission addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, Attention: Rulemakings and Adjudications Staff at (301) 415–1101, verification number is (301) 415–1966. A copy of the request for hearing and petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and it is requested that copies be transmitted either by means of facsimile transmission to 301–415–3725 or by e-mail to *OGCMailCenter@nrc.gov*. A copy of the request for hearing and petition for leave to intervene should also be sent to the Mr. Bradley J. Fewell, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555, attorney for the licensee.

For further details with respect to this action, see the application for amendment dated July 10, 2007, which is available for public inspection at the Commission's PDR, located at One White Flint North, File Public Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/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, 301–415–4737, or by e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 29th day of August 2007.

For the Nuclear Regulatory Commission.

Christopher Gratton, Sr.,

Project Manager, Plant Licensing Branch III–2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E7–17493 Filed 9–4–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–298]

Nebraska Public Power District; Cooper Nuclear Station; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Facility Operating License No. DPR–46, issued to Nebraska Public Power District (NPPD, the licensee), for operation of the Cooper Nuclear Power Station (CNS) located in Nemaha County, Nebraska. Therefore, as specified in Title 10 of the *Code of Federal Regulations* (10 CFR) section 51.21, the NRC is issuing this environmental assessment and finding of no significant impact.

Environmental Assessment

Identification of the Proposed Action

The proposed action is in response to the licensee's application dated October 17, 2006, as supplemented by letters dated February 7, April 17, May 4, and July 26, 2007, requesting an amendment to the operating license for CNS to increase the storage capacity of its spent fuel pool (SFP) to maintain the capability to fully offload the core from the reactor as the unit approaches the end of its operating license. To achieve this goal, the licensee plans to install two additional high-density spent fuel racks into the SFP. Existing spent fuel racks will remain in the pool in their current configuration. The proposed additional racks will have a closer assembly-to-assembly spacing to increase fuel storage capacity. The number of fuel assemblies that can be stored in the SFP would be increased from 2366 assemblies to 2651 assemblies (an increase of 285 assemblies).

The Need for the Proposed Action

An increase in spent fuel storage capacity is needed to maintain the capability for a full-core offload and to allow CNS to operate at full power until the next refueling outage. Loss of full-core offload capability occurred when the spent fuel was discharged to the SFP following Cycle 22 in January 2005. The licensee plans to install one of the additional high-density storage racks (with the capacity to store 117 fuel assemblies) immediately following issuance of the proposed amendment, with the second high-density storage rack (with the capacity to store 168 fuel assemblies) to be installed later if necessary, while keeping the existing racks in place. The additional capacity will ensure the capability of a full-core offload as the unit approaches the end of Cycle 25, at which point it will receive new fuel for Cycle 26 during the summer of 2009.

Environmental Impacts of the Proposed Action

The NRC has completed its safety evaluation of the proposed action and concludes that the proposed addition of two new storage racks to the SFP is acceptable. The details of the staff's safety evaluation will be provided in the license amendment that will be issued as part of the letter to the licensee approving the license amendment.

The staff has reviewed the licensee's plan for the expanded fuel storage capacity with respect to the radiological impact. The specifics of this review are presented below:

1. Radioactive Wastes

CNS uses waste treatment systems designed to collect and process gaseous, liquid, and solid waste that might contain radioactive material in a safe and controlled manner so that the discharges are in accordance with the regulatory standards of 10 CFR Part 20, and Appendix I to 10 CFR Part 50.

2. Solid Radioactive Wastes

The NRC staff reviewed the impact of the expanded fuel storage capacity on the production and release of radioactive waste during normal operations. The level of radioactive material in the pool water and the degree of water clarity determines the amount of solid waste produced by pool purification system resins. The licensee expects that during the fuel pool expansion work, small amounts of additional resins may be generated. This additional waste will be generated on a one-time basis. During normal operations, the licensee does not expect there to be a significant increase in the amount of solid radioactive wastes. Overall, the staff concludes that during routine operations, there will be no significant increase in the volume of solid radioactive wastes generated as a result of the proposed action.

3. Gaseous Radioactive Effluents

Radioactive gases that evolve from the surface of the pool water contribute to the plant's gaseous effluents. However, the levels of gaseous and particulate radioactivity in the pool water and in the area around the SFP are dominated by the most recent reactor offload to the SFP, not the older cooled fuel in the pool. Therefore, the storage of additional spent fuel assemblies resulting from the proposed action will have a minimal contribution to the gaseous effluents. The licensee has area radiation monitors in the immediate vicinity of the SFP, which monitor ambient airborne particulate and iodine radioactivity, and additional radiation monitors that monitor gaseous discharges into the environment. This radiation monitoring is performed to ensure continued compliance with the regulatory dose limits for the workers and members of the public. Overall, the staff concludes that during routine operations, there will be no significant increase in the amount of gaseous radiological effluents released into the area around the SFP and into the environment as a result of the proposed action.

4. Liquid Radiological Effluents

The number of stored spent fuel assemblies does not directly affect the release of radioactive liquids from the plant. The contribution from the stored fuel assemblies of radioactive materials in the SFP water is minor relative to other sources of activity, such as the reactor coolant system and its associated sub-systems. The volume of SFP water processed for discharge is independent of the quantity of stored spent fuel assemblies. Therefore, the installation of the new fuel racks would not be expected to increase the amount of radioactive liquid wastes generated at the CNS. Overall, the staff concludes that during routine operations, there will be no significant increase in the amount of liquid radiological effluents released into the environment as a result of the proposed action.

5. Occupational Radiation Dose

During normal operations, personnel working in the fuel storage area are exposed to low levels of radiation from the SFP. Operating experience across the nuclear industry has shown that area dose rates originate primarily from radionuclides in the pool water, not the fuel itself, which is well shielded. The radiological conditions in the SFP area are typically dominated by the most recent discharge of spent fuel. The radioactivity inventory available for release into the general area from the older spent fuel, including the fuel from the expanded storage, is expected to be insignificant in comparison to freshly discharged fuel. During refueling and other fuel movement activities, pool water concentrations of radionuclides might be expected to increase to a small degree. However, the installation of the new fuel storage racks is not expected to cause any detectable increase in airborne activities or changes in the general area dose rates which might impact personnel working in the area.

All operations involved in the installation of the new fuel racks and the removal of any stored equipment or material from the SFP will be governed by plant procedures. The licensee's procedures incorporate the principle of keeping doses as low as reasonably achievable (ALARA), as required by NRC regulations.

The licensee does not expect to use underwater divers for the installation of the new fuel racks. However, in the event that diving operations are needed, the licensee is prepared to use specialized procedures and underwater radiation monitoring equipment to provide constant oversight and control to ensure the health and safety of the diver.

On the basis of our review of the CNS proposed expansion of the SFP storage capacity, the NRC staff concludes that the SFP work can be performed in a manner that will ensure that doses to the workers and the public, as well as the discharge of radioactive solid, gaseous, and liquid into the environment will be maintained within NRC regulations and standards. Therefore, there are no significant radiological impacts associated with the proposed action.

6. Postulated Accident Considerations

The proposed modification increases the SFP storage capacity, but it does not change the method for handling spent fuel assemblies.

The proposed expansion of the SFP will not affect any of the assumptions or inputs used in evaluating the dose consequences of a fuel handling accident and, therefore, will not result in an increase in the doses from the previously analyzed postulated fuel handling accident. In summary, the staff has evaluated the proposed action and concludes that it does not increase the probability or consequences of a postulated accident.

7. Non-Radiological Impact

The proposed amendment to the current operating license of CNS does not modify land use at the site; no new facilities or laydown areas are needed to support the rerack or operation after rerack; therefore, the proposed amendment does not affect land use or land with historical or archeological sites.

With regard to potential non-radiological environmental impacts, the proposed action does not result in any significant changes to land use or water use, or result in any significant changes to the quality or quantity of effluents. The proposed action does not affect non-radiological plant effluents, and no changes to the National Pollution Discharge Elimination System permit are needed. No effects on the aquatic or terrestrial habitat in the vicinity or the plant, or to endangered or threatened species, or to the habitats of endangered or threatened species are expected.

The proposed action will not change the method of generating electricity or the method of handling any influents from the environment or non-radiological effluents to the environment. Therefore, no changes or different types of non-radiological environmental impacts are expected as a result of the proposed action.

8. Summary

The proposed action will not significantly increase the probability or consequences of accidents, no changes are being made in the types of radioactive effluents that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational or public exposure. Accordingly, the staff concludes that there are no significant radiological environmental

impacts associated with the proposed action.

With regard to potential non-radiological impacts, the proposed action involves features located entirely within the restricted area, as defined in 10 CFR Part 20. It does not affect non-radiological plant effluents and is not expected to have any other environmental impact. Accordingly, the staff concludes that there are no significant non-radiological environmental impacts associated with the proposed action.

Environmental Impacts of Alternatives to the Proposed Action

1. Shipping Fuel to a Permanent Fuel Storage/Disposal Facility

Shipping of spent fuel to a high-level radioactive storage facility is an alternative to increasing onsite spent fuel storage capacity. The Department of Energy (DOE) has identified Yucca Mountain, Nevada, as the single candidate site for characterization as a potential geologic repository for high-level radioactive waste. However, this repository is not expected to begin receiving spent fuel until approximately 2025, provided that the DOE receives a license from the NRC. DOE plans to submit its license application for the proposed Yucca Mountain, Nevada, repository to the NRC in June 2008. Therefore, shipping spent fuel to the DOE repository is not considered an alternative to increased onsite spent fuel storage capacity at this time.

2. Shipping Fuel to a Reprocessing Facility

Reprocessing of spent fuel from CNS is not a viable alternative since there are no operating commercial reprocessing facilities in the United States. Therefore, spent fuel would have to be shipped to an overseas facility for reprocessing. However, this approach has never been used and would require approval by the Department of State as well as other entities. Additionally, the cost of spent fuel reprocessing is not offset by the current salvage value of the residual uranium; reprocessing would represent an added cost.

3. Shipping Fuel to Another Utility or SFP Site for Storage

The shipment of fuel to another utility's SFP for storage could provide short-term relief from the storage problem at CNS. The Nuclear Waste Policy Act of 1982 and 10 CFR Part 53, however, clearly place the responsibility for the interim storage of spent fuel with each owner or operator of a nuclear plant. SFPs at other nuclear stations have been designed with the capacity to accommodate each of those units and, therefore, transferring spent fuel from CNS to these pools would eventually create fuel storage capacity problems at those stations. The shipment of fuel to another site is not an acceptable alternative because of increased fuel handling risks and additional occupational radiation exposure, as well as the fact that no additional storage capacity would be created.

4. Alternative Creation of Additional Storage Capacity

Alternative technologies that would create additional storage capacity include rod consolidation, new SFP construction, dry cask storage, and modular vault dry storage. Rod consolidation involves disassembling the spent fuel assemblies and storing the fuel rods from two or more assemblies in a stainless steel canister that can be stored in the spent fuel racks. Industry experience with rod consolidation is currently limited, primarily due to concerns for potential gap activity release due to rod breakage, the potential for increased fuel cladding corrosion due to some of the protective oxide layers being scraped off, and concern that the prolonged consolidation activity could interfere with ongoing plant operations.

Dry cask storage is a method of transferring spent fuel, after storage in the pool for several years, to high-capacity casks with passive-heat dissipation features. After loading, the casks are stored outdoors on a seismically qualified concrete pad. The casks provide housing for the spent fuel in shielded steel cylinders in a horizontal configuration within a reinforced concrete vault. The concrete vault provides missile and earthquake protection and radiation shielding. Though CNS is in the process of evaluating dry cask storage as a long-term storage option, it is not an alternative for resolving the current need for full-core offload capability due to the long lead time for an NRC license, time requirements for site preparation and construction, and the limited production of the dry casks used for storage. For these reasons, dry cask storage is not the licensee's preferred short-term method of storage.

5. Reduction of Spent Fuel Generation

Generally, improved usage of the fuel and/or operation at a reduced power level would be an alternative that would decrease the amount of fuel being stored in the pool and thus increase the amount of time before full-core offload capacity is lost. With extended burnup of fuel assemblies, the fuel cycle would be extended and fewer offloads would be necessary. This is not an alternative for resolving the loss of full-core offload capacity that occurred as a result of the CNS refueling outage in January of 2005, because the spent fuel transferred to the pool for storage during this outage eliminated the licensee's ability to conduct a full-core offload. Operating the plant at a reduced power level would not make effective use of available resources, and would cause unnecessary economic hardship on the licensee and its customers. Therefore, reducing the amount of spent fuel generated by increasing burnup further or reducing power is not considered a practical alternative.

6. The No-Action Alternative

As an alternative to the proposed action, the staff considered denial of the proposed action. Denial of the amendment request would result in no change in current environmental impacts. The environmental impacts of the proposed amendment and this alternative are similar.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Cooper Nuclear Station Final Environmental Impact Statement dated February 1973.

Agencies and Persons Contacted

In accordance with its stated policy, on August 27, 2007, the staff consulted with the Nebraska State official, Ms. J. Schmitt of the Nebraska Department of HHS Regulation and Licensure, Office of Radiological Health, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's letter dated October 17, 2006, as supplemented by letters dated February 7, April 17, May 4, and July 26, 2007. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide

Document 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 301–415–4737, or send an e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 28th day of August, 2007.

For the Nuclear Regulatory Commission.

Carl F. Lyon,

Project Manager, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E7–17500 Filed 9–4–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–143–CO; ASLBP No. 07–857–01–CO–BD01]

Nuclear Fuel Services, Inc.; Establishment of Atomic Safety and Licensing Board

Pursuant to delegation by the Commission dated December 29, 1972, published in the **Federal Register**, 37 FR 28,710 (1972), and the Commission's regulations, *see* 10 CFR 2.104, 2.300, 2.303, 2.309, 2.311, 2.318, and 2.321, notice is hereby given that an Atomic Safety and Licensing Board is being established to preside over the following proceeding:

Nuclear Fuel Services, Inc., Special Nuclear Materials Facility (Confirmatory Order)

This Board is being established in response to requests for hearing that were filed pursuant to a Notice of Publication of Confirmatory Order and Opportunity for Hearing (72 Fed. Reg. 41,528 (July 30, 2007)), regarding a Confirmatory Order issued to Nuclear Fuel Services, Inc. (''NFS'') on February 21, 2007 that became immediately effective on the date of issuance. This proceeding arose from inspections and investigations at NSF by the NRC Staff that identified apparent violations for which escalated enforcement action was considered. The NRC Staff determined that its concerns regarding public health and safety could be resolved through confirmation of NFS's commitments as prescribed in the Confirmatory Order. Hearing requests have been submitted by: (1) Ken Silver, (2) R. Feher, (3) Linda Cataldo Modica on behalf of the Sierra Club, (4) Wanda Sue Kelley, (5) Barbara A. O'Neal, and (6) A. Christine Tipton.

The Board is comprised of the following administrative judges:

Lawrence G. McDade, Chair, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Dr. Richard F. Cole, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Dr. Peter S. Lam, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

All correspondence, documents, and other materials shall be filed with the administrative judges in accordance with 10 CFR 2.302.

Issued at Rockville, Maryland, this 29th day of August 2007.

E. Roy Hawkens,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. E7–17501 Filed 9–4–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–139]

Notice of License Termination for University of Washington Research Reactor (UWAR)

The U.S. Nuclear Regulatory Commission (NRC) is announcing the termination of facility Operating License No. R–73 for the University of Washington Research Reactor (UWAR).

The NRC has terminated the license of the decommissioned UWAR, at the University of Washington (UWA) in Seattle, Washington, and has released the site for unrestricted use. The UWAR was an Argonaut-type training and research reactor with an initial power output of 10 kilowatts, which later received authority to increase power output to 100 kilowatts. The reactor was permanently shut down on June 30, 1988. By application dated August 2, 1994, the licensee requested authorization to dismantle the UWAR and to dispose of the component parts, in accordance with the decommissioning plan submitted as part of the application. Opportunity for a hearing was afforded by ''Notice of Proposed Issuance of Orders Authorizing Disposition of Component Parts and Terminating Facility License'' published in the **Federal Register** on September 2, 1994 (59 FR 45738). No request for a hearing or petition for leave to intervene was filed following notice of the proposed action. The NRC reviewed the application with respect to the Commission's rules and regulations and found that the dismantling and disposal of component parts as stated in the licensee's decommissioning plan are consistent with the regulations in 10 CFR Chapter I and are not inimical to the common defense and security or to the health and safety of the public. On May 1, 1995, the Commission issued the ''Order Authorizing Dismantling of Facility and Disposition of Component Parts.''

The licensee conducted remediation activities and completed final status surveys in October 2006. The licensee's request for termination of the license was supported by the submittal of a Final Status Survey Report (FSSR). The NRC completed its review of the UWAR FSSR submitted to NRC by letter dated December 13, 2006, as supplemented February 26 and March 12, 2007. The FSSR documented the level of residual radioactivity remaining at the facility and stated that compliance with the criteria in the NRC-approved decommissioning plan for the reactor has been demonstrated. The NRC staff verified that the criteria in the approved decommissioning plan had been met and determined that the facility and site met the criteria in 10 CFR 20.1402 for unrestricted use.

Pursuant to 10 CFR 50.82(b)(6), the NRC staff has concluded that the reactor has been decommissioned in accordance with the approved decommissioning plan and that the terminal radiation survey and associated documentation demonstrate that the facility and site may be released in accordance with the criteria in the NRC-approved decommissioning plan. Further, on the basis of the decommissioning activities carried out by UWA, the NRC's review of the licensee's FSSR, the results of NRC inspections conducted at the UWAR, and the results of NRC confirmatory surveys, the NRC has concluded that the decommissioning process is complete and the facility and site may be released for unrestricted use. Therefore Facility Operating License No. R–73 is terminated.

For further details with respect to the proposed action, see the licensee's letter dated December 13, 2006, as supplemented February 26 and March 12, 2007; and NRC Inspection Report No. 50–139/2006–204, dated May 21, 2007. The above referenced documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR) 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 have problems in accessing the documents in ADAMS should call the NRC PDR reference staff at 1–800–397–4209 or 301–415–4737 or e-mail *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 29th day of August 2007.

For the Nuclear Regulatory Commission.

Keith I. McConnell,

Deputy Director, Decommissioning and Uranium Recovery Licensing Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Programs.

[FR Doc. E7–17494 Filed 9–4–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Sunshine Act Meetings

Agency Holding the Meetings: Nuclear Regulatory Commission.

Date: Weeks of September 3, 10, 17, 24, October 1, 8, 2007.

Place: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

Status: Public and Closed.

Matters To Be Considered

Week of September 3, 2007

Tuesday, September 4, 2007

2:30 p.m. Briefing on Radioactive Materials Security and Licensing (Public Meeting) (Contact: Robert Lewis, 301–415–8722).

This meeting will be webcast live at the Web address— *http://www.nrc.gov.*

Week of September 10, 2007—Tentative

There are no meetings scheduled for the Week of September 10, 2007.

Week of September 17, 2007—Tentative

There are no meetings scheduled for the Week of September 17, 2007.

Week of September 24, 2007—Tentative

There are no meetings scheduled for the Week of September 24, 2007.

Week of October 1, 2007—Tentative

Tuesday, October 2, 2007

9:30 a.m. Periodic Briefing on Security Issues (Closed—Ex. 1 & 3).

Wednesday, October 3, 2007

2 p.m. Briefing on NRC's International Programs, Performance, and Plans (Public Meeting) (Contact: Karen Henderson, 301–415–0202).

This meeting will be webcast live at the Web address— *http://www.nrc.gov.*

Week of October 8, 2007—Tentative

There are no meetings scheduled for the Week of October 8, 2007.

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*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Michelle Schroll, (301) 415–1662.

* * * * *

Additional Information

Affirmation of ''Pacific Gas and Electric Co. (Diablo Canyon ISFSI), Docket No. 72–26–ISFSI, San Luis Obispo Mothers for Peace's Contentions and Request for Hearing Regarding Diablo Canyon Environmental Assessment Supplement'' tentatively scheduled on August 30, 2007, at 9 a.m. has been postponed and not yet rescheduled.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/about-nrc/policy-making/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify the NRC's Disability Program Coordinator, Rohn Brown, at 301–492–2279, TDD: 301–415–2100, or by e-mail at *REB3@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov.*

Dated: August 30, 2007.

R. Michelle Schroll,

Office of the Secretary.

[FR Doc. 07–4351 Filed 8–31–07; 11:51 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 27958; 812–13387]

Rydex ETF Trust, et al.; Notice of Application

August 28, 2007.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application to amend a prior order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d), 22(e), and 24(d) of the Act and rule 22c–1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (a)(2) of the Act.

Summary of Application: Applicants request an order to amend a prior order that permits (a) An open-end management investment company comprised of multiple series based on domestic equity securities indexes (each a ''Fund'') to issue shares (''Shares'') that can be redeemed only in large aggregations (''Creation Units''); (b) secondary market transactions in Shares to occur at negotiated prices; (c) dealers to sell Shares to purchasers in the secondary market unaccompanied by a prospectus when prospectus delivery is not required by the Securities Act of 1933; and (d) certain affiliated persons of the Funds to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units (''Prior Order'').[1] Applicants seek to amend the Prior Order in order to offer two new series (the ''New Funds'') and future series (''Future Funds'') including Future Funds based on international equity securities indexes (collectively, this subset of Future Funds, together with the New Funds, the ''International Funds'').[2] In addition the order would delete a condition related to future relief in the Prior Order.

Applicants: Rydex ETF Trust (''Trust''), PADCO Advisors II, Inc. (''Adviser''), and Rydex Distributors, Inc. (''Distributor'').

[1] *Rydex ETF Trust, et al.,* Investment Company Act Release Nos. 25948 (Feb. 27, 2003) (notice) and 25970 (Mar. 25, 2003) (order).

[2] The existing Funds, the New Funds and the Future Funds are referred to collectively as the ''Funds.''

Filing Dates: The application was filed on May 23, 2007, and amended on August 6, 2007.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on September 24, 2007, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090; Applicants, 9601 Blackwell Road, Suite 500, Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Bruce R. MacNeil, Senior Counsel, at (202) 551–6817, or Michael W. Mundt, Assistant Director, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Public Reference Desk, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–0102 (telephone (202) 551–5850).

Applicants' Representations

1. The Trust, a Delaware statutory trust, is an open-end management investment company registered under the Act and is comprised of multiple Funds. The Adviser, which is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''), serves as investment adviser to each Fund. The Adviser may in the future retain one or more sub-advisers (''Sub-Advisers'') to manage particular Funds' portfolios. Any Sub-Adviser will be registered under the Advisers Act. The Distributor, a broker-dealer registered under the Securities Exchange Act of 1934 (''Exchange Act''), serves as the principal underwriter and distributor for the Funds.

2. The Trust currently offers Funds based on underlying equity income securities indexes (each an ''Underlying Index'') comprised of domestic equity securities in reliance on the Prior Order. Applicants seek to amend the Prior Order to permit the Trust to offer the New Funds, which are based on Underlying Indexes comprised of foreign equity securities.[3] The New Funds would operate in a manner identical to the existing Funds, except as described in the application (and summarized in this notice). No entity that creates, compiles, sponsors, or maintains an Underlying Index is or will be an affiliated person, as defined in section 2(a)(3) of the Act, or an affiliated person of an affiliated person, of a Trust, the Adviser, any Sub-Adviser, the promoter or Distributor of a Fund.

3. Under the Prior Order, each Fund is subject to the representation that it will invest at least 90% of its assets in the component securities of its Underlying Index (''Component Securities''). Applicants request relief to amend the prior order to permit a Fund to invest at least 80% or 90% of its assets, as disclosed in the relevant prospectus, in the Component Securities of the Underlying Index.[4] In addition, applicants request relief to permit each International Fund, for purposes of satisfying this requirement, to count certain depositary receipts (''Depositary Receipts'') that represent Component Securities as well as Component Securities. Applicants represent that each International Fund would thus invest at least 80% of its assets in the Component Securities of its Underlying Index and Depositary Receipts representing such Component Securities.[5] Applicants state that an International Fund generally would only hold Depositary Receipts if the Adviser believed that holding the Depositary Receipts, rather than holding the Component Securities, would benefit the International Fund.

4. Applicants state that all discussions contained in the application for the Prior Order are equally applicable to the New Funds, except as specifically noted by applicants (as summarized in this notice). Applicants assert that the New Funds will operate in a manner identical to the existing Funds and will comply with all of the terms, provisions and conditions of the Prior Order, as amended by the present application. Applicants believe that the requested relief continues to meet the necessary exemptive standards.

Applicants' Legal Analysis

Section 22(e) of the Act

1. In connection with applicants' request for relief to permit the operations of the New Funds, applicants seek to amend the Prior Order to add relief from section 22(e) of the Act. Section 22(e) generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. The principal reason for the requested exemption is that settlement of redemptions for the International Funds is contingent not only on the settlement cycle of the United States market, but also on currently practicable delivery cycles in local markets for underlying foreign securities held by the International Funds. Applicants state that local market delivery cycles for transferring certain foreign securities to investors redeeming Creation Units, together with local market holiday schedules, will, under certain circumstances, require a delivery process in excess of seven calendar days for the International Funds. Applicants request relief under section 6(c) of the Act from section 22(e) in such circumstances to allow the International Funds to pay redemption proceeds up to 14 calendar days after the tender of any Creation Units for redemption. At all other times and except as disclosed in the relevant prospectus, product description, or statement of additional information (''SAI''), applicants expect that each International Fund will be able to deliver redemption proceeds within seven days.[6] With respect to Future Funds that are International Funds, applicants seek the same relief from section 22(e) only to the extent that circumstances similar to those described in the application exist.

2. Applicants state that section 22(e) was designed to prevent unreasonable, undisclosed and unforeseen delays in the payment of redemption proceeds. Applicants assert that the requested relief will not lead to the problems that

[3] The New Funds will seek to track the S&P International Equal Weight Index and the Russell Emerging Markets Index.

[4] Applicants state that at all times a Fund will hold, in the aggregate, at least 80% of its total assets in Component Securities and investments that have economic characteristics that are substantially identical to the economic characteristics of the Component Securities of its Underlying Index.

[5] Applicants state that the Depositary Receipts will be listed on a national securities exchange, as defined in section 2(a)(26) of the Act (''Exchange'') or a foreign exchange. The Adviser, Sub-Adviser and their affiliated persons will not serve as the depositary bank for any Depositary Receipts held by an International Fund.

[6] Rule 15c6–1 under the Exchange Act requires that most securities transactions be settled within three business days of the trade. Applicants acknowledge that no relief obtained from the requirements of section 22(e) will affect any obligations applicants may have under rule 15c6–1.

section 22(e) was designed to prevent. Applicants state that the SAI for each International Fund will disclose those local holidays (over the period of at least one year following the date of the SAI), if any, that are expected to prevent the delivery of redemption proceeds in seven calendar days, and the maximum number of days needed to deliver the proceeds for the relevant International Fund.

Future Relief

3. Applicants also seek to amend the Prior Order to modify the terms under which the Trust may offer Future Funds. The Prior Order is currently subject to a condition that does not permit relief for Future Funds unless applicants request and receive with respect to such Future Fund, either exemptive relief from the Commission or a no-action letter from the Division of Investment Management of the Commission, or the Future Fund could be listed on an Exchange without the need for a filing pursuant to rule 19b–4 under the Exchange Act.

4. The order would amend the Prior Order to delete this condition. Any Future Fund will: (a) Be advised by the Adviser, or an entity controlled by or under common control with the Adviser; (b) track an Underlying Index that is created, compiled, sponsored or maintained by an entity that is not an affiliated person, as defined in section 2(a)(3) of the Act, or an affiliated person of an affiliated person, of the Adviser, the Distributor, the Trust or any Sub-Adviser or promoter of a Fund; and (c) comply with the respective terms and conditions of the Prior Order, as amended by the present application.

5. Applicants believe that the modification of the future relief available under the Prior Order would be consistent with sections 6(c) and 17(b) of the Act and that granting the requested relief will facilitate the timely creation of Future Funds by removing the need to seek additional exemptive relief. Applicants submit that the terms and conditions of the Prior Order have been appropriate for the existing Funds and would remain appropriate for Future Funds. Applicants also submit that tying exemptive relief under the Act to the ability of a Future Fund to be listed on an Exchange without the need for a rule 19b–4 filing under the Exchange Act is not necessary to meet the standards under sections 6(c) and 17(b) of the Act.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the same conditions as those imposed by the Prior Order, except for condition 1 to the Prior Order, which will be deleted.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Nancy M. Morris,

Secretary.

[FR Doc. E7–17499 Filed 9–4–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56330; File No. SR–Amex–2007–92]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Amending the Payment for Order Flow Plan To Apply the Current Marketing Fee to Orders Sent to Directed Order Participants

August 28, 2007.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 20, 2007, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by the Exchange. Amex has designated this proposal as one establishing or changing a due, fee, or other charge imposed by Amex under section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Payment for Order Flow Plan to apply the current marketing fee to orders sent to Directed Order Participants.[5] The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.amex.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. Amex has substantially prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the current fee schedule to apply the marketing fee charged to equity options (the ''Payment for Order Flow Plan'') to orders sent to Directed Order Participants.[6]

A Directed Order Participant may choose to opt in or opt out of the Payment for Order Flow Plan.[7] If the Directed Order Participant chooses to opt into the Payment for Order Flow Plan, the Exchange will collect the applicable marketing fee per contract from the participating specialists, ROTs, RROTs, and SROTs, for all electronic customer orders directed to that Directed Order Participant. The pool of funds collected would be used to fund

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The Exchange's Directed Order Program (the ''Program'') was recently approved by the Commission. *See* Securities Exchange Act Release No. 56269 (August 15, 2007), 72 FR 47086 (August 22, 2007) (Notice of Filing and Order Granting Accelerated Approval of SR–Amex 2007–75). A Directed Order Participant, as defined in proposed Rule 996–ANTE is any specialist, Registered Options Trader (''ROT''), Supplemental Registered Options Trader (''SROT''), and Remote Registered Options Trader (''RROT'') that enters into arrangements with an Order Flow Provider, whereby they could receive directed orders upon meeting certain eligibility requirements.

[6] Under the current plan, the Exchange charges an equity options marketing fee of $0.75, $0.35, or $0.40 per contract solely to customer orders that are from payment accepting firms with whom a specialist or SROT has negotiated a payment for order flow arrangement. SPDR Options are currently subject to a $1.00 or $.40 per contract fee. The $0.75 and $0.35 fee solely applies to those orders that are executed electronically through the Exchange's ANTE system, while the $0.40 fee applies to those series of equity options, exchange traded fund share options (including SPY options), Trust Issued Receipt Options, NDX, and RUT options that are manually executed customer orders of 1,000 contracts or greater.

[7] Once a Directed Order Participant opts into the Payment for Order Flow Plan, no notice to the Exchange is required in a subsequent month unless there is a change in the participation status.

Payment for Order Flow arrangements with payment accepting firms.

A Directed Order Participant who chooses to opt into the Payment for Order Flow Plan must notify the Exchange of the election to participate in the Payment for Order Flow Plan no later than two business days prior to the date on which the marketing fee would be assessed. Directed Order Participants may only opt into or out of the Exchange's Payment for Order Flow Plan one time in any given month. If at any time during a month a Directed Order Participant opts into the Payment for Order Flow Plan, the marketing fee would be assessed for that remaining portion of the month commencing on the third business day following notice to the Exchange.

Directed Order Participants who enter into a Payment for Order Flow arrangement with an Order Flow Provider will be given instructions as to how to submit their payment directions. The Exchange will not be involved in negotiating the terms governing the orders that qualify for payment or the amount of any payment. The Exchange will, however, pay the requested amount to the Order Flow Provider on behalf of the Directed Order Participant. The requested amount is limited to the amount billed and collected for that month, plus any excess funds that were carried over from previous months (funds collected but not requested by a Directed Order Participant).

The Exchange will further provide administrative support for the program in such matters as maintaining the funds, keeping track of the number of qualified orders each Directed Order Participant directs to the Exchange, and making payments to the Order Flow Providers on behalf of, and at the direction of, the Directed Order Participants.

Separate pools of funds will be available to each Directed Order Participant solely for those trades where the marketing fee was assessed, at the post it was collected. This pool of funds will be used by each Directed Order Participant to attract customer orders to the Exchange from Order Flow Providers.[8] The Exchange notes that Directed Order Participants are limited to spending any funds collected from SROTs only in those options classes in which the SROT is able to trade. Directed Order Participants participating in the Exchange's current Payment for Order Flow Plan will be rebated any unused funds at the end of a quarter on a pro rata basis.[9]

Finally, the Exchange proposes to amend Footnote 11 in the Options Fee Schedule, to clarify that that the $.40 options marketing fee, which only applies to manually executed orders, shall not be applicable to Directed Orders, since they are solely electronically executed orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act[10] in general, and section 6(b)(4) of the Act[11] in particular, in that it is designed to provide for an equitable allocation of reasonable dues, fees, and other charges among exchange members and other persons using exchange facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has been designated as a fee change pursuant to section 19(b)(3)(A)(ii) of the Act[12] and Rule 19b–4(f)(2)[13] thereunder, because it establishes or changes a due, fee, or other charge imposed by the Exchange. Accordingly, the proposal will take effect upon filing with the Commission. At any time within 60 days of the filing of such proposed rule change the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, 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–Amex–2007–92 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F. Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Amex–2007–92. 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–Amex–2007–92 and should be submitted on or before September 26, 2007.

[8] The Exchange notes that if a specialist acts as a Directed Order recipient and specialist, there shall be two separate pools of funds collected for each.

[9] Specialists, SROTs, RROTs, or ROTs participating in the Exchange's current marketing fee program are rebated any unused funds at the end of a quarter on a pro rata basis.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4).

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

[13] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Nancy M. Morris,

Secretary.

[FR Doc. E7–17478 Filed 9–4–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56331; File No. SR–Amex–2007–93]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the Options Directed Order Participant Transaction Charge Rebate Program

August 28, 2007.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 20, 2007, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by the Exchange. Amex has designated this proposal as one establishing or changing a due, fee, or other charge imposed by Amex under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the transaction charge rebates currently applicable to supplemental registered options traders (''SROTs'') to all Directed Order Participants. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.amex.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. Amex has substantially prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the options transaction charge[5] rebates currently applicable to SROTs[6] to all Directed Order Participants (including SROTs) that provide liquidity to the Exchange and receive electronic directed customer orders (the ''Directed Order Fee Rebate Program''). This Directed Order Fee Rebate Program would provide fee rebates to Directed Order Participants that provide order flow to the Exchange from an order flow provider firm.[7]

This proposal would allow the Exchange to provide Directed Order Participants with options transaction charge rebates for the number of options contracts that are electronically directed to them and executed on the Exchange. The following rebate schedule is proposed:

Monthly directed order volume (in contracts)	Rebate per contract
0–1,000,000	$0.05
1,000,001–2,000,000	.10
2,000,001–3,000,000	.125
3,000,001 and up	.15

Rebates would be capped at 100% of transaction charges so that once a Directed Order Participant's transaction charges reach zero, the Exchange would not pay out any additional credits.[8]

The Exchange notes that Directed Order Participants are entitled to the options transaction charge rebate, which is separate and apart from the Exchange's Payment for Order Flow Plan.[9] The proposed options transaction charge rebate, which is provided to Directed Order Participants, will not come from the marketing fees collected on those transactions.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[10] in general, and Section 6(b)(4) of the Act[11] in particular, in that it is designed to provide for an equitable allocation of reasonable dues, fees, and other charges among exchange members and other persons using exchange facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has been designated as a fee change pursuant to Section 19(b)(3)(A)(ii) of the Act[12] and Rule 19b–4(f)(2)[13] thereunder, because it establishes or changes a due, fee, or other charge imposed by the Exchange. Accordingly, the proposal will take effect upon filing with the Commission. At any time within 60 days of the filing of such proposed rule change the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing,

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The options transaction charge is the collective of the Options Transaction Fee, the Options Comparison Fee, and the Options Floor Brokerage fee, as noted on the Options Fee Schedule.

[6] *See* Securities Exchange Act Release No. 56002 (July 2, 2007), 72 FR 37548 (July 10, 2007) (SR–Amex 2007–55).

[7] *See* Securities Exchange Act Release No. 56269 (August 15, 2007), 72 FR 47086 (August 22, 2007) (Notice of Filing and Order Granting Accelerated Approval of SR–Amex 2007–75). Generally, for purposes of the Directed Order Flow Program, a directed order is deemed to be an electronic customer order from an order flow provider that is directed to a specific specialist, registered options trader (''ROT''), SROT, or remote registered options trader (''RROT'').

[8] For example, a Directed Order Participant which pays $100,000 in transaction charges per month, could not receive more than a $100,000 rebate.

[9] *See supra* note 7.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4).

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

[13] 17 CFR 240.19b–4(f)(2).

including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–Amex–2007–93 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Amex–2007–93. 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–Amex–2007–93 and should be submitted on or before September 26, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Nancy M. Morris,

Secretary.

[FR Doc. E7–17479 Filed 9–4–07; 8:45 am]

BILLING CODE 8010–01–P

[14] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 11012 and # 11013]

Ohio Disaster # OH–00012

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Ohio (FEMA–1720–DR), dated 08/27/2007.

Incident: Severe Storms, Flooding, and Tornadoes.

Incident Period: 08/20/2007 and continuing.

Effective Date: 08/27/2007.

Physical Loan Application Deadline Date: 10/26/2007.

Economic Injury (EIDL) Loan Application Deadline Date: 05/27/2008.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 08/27/2007, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans):

Allen, Crawford, Hancock, Putnam, Richland, Wyandot.

Contiguous Counties (Economic Injury Loans Only):

Ohio: Ashland, Auglaize, Defiance, Hardin, Henry, Huron, Knox, Marion, Morrow, Paulding, Seneca, Van Wert, Wood.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	6.250
Homeowners Without Credit Available Elsewhere	3.125
Businesses With Credit Available Elsewhere	8.000
Other (Including Non-Profit Organizations) With Credit Available Elsewhere	5.250
Businesses And Non-Profit Organizations Without Credit Available Elsewhere	4.000
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 110126 and for economic injury is 110130.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E7–17528 Filed 9–4–07; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 10968]

Vermont Disaster Number VT–00005

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Vermont (FEMA–1715–DR), dated 08/03/2007.

Incident: Severe Storms and Flooding.

Incident Period: 07/09/2007 through 07/11/2007.

Effective Date: 08/24/2007.

Physical Loan Application Deadline Date: 10/02/2007.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of VERMONT, dated 08/03/2007, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties:

Caledonia, Orleans.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E7–17530 Filed 9–4–07; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Washington, DC District Advisory Council: Public Meeting

Pursuant to the Federal Advisory Committee Act, Appendix 2 of Title 5, United States Code, Public Law 92–463, notice is hereby given that the U.S. Small Business Administration, Washington, DC District Advisory Council will host a federal public meeting on Monday, October 22, 2007 from 10 a.m until 12:30 p.m. The meeting will be held at the Washington Metropolitan Area District Office located at 740 15th Street, NW., 3rd Floor, Washington, DC 20005.

The purpose of the meeting is to discuss the district's FY 2008 goals, update on new initiatives and other matters that may be presented by members and staff of the U.S. Small Business Administration's Washington Metropolitan Area District Office or others present.

Anyone wishing to attend or make an oral presentation to the Board must contact Joseph P. Loddo in writing by letter or fax no later than Monday, October 1, 2007. Joseph P. Loddo, District Director, Washington Metropolitan Area District Office, 740 15th Street, NW., 3rd Floor, Washington, DC 20005. Telephone (202) 272–0345 or Fax (202) 481–1656.

Matthew Teague,

Committee Management Officer.

[FR Doc. E7–17527 Filed 9–4–07; 8:45 am]

BILLING CODE 8025–01–P

OFFICE OF SPECIAL COUNSEL

Privacy Act of 1974; Systems of Records

AGENCY: Office of Special Counsel

ACTION: Notice of systems of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, this notice describes two U.S. Office of Special Counsel (OSC) systems of records consisting of internal agency administrative records dealing with employee security and suitability and pay management. The public is invited to comment on these notices.

DATES: Public comments must be received by October 5, 2007. The proposed routine uses will become effective without change and without further notice on October 15, 2007, unless comments are received that result in a contrary determination by OSC.

ADDRESSES: Written comments should be sent by mail to: Office of Special Counsel, 1730 M. Street, NW., Suite 218, Washington, DC 20036–4505, Attention: Kathryn Stackhouse, or by fax to (202) 653–5161, Attn: Kathryn Stackhouse.

FOR FURTHER INFORMATION CONTACT: Kathryn Stackhouse, General Law Counsel, Office of Special Counsel, by telephone at (202) 254–3600 or (800) 877–8339 (TDD), or by fax at (202) 653–5161.

SUPPLEMENTARY INFORMATION: This notice describes two systems of records consisting of internal agency administrative records dealing with employee security and suitability and pay management. Implementation of the system identified in this notice as OSC–2 (Personnel Security Records) will facilitate OSC's collection and management of personnel security information needed to comply with Homeland Security Presidential Directive (HSPD) 12 (''Policy for a Common Identification Standard for Federal Employees and Contractors''), dated August 27, 2004, and implementing guidance issued by the Office of Management and Budget. The records covered by OSC–2 are those dealing with decisions about clearance for access to classified information; suitability, eligibility, and fitness for service of applicants for federal employment and contract positions, including students, interns, volunteers and other individuals to the extent their duties require access to federal facilities, information, systems, or applications. Records covered by the system proposed as OSC–3 (Pay Management Records) are those dealing with pay and leave.

OSC–2

SYSTEM NAME:

Personnel Security Records

SYSTEM LOCATION:

Security Office, U.S. Office of Special Counsel, 1730 M. Street, NW., Suite 218, Washington, DC 20036–4505.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who require regular, ongoing access to federal facilities, information technology systems, or information classified in the interest of national security, including applicants for employment or contracts, federal employees, temporary hires, contractors, students, interns (both paid and unpaid), volunteers, affiliates, individuals authorized to perform services provided in OSC facilities (e.g., building security, office cleaning, building contractors, etc.), and individuals formerly in any of these positions. The system also includes individuals accused of security violations or found in violation.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, former names, birth date, birth place, Social Security number, home address, phone numbers, employment history, residential history, education and degrees earned, names of associates and references and their contact information, citizenship, names of relatives, birthdates and places of relatives, citizenship of relatives, names of relatives who work for the federal government, criminal history, mental health history, drug use, financial information, fingerprints, summary report of investigation, results of suitability decisions, level of security clearance, date of issuance of security clearance, requests for appeal, witness statements, investigator's notes, tax return information, credit reports, security violations, circumstances of violation, and agency action taken; Standard Forms SF–85, SF–85P, SF–86, SF–86C, SF–87, FD–258.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Depending upon the purpose of the investigation, the U.S. government is authorized to ask for this information under Executive orders 10450, 10865, 12333, and 12356; 5 U.S.C. 3301 and 9101; 42 U.S.C. 2165 and 2201; 50 U.S.C. 781–887; 5 C.F.R. parts 5, 732, and 736; and HSPD 12.

PURPOSES:

The records in this system of records are used to document and support decisions about clearance for access to classified information, the suitability, eligibility, and fitness for service of applicants for federal employment and contract positions, including students, interns, volunteers and other individuals to the extent their duties require access to federal facilities, information, systems, or applications. The records may be used to document security violations and supervisory actions taken.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

When determined by OSC that disclosure of a record is a use of information in the record compatible with the purpose for which the record was collected -

a. To the Department of Justice (DOJ) when:

(1) The OSC, or

(2) Any employee of the OSC in his or her official capacity, or

(3) Any employee of the OSC in his or her individual capacity when the DOJ has been asked, or has agreed, to represent the employee, or

(4) The United States, when the OSC determines that litigation is likely to affect the agency, is a party to litigation, or has an interest in such litigation, and the use of such records by the DOJ is deemed by the OSC to be relevant and necessary to the litigation.

b. To a court or adjudicative body in a proceeding, when:

(1) The OSC, or

(2) Any employee of the OSC in his or her official capacity,

(3) Any employee of the OSC in his or her individual capacity when the OSC has agreed to represent the employee, or

(4) The United States, when the OSC determines that litigation is likely to affect the OSC, is a party to litigation or has an interest in such litigation, and the use of such records by the DOJ is deemed by the OSC to be relevant and necessary to the litigation.

c. Except as noted on Standard Forms SF 85, 85–P, 86, and 86–C, when a record, alone or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant to such a statute, to the appropriate public authority, whether federal, state, local, foreign, tribal, or otherwise, responsible for enforcing, investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant to the statute, if the information disclosed is relevant to any enforcement, regulatory, investigative or prosecutorial responsibility of the receiving entity.

d. To a congressional office in response to an inquiry from that office made at the written request of the constituent about whom the record is maintained.

e. To the National Archives and Records Administration (NARA) for records management functions authorized by laws, regulations, and policies governing NARA operations and agency records management responsibilities.

f. To agency contractors, experts, consultants, detailees, or non-OSC employees performing or working on a contract, service, or other activity related to the system of records, subject to the requirements of the Privacy Act, when necessary to accomplish an agency function related to the system of records.

g. To any source or potential source from which information is requested in the course of an investigation concerning the retention of an employee or other personnel action (other than hiring), or the retention of a security clearance, contract, grant, license, or other benefit, to the extent necessary to identify the individual, inform the source of the nature and purpose of the investigation, and to identify the type of information requested.

h. To a federal, state, local, foreign, or tribal or other public authority the fact that this system of records contains information relevant to the retention of an employee, the retention of a security clearance, the letting of a contract, or the issuance or retention of a license, grant, or other benefit. The other agency or licensing organization may then make a request supported by the written consent of the individual for the entire record if it so chooses. No disclosure will be made unless the information has been determined to be sufficiently reliable to support a referral to another office within the agency or to another federal agency for criminal, civil, administrative personnel or regulatory action.

i. To the news media or the general public, factual information the disclosure of which would be in the public interest and which would not constitute an unwarranted invasion of personal privacy, consistent with Freedom of Information Act standards.

j. To a federal, state, or local agency, or other appropriate entities or individuals, or through established liaison channels to selected foreign governments, in order to enable an intelligence agency to carry out its responsibilities under the National Security Act of 1947 as amended, the CIA Act of 1949 as amended, Executive Order 12333 or any successor order, applicable national security directives, or classified implementing procedures approved by the Attorney General and promulgated pursuant to such statutes, orders or directives.

k. To the Office of Management and Budget (OMB) when necessary to the review of private relief legislation pursuant to OMB Circular No. A–19.

l. To appropriate agencies, entities, and persons when: (1) The OSC suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) the OSC has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the OSC or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with OSC efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on paper in a secure location on government premises.

RETRIEVABILITY:

Background investigation files are retrieved by name.

SAFEGUARDS:

Records are kept in a locked metal file cabinet in a lockable room at the OSC office responsible for suitability determinations. Access to the records is limited to those employees who have a need for them in the performance of their official duties.

RETENTION AND DISPOSAL:

Records in the system are retained and disposed of in accordance with General Records Schedule 18, item 22a, issued by NARA. The records are disposed of in accordance with OSC's disposal policies which call for shredding. Records are destroyed upon notification of death or not later than six months after separation or transfer of employee to another agency or department, whichever is applicable.

SYSTEM MANAGER AND ADDRESS:

Security Officer, U.S. Office of Special Counsel, 1730 M. Street, NW., Suite 218, Washington, DC 20036–4505.

NOTIFICATION PROCEDURES:

Individuals who wish to inquire whether this system contains information about them should contact the Privacy Act Officer, U.S. Office of Special Counsel: (1) by mail at: 1730 M. Street, NW., Suite 218, Washington, DC 20036–4505; (2) by telephone at: 202–254–3600; or (3) by fax at: 202–653–5161. To assist in the process of locating and identifying records, individuals should furnish the following:

a. Name and home address;

b. Business title and address;

c. A description of the circumstances under which records may have been included in the system; and

d. Any other information deemed necessary by OSC to properly process the request.

RECORDS ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Rules about access to Privacy Act records appear in 5 C.F.R. part 1830.

CONTESTING RECORD PROCEDURES:

Individuals who wish to contest records about themselves should contact the OSC Privacy Act Officer, identify any information they believe should be corrected, and furnish a statement of the basis for the requested correction along with all available supporting documents and materials. See OSC Privacy Act regulations at 5 C.F.R. part 1830.

RECORD SOURCE CATEGORIES:

Information is obtained from a variety of sources including the employee, contractor, or applicant through use of the SF–85, SF–85P, SF–86, or SF–86C and personal interviews; employers' and former employers' records; FBI criminal history records and other databases; financial institutions and credit reports; medical records and health care providers; educational institutions; interviews of witnesses such as neighbors, friends, co-workers, business associates, teachers, landlords, or family members; tax records; and other public records. Security violation information is obtained from a variety of sources, such as guard reports, security inspections, witnesses, supervisor's reports, audit reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Upon publication of a final rule in the **Federal Register**, this system of records will be exempt in accordance with 5 U.S.C. 552a(k)(5). Information will be withheld to the extent it identifies witnesses promised confidentiality as a condition of providing information during the background investigation.

OSC–3

SYSTEM NAME:

Pay Management Records

SYSTEM LOCATION:

Human Resources Branch, U.S. Office of Special Counsel, 1730 M. Street, NW., Suite 218, Washington, DC 20036–4505, and in the offices of other federal agencies or entities retained by OSC to provide administrative processing services, including associated budget, accounting, audit, and other oversight functions.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former OSC employees, including consultants.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains financial information relating to pay, cash awards and leave awards, incentive payments, deductions and payments to other accounts, leave, and time and attendance. This includes, but is not limited to, information such as name, date of birth, social security number, home address, grade, employing organization, salary, pay plan, number of hours worked, leave accrual rate, usage, and balances; Civil Service Retirement System and Federal Employees Retirement System contributions, including Thrift Savings Plan data; Federal Insurance Contributions Act (FICA) withholdings; federal, state, and local tax withholdings; Federal Employee Group Life Insurance (FEGLI) withholdings; Federal Employee Health Benefits (FEHB) withholdings; charitable deductions; allotments to financial organizations; garnishment data; savings bond allotments; deductions for Internal Revenue Service (IRS) levies; court-ordered child support levies; federal salary offset deductions; injury compensation; unemployment compensation; leave transfer program data; direct deposit accounts; time and attendance reports; and leave requests and approvals.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 1212, and chapters 55 and 63; 31 U.S.C. 1501(a); and the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) (Pub. L. 104–193).

PURPOSE:

To administer agency pay and leave functions and obligations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

When determined by OSC, or by other agencies or entities retained by OSC to provide administrative processing services, that disclosure of a record is a use of information in the record compatible with the purpose for which the record was collected -

a. To authorized employees of other agencies retained by the OSC to provide administrative processing services, including associated budget, accounting, audit, and other oversight functions.

b. To the Department of the Treasury in connection with issuance of funds electronically and by check, and U.S. Savings Bonds.

c. To the Department of Labor (DOL) in connection with a claim by an employee for compensation based on job-connected injury or illness.

d. To state and District of Columbia offices of unemployment compensation in connection with a claim by a former employee for unemployment compensation.

e. To federal, state, and local tax authorities and the Social Security Administration (SSA) in connection with income tax withholding, FICA tax withholding and other employment tax withholding and benefits.

f. To the Office of Personnel Management (OPM) in connection with payroll deductions for federal employee retirement systems, or otherwise as needed in the performance of its duties.

g. To FEGLI and FEHB plan providers in connection with survivor annuity or health benefits enrollment, claims, or records reconciliation.

h. To the Combined Federal Campaign in connection with authorized payroll deductions for charitable contributions.

i. To banking institutions in enabling individual receipt of payments by direct deposit and electronic funds transfer.

j. To any source from which OSC requests information relevant to an OSC determination about an individual's pay, deductions, reimbursement, leave, or related transaction, to the extent necessary to identify the individual, inform the source of the purpose of the request, and describe the type of information requested.

k. To a congressional office in response to an inquiry from that office made at the written request of the constituent about whom the record is maintained.

l. If the individual to whom the record pertains dies, to the executor or personal representative of the estate of the individual, the individual's designee or designated beneficiary, or next of kin, in connection with estate administration.

m. To the Office of Management and Budget (OMB) when necessary to the review of private relief legislation pursuant to OMB Circular No. A–19.

n. To the Department of Justice (DOJ), OPM, DOL, IRS, or other agency with subject matter expertise to the extent necessary to obtain advice on any

authorities, programs, or functions associated with records in this system.

o. When a record, alone or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant to such a statute, disclosure may be made to the appropriate public authority, whether federal, state, local, foreign, or otherwise, responsible for enforcing, investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant to the statute, if the information disclosed is relevant to any enforcement, regulatory, investigative or prosecutorial responsibility of the receiving entity.

p. To agency contractors, experts, consultants, detailees, or non-OSC employees performing or working on a contract, service, or other activity related to the system of records, subject to the requirements of the Privacy Act, when necessary to accomplish an agency function related to the system of records.

q. To a federal, state, or local agency requesting information for purposes associated with the hiring or retention of an employee, the conduct of a suitability or security investigation, the issuance of a security clearance, the classification of a job, the letting of a contract, or the issuance of a license, grant or other benefit, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

r. To the National Archives and Records Administration (NARA) for records management functions authorized by laws, regulations, and policies governing NARA operations and agency records management responsibilities.

s. To OMB for the purpose of providing reports required of OSC in carrying out OSC's financial and other management functions.

t. To DOJ when:

(1) The OSC, or

(2) Any employee of the OSC in his or her official capacity, or

(3) Any employee of the OSC in his or her individual capacity when the DOJ has been asked, or has agreed, to represent the employee, or

(4) The United States, when the OSC determines that litigation is likely to affect the agency, is a party to litigation, or has an interest in such litigation, and the use of such records by the DOJ is deemed by the OSC to be relevant and necessary to the litigation.

u. To disclose records maintained by the OSC in a proceeding before a court or adjudicative body before which the OSC is authorized to appear, when:

(1) The OSC, or

(2) Any employee of the OSC in his or her official capacity,

(3) Any employee of the OSC in his or her individual capacity when the OSC has agreed to represent the employee, or

(4) The United States, when the OSC determines that litigation is likely to affect the OSC,

v. is a party to litigation or has an interest in such litigation, and the use of such records by the DOJ is deemed by the OSC to be relevant and necessary to the litigation.

w. To disclose information to a grievance or complaint examiner, equal employment opportunity counselor or investigator, or other federal official engaged in investigating, or settling, a grievance, complaint, or appeal filed by an employee, or disciplinary or competence determination proceedings, when the OSC determines that use of such records is relevant and necessary to the matter.

x. To an employer for the purpose of effecting salary or administrative offsets to satisfy a debt owed the United States by the record subject, in accordance with the requirements of federal debt collection laws.

y. To a court of competent jurisdiction, an authorized official, or authorized state agency, as defined in 5 C.F.R. parts 581 and 582, in compliance with orders, interrogatories, and other information requests relevant to garnishment orders with which OSC is required to comply under applicable federal law.

z. To the Department of Health and Human Services child support enforcement office, for the purpose of locating individuals to establish paternity, establishing and modifying orders of child support, identifying sources of income; and for other child support enforcement actions pursuant to the PRWORA, the names, social security numbers, home addresses, dates of birth, dates of hire, quarterly earnings, employer identifying information, and state of hire of employees.

aa. To appropriate agencies, entities, and persons when: (1) the OSC suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) the OSC has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the OSC or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with OSC efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

These records are maintained in file folders and on electronic media, including at such other agency or entity as the OSC may retain to provide administrative processing services, including associated budget, accounting, audit, and other oversight functions.

RETRIEVABILITY:

Files in this system of records are retrieved by the names of individuals, and when accessed electronically, by Social Security number.

SAFEGUARDS:

Records in file folders are stored by the OSC in secured areas on government premises. Records on computers may only be accessed by those authorized personnel who have a need for access to perform their duties, or to those individuals on whom the record is maintained. Electronic records are only accessible using passwords and other system protection methods.

RETENTION AND DISPOSAL:

These records are kept by OSC in accordance with retention periods for such records established by NARA in applicable General Records Schedules.

SYSTEM MANAGER AND ADDRESS:

Director, Human Resources Branch, U.S. Office of Special Counsel, 1730 M. Street, NW., Suite 218, Washington, DC 20036–4505.

NOTIFICATION PROCEDURES:

Individuals who wish to inquire whether this system contains information about them should contact the Privacy Act Officer, U.S. Office of Special Counsel: (1) by mail at: 1730 M. Street, NW., Suite 218, Washington, DC 20036–4505; (2) by telephone at: 202–254–3600; or (3) by fax at: 202–653–5161. To assist in the process of locating and identifying records, individuals should furnish the following:

a. Name and home address;

b. Business title and address;

c. A description of the circumstances under which records may have been included in the system; and

d. Any other information deemed necessary by OSC to properly process the request.

RECORDS ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Rules about access to Privacy Act records appear in 5 C.F.R. part 1830.

CONTESTING RECORD PROCEDURES:

Individuals who wish to contest records about themselves should contact the OSC Privacy Act Officer, identify any information they believe should be corrected, and furnish a statement of the basis for the requested correction along with all available supporting documents and materials. See OSC Privacy Act regulations at 5 C.F.R. part 1830.

RECORD SOURCE CATEGORIES:

Information in this system of records is obtained from a number of sources, including the individual to whom the record pertains, officials in OSC, official personnel records at OSC, OPM, IRS, SSA, DOL, and state government offices, and courts.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

OSC reserves the right to assert exemptions for records received from another agency that could be properly claimed by that agency in responding to a request. OSC may, pursuant to subsection (d)(5) of the Privacy Act (5 U.S.C. 552a), refuse access to information compiled in reasonable anticipation of a civil action or proceeding.

Dated: August 29, 2007.

James Byrne,

Deputy Special Counsel.

[FR Doc. E7–17496 Filed 9–4–07; 8:45 am]

BILLING CODE 7405–01–S

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending July 27, 2007

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 et. seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: OST–2005–21841.

Date Filed: July 24, 2007.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: August 14, 2007.

Description: Application of Comlux Aviation AG, (''Comlux Aviation'') requesting an exemption and an amended foreign air carrier permit authorizing Comlux Aviation to engage in charter foreign air transportation of persons, property and mail to the full extent permitted by the U.S.-Switzerland open skies agreement using large aircraft.

Docket Number: OST–2007–28867.

Date Filed: July 26, 2007.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: August 16, 2007.

Description: Application of Pinnacle Airlines, Inc., requesting a certificate of public convenience and necessity to engage in scheduled interstate air transportation of persons, property, and mail between the United States and Canada.

Docket Number: OST–2007–28868.

Date Filed: July 26, 2007.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: August 16, 2007.

Description: Application of Pinnacle Airlines, Inc., requesting a certificate of public convenience and necessity to engage in scheduled foreign air transportation of persons, property, and mail from points in the United States to a point or points in Canada.

Docket Number: OST–2006–26328.

Date Filed: July 26, 2007.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: August 16, 2007.

Description: Application of VistaJet Luftfahrtunternehmen GmbH, (''VistaJet'') requesting an exemption and an amended foreign air carrier permit Authorizing VistaJet to conduct the following services using small aircraft, in addition to the charter services authorized under its existing foreign air carrier permit, as of March 30, 2008: (i) Charter foreign air transportation of persons, property and mail from any point or points behind any Member State of the European Union, via any point or points in any EU Member State and via intermediate points, to any point or points in the United States and beyond; (ii) charter foreign air transportation of persons, property and mail between any point or points in the United States and any point or points in any member of the European Common Aviation Area (''ECAA''); (iii) other charters; and (iv) charter transportation authorized by any additional route rights made available to European Community carriers in the future, to the extent permitted by VistaJet's homeland license on file with the Department.

Docket Number: OST–2007–28865.

Date Filed: July 27, 2007.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: August 17, 2007.

Description: Application of Metropix UK LLP, (''Metropix'') requesting an exemption and an amended foreign air carrier permit authorizing Metropix to conduct the following charter services to engage in air charter transportation of persons and property: (i) Between any point or points behind any European Community Member State via any point(s) in the European Community Member States and intermediate points to any point(s) in the United States and beyond; (ii) charter foreign air transportation of persons and property between any point(s) in the United States and any point(s) in the European Common Aviation Area; and (iii) subject to the prior approval requirements, between any point or points in the United States and any point or points not in the United Kingdom or the United States.

Docket Number: OST–2007–28875.

Date Filed: July 27, 2007.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: August 17, 2007.

Description: Joint Application of Cargo 360, Inc. (''Cargo'') and Southern Air Inc. (''Southern''), requesting approval of the de facto transfer of certain international certificate authority held by Southern.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. E7–17536 Filed 9–4–07; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA–2007–29113]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: The Federal Transit Administration invites public comment about our intention to request the Office of Management and Budget's (OMB) approval of the following new information collection: Customer Service Surveys of FTA Grantees and Stakeholders. The information to be collected from the surveys covered in this request will provide FTA with a means to gather data directly from its customers. The surveys will be used to assess how FTA's services are perceived by customers and stakeholders, determine opportunities for improvement and establish goals to measure results. The surveys will be limited to data collections that solicit voluntary opinions and will not involve information that is required by regulations. The **Federal Register** Notice with a 60-day comment period soliciting comments was published on June 8, 2007.

DATES: Comments must be submitted before October 5, 2007. A comment to OMB is most effective if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: Sylvia L. Marion, Office of Administration, Office of Management Planning, (202) 366–6680.

SUPPLEMENTARY INFORMATION:

Title: Customer Service Surveys of FTA Grantees and Stakeholders (OMB Number 2132–New).

Abstract: Executive Order 12862, ''Setting Customer Service Standards,'' requires FTA to identify its customers and determine what they think about FTA's service. The surveys covered in this request will provide FTA with a means to gather data directly from its customers. The information obtained from the surveys will be used to assess how FTA's services are perceived by customers and stakeholders, determine opportunities for improvement and establish goals to measure results. The surveys will be limited to data collections that solicit voluntary opinions and will not involve information that is required by regulations.

Estimated Total Annual Burden: 1,800 hours.

ADDRESSES: All written comments must refer to the docket number that appears at the top of this document and be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: FTA Desk Officer.

Comments are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued On: August 29, 2007.

Ann M. Linnertz,

Acting Associate Administrator for Administration.

[FR Doc. E7–17456 Filed 9–4–07; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. 2007–29111]

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: The Federal Transit Administration invites public comments about our intention to request the Office of Management and Budget's (OMB) approval to renew the following information collection: 49 U.S.C. 5335(a) and (b) National Transit Database. The information to be collected will be used to accumulate mass transportation financial and operating information using a uniform system of accounts and records. The **Federal Register** Notice with a 60-day comment period soliciting comments was published on June 27, 2007.

DATES: Comments must be submitted before October 5, 2007. A comment to OMB is most effective if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: Sylvia L. Marion, Office of Administration, Office of Management Planning, (202) 366–6680.

SUPPLEMENTARY INFORMATION: *Title:* 49 U.S.C. 5335(a) and (b) National Transit Database *(OMB Number: 2132–0008).*

Abstract: Title 49 U.S.C. 5335(a) and (b) requires the Secretary of Transportation to maintain a reporting system by uniform categories to accumulate mass transportation financial and operating information using a uniform system of accounts and records. Congress created the NTD to be the repository of transit data for the nation, on which to base public transportation service planning. Section 3033 of SAFETEA–LU amended 49 U.S.C. 5335 to require recipients of 49 U.S.C. 5311 grants to submit an annual report containing total annual revenue; sources of revenue; total annual operating costs; total annual capital costs; fleet size and type; and related facilities: revenue vehicle miles and ridership. The addition of this requirement for recipients of 49 U.S.C. section 5311 does not affect the existing NTD data collection from urbanized area agencies, including the mandatory NTD reporting requirement for recipients of 49 U.S.C. section 5307 grants (Urbanized Area Formula grants).

FTA will not require these smaller rural agencies to submit the same level of detail to the NTD as a system in an urbanized area. FTA will only require the State Department of Transportation (DOT) to submit a one-page form for each rural agency in the State that is the recipient or beneficiary of grants under 49 U.S.C. 5311. Most State DOTs already produce reports for their State legislatures with this summary data. Additionally, FTA will require each State DOT to report the number of counties in the State that are served by recipients of grants under 49 U.S.C. 5311. For purposes of this data collection, Puerto Rico, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands will report as States (by 49 U.S.C. 5307(1)). The U.S. Virgin Islands is an urbanized area for purposes of FTA grantmaking and does not receive grants under 49 U.S.C. section 5311. Additionally, FTA will require this report from federally-recognized Native American tribes that are direct recipients of grants under 49 U.S.C. 5311 and whose information is not included in a report of a State DOT. The reporting requirements for this program have been developed after years of consultation with State DOTs and rural transit agencies.

On November 30, 2005, FTA published in the **Federal Register** (70 FR 71950, November 30, 2005) the procedures and start dates for mandatory annual reporting that State DOTs must follow when submitting

rural transit data to FTA. The rural transit data reporting procedures are specified in the Rural NTD Module Reporting Manual which contains detailed reporting instructions for this data collection. It can be reviewed on the NTD Web site at *http://www.ntdprogram.gov* and will be submitted for notice and comment in a future **Federal Register** announcement. For 2006, many States have reported data to the NTD for approximately 1,600 rural systems under a voluntary pilot program. The majority of States reported all of their data without any formal training.

FTA is requesting a revision of the currently approved NTD information collection (OMB Control Number 2132–0008) to include the addition of rural reporting.

Estimated Total Annual Burden: 230,700 hours.

ADDRESSES: All written comments must refer to the docket number that appears at the top of this document and be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: FTA Desk Officer.

Comments Are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued: August 29, 2007.

Ann M. Linnertz,

Associate Administrator for Administration.

[FR Doc. E7–17461 Filed 9–4–07; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA–2007–27523]

Reports, Forms, and Recordkeeping Requirements Agency Information Collection Activity Under OMB Review

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), this notice announces that the Information Collection Request (ICR) below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and the expected burden. The **Federal Register** Notice with a 60-day comment period was published on March 14, 2007 (72 FR 11931–11932).

DATES: Comments must be received on or before October 1, 2007.

ADDRESSES: Direct all written comments to U.S. Department of Transportation Dockets, 1200 New Jersey Avenue, SE., W12–140, Washington, DC 20590. Docket No. NHTSA–2007–27523.

FOR FURTHER INFORMATION CONTACT: Ms. Laurie Flaherty, Program Analyst, Office of Emergency Medical Services, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., NTI–140, W44–322, Washington, DC 20590, (202) 366–2705 or via e-mail at *laurie.flaherty@dot.gov.*

SUPPLEMENTARY INFORMATION:

National Highway Traffic Safety Administration

Title: Request for Information, National E9–1–1 Implementation Coordination Office.

OMB Number: 2127—New.

Type of Request: New information collection request.

Supporting Statement for Paperwork Reduction Act Submissions

A. Justification

1. Explain the circumstances that make the collection of information necessary.

The ENHANCE 911 Act of 2004 requires the establishment of a National E911 Implementation Coordination Office (National 9–1–1 Office), as a joint effort between the National Highway Traffic Safety Administration (NHTSA) and the National Telecommunications and Information Administration (NTIA). It delineates the responsibilities of the office to include a joint program to facilitate coordination and communication between Federal, State, and local emergency communications systems, emergency personnel, public safety organizations, telecommunications carriers, and telecommunications equipment manufacturers and vendors involved in the implementation of E–911 services.

The NHTSA and NTIA intend to use the National 9–1–1 Office to work cooperatively with public and private 9–1–1 stakeholders to establish a vision for the future of 9–1–1 services in the Nation. The 9–1–1 constituency is a diverse group of entities, including:

Government Agencies:

- Local, State and Federal policy, regulation, and funding agencies.
- Local and State emergency communications agencies.
- Local, State and Federal emergency response agencies.

Non-Governmental Organizations:

- Professional and industry associations.
- Standards Development Organizations.
- Citizen and special interest advocacy organizations.
- Private emergency response and recovery organizations.
- Research and academic organizations.

IT/Telecommunications Service Providers:

- ''Traditional'' telecommunication service providers.
- ''Public Safety/emergency'' service providers.
- ''Other'' IT/telecommunication application service providers.
- IP-network access infrastructure/service providers.

IT/Telecommunications Equipment Providers:

- Equipment and support service suppliers to ''traditional'' telecommunication companies.
- Equipment and support service suppliers to IT network providers.
- ''Public Safety/emergency services network'' equipment providers.
- Personal communication device providers.
- Third party service providers such as telematics, poison control, medical alert, central alarm monitoring, relay services, and N–1–1 services e.g., 4–1–1, 5–1–1).

In order to collect information needed to develop and implement effective strategies that meet the National 9–1–1 Office's mandate to provide leadership, coordination, guidance and direction to the enhancement of the Nation's 9–1–1 services, NHTSA, in cooperation with NTIA, must utilize efficient and effective means of eliciting the input and opinions of its constituency groups. The proposed annual RFIs would assist the National 9–1–1 Office in addressing the myriad of issues posed by implementing new technologies in 9–1–1 services in a systematic, prioritized fashion, with active involvement of its constituency in this process.

2. Indicate how, by whom, and for what purpose the information is to be used.

The results of the proposed annual RFIs would be used by staff of the

National 9–1–1 Office to: (1) Identify areas to target programs and activities to achieve the greatest benefit; (2) develop programs and initiatives aimed at cooperative efforts to Enhance 9–1–1 services nationwide; and (3) to provide informational support to States, regions, and localities in their own efforts to Enhance 9–1–1 services. The survey will answer questions and address issues raised by staff of the National 9–1–1 Office.

The results of the proposed annual RFIs would provide a status report on constituent attitudes, knowledge, opinions, and advice related to the activities undertaken by the National 9–1–1 Office. The results would be studied to determine appropriate emphases for future activities. The results would also be disseminated to others for use in their program development activities. If the RFI were not conducted, the National 9–1–1 Office would lack sufficient direction due to inadequate information upon which to base program decisions, and limiting the effectiveness of the office in reaching the goals established by Congress.

3. Describe whether, and to what extent, the collection of information involves the use of technological collection techniques or other forms of information technology.

Collection of information will be accomplished through the electronic submission of comments and responses to specific questions and soliciting comments on the priorities and strategies used by the National 9–1–1 Office to accomplish its agreed functions, goals and vision. Since the information solicited is almost exclusively qualitative in nature, analysis and aggregation of information would not be done using technological analysis techniques.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used.

The National 9–1–1 Office is the Federal entity established specifically to facilitate coordination and communication between Federal, State, and local emergency communications systems, emergency personnel, public safety organizations, telecommunications carriers, and telecommunications equipment manufacturers and vendors involved in the implementation of E9–1–1 services. While the Federal Communications Commission (FCC) does have jurisdiction over private sector entities such as telecommunications carriers, the National 9–1–1 Office is responsible for coordinating efforts among both private and public entities at the Federal, State and local levels. While the data collected by the FCC are useful, these limited excursions into issues related to 9–1–1 services do not provide sufficient information to meet the needs of the National 9–1–1 Office for programmatic decision making, and facilitating coordination and communication among the numerous and disparate entities involved in providing and supporting 9–1–1 services.

Overall, the following criteria were applied to determine whether existing information may be duplicative:

- Currency of information—the data must be current in order to have utility for making sound strategic decisions regarding future programmatic activity.
- National basis—The efforts of the National 9–1–1 Office are national in scope. The National 9–1–1 Office therefore requires national-level data for its planning. Data derived from limited constituencies are also unsuitable because the data are representative of only a small portion of the constituency.
- Focus on program concerns—the items within the proposed RFI concern issues crucial to developing appropriate strategies for improving the Nation's 9–1–1 services.

5. If the collection of information impacts small businesses or other small entities, describe methods used to minimize burden.

The collection of information from all respondents has been minimized by the limiting the RFI contents to a number of questions that would require an average of one hour to complete.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently.

The information is necessary for the National 9–1–1 Office to be able to make strategic planning decisions in program areas on an informed basis. This is particularly important with the priority assigned to 9–1–1 services by Congress and the Administration. In addition, the technology impacting 9–1–1 services has changed substantially in recent years. Both public and private sectors have increasingly focused on addressing the need to enhance the technology utilized by 9–1–1 services across the nation. Without up-to-date information, the National 9–1–1 Office will not be able to adequately address new opportunities to promote advanced technology for 9–1–1 services, or identify emerging obstacles.

7. Explain any special circumstances that would cause the information collection to be conducted in a manner inconsistent with the guidelines set forth in 5 CFR 1320.6.

No special circumstances require the collection of information to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.6.

8. Provide a copy and identify the date and page number of the publication in the **Federal Register** of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize the public comments received in response to that notice and describe actions to consult with persons outside the agency to obtain their views.

Federal Register Notice: A copy of the **Federal Register** Notice is provided in Appendix A. The Notice appeared in the **Federal Register**, Volume 72, Number 49, pages 11931–11932, March 14, 2007. The closing date for comments was May 14, 2007. No comments were received.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payments or gifts will be offered to the respondents participating in the annual RFI process.

10. Describe any assurance of confidentiality provided to respondents.

No assurances of confidentiality are given by the agency. There is no requirement that information be sent to the agency. All information submitted by respondents is done so on a voluntary basis and is intended for inclusion in a public document.

11. Provide additional justification for questions of a sensitive nature.

The RFI process will not contain any questions related to matters that are commonly considered sensitive or private.

12. Provide estimates of the hour burden of the collection of information on the respondents.

The NHTSA estimates that responses to the questions included in the proposed RFIs would require an average of one hour to complete. Estimating the number of respondents at 50, this would result in a total burden of 50 hours.

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information.

There are no record keeping or reporting costs to respondents. Each respondent only participates once in the information collection process. Thus there is no preparation of data required or expected of respondents. Respondents do not incur: (a) Capital or start up costs, (b) operation, maintenance or purchase costs, as a result of participating in the RFI process.

14. Provide estimates of annualized cost to the Federal government.

Total estimated cost to the government for conducting the RFI is as follows:

Contractor costs associated with analysis and report: $18,000. This estimate is based on the total cost for contractor supported analysis and report of information obtained in the RFI process, including 120 fully loaded hours at $150 per hour.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB form 83–1.

Since this is a new request, there are no program changes or adjustments to report in Items 13 or 14 of the OMB form 83–1.

16. For collections of information whose results will be published, outline plans for tabulation and publication.

The NHTSA plans to complete a status report based on the results of the RFI, of constituent attitudes, knowledge, opinions, and advice related to the activities undertaken by the National 9–1–1 Office. This report would also be made available to public and private entities, upon request, for use in their program development activities.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

Approval is not sought to not display the expiration date.

18. Explain each exception to the certification statement identified in Item 19, Certification for Paperwork Reduction Act Submissions,'' of OMB Form 83–1.

No exceptions to the certification statement are made.

B. Collections of Information Employing Statistical Methods

The proposed RFI will not employ statistical methods to analyze the information collected from respondents.

Comments are invited on: Whether the proposed collection of information is necessary for the performance of the functions of the National E9–1–1 Implementation Coordination Office, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. A comment to OMB is most effective if OMB received it within 30 days of publication.

(Authority: 44 U.S.C. 3506(c)(2)(A); 47 U.S.C. 942)

Issued on: August 24, 2007.

Marilena Amoni,

Associate Administrator, Research and Program Development.

[FR Doc. E7–17144 Filed 9–4–07; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–6 (Sub-No. 457X)]

BNSF Railway Company—Abandonment Exemption—in Stevens County, MN

BNSF Railway Company (BNSF) has filed a notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon a rail line between mileposts 86.00 and 86.65, in Morris, Stevens County, MN, a distance of 0.65 miles. The line traverses United States Postal Service Zip Code 56267.

BNSF has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line to be rerouted; (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 or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements of 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 employees 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 October 5, 2007, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by September 17, 2007. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by September 25, 2007, with: Surface Transportation Board, 395 E. Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to BNSF's representative: Sidney L. Strickland, Jr., 3050 K Street, NW., Suite 101, Washington, DC 20007.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

BNSF has filed environmental and historic reports which address the effects, if any, of the abandonment on the environment and historic resources. SEA will issue an environmental assessment (EA) by September 10, 2007. 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.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), BNSF 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 BNSF's filing of a notice of consummation by September 5, 2008, 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: August 24, 2007.

[1] 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.

[2] Each OFA must be accompanied by the filing fee which is currently set at $1,300. *See* 49 CFR 1002.2(f)(25).

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E7–17172 Filed 9–4–07; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

[Docket: OST–2007–26835]

Research and Innovative Technology Administration; Agency Information Collection; Activity Under OMB Review; Airline Service Quality Performance—Part 234

AGENCY: Research and Innovative Technology Administration (RITA), Bureau of Transportation Statistics (BTS), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, Public Law 104–13, the Bureau of Transportation Statistics (BTS) invites the general public, industry and other governmental parties to comment on the continuing need for and usefulness of the U.S. Department of Transportation (DOT) requiring large certificated air carriers to file ''On-Time Flight Performance Reports'' and ''Mishandled-Baggage Reports'' pursuant to 14 CFR 234.4 and 234.6. These reports are used to monitor the quality of air service that major air carriers are providing the flying public.

DATES: Written comments should be submitted by November 5, 2007.

ADDRESSES: You may submit comments identified by RITA docket number OST–2007–26835 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

Web site: http://dms.dot.gov (electronic submission).

Mail: U.S. Department of Transportation, Docket Operations, M–30, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Fax: 202–493–2251.

Delivery: Room W12–140 in the West Tower of the U.S. Department of Transportation Headquarters Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, 202–493–0402.

Instructions for Comments: Comments should identify the OMB # 2138–0041. Persons wishing the DOT to acknowledge receipt of their comments must submit with those comments a self-addressed stamped postcard on which the following statement is made: Comments on OMB # 2138–0041. The postcard will be date/time stamped and returned.

FOR FURTHER INFORMATION CONTACT: Bernie Stankus, Office of Airline Information at (202) 366–4387, or by mail at the Bureau of Transportation Statistics, 1200 New Jersey Avenue, SE., E–34, RTS–42, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

OMB Approval No.: 2138–0041.

Title: Airline Service Quality Performance—Part 234.

Form No.: BTS Form 234.

Type of Review: Extension of a currently approved collection.

Respondents: Large certificated air carriers that account for at least 1 percent of the domestic scheduled passenger revenues.

Number of Respondents: 20.

Total Burden Per Response: 20 hours.

Total Annual Burden: 4,800 hours.

Needs and Uses:

Consumer Information

Part 234 gives air travelers information concerning their chances of on-time flights and the rate of mishandled baggage by the 20 largest scheduled domestic passenger carriers.

Reducing and Identifying Traffic Delays

The Federal Aviation Administration (FAA) uses Part 234 data to pinpoint and analyze air traffic delays. Wheels-up and wheels-down times are used in conjunction with departure and arrival times to show the extent of ground delays. Actual elapsed flight time, wheels-down minus wheels-up time, is compared to scheduled elapsed flight time to identify airborne delays. The reporting of aircraft tail number allows the FAA to track an aircraft through the air network, which enables the FAA to study the ripple effects of delays at hub airports. The data can be analyzed for airport design changes, new equipment purchases, the planning of new runways or airports based on current and projected airport delays, and traffic levels. The identification of the reason for delays allows the FAA, airport operators, and air carriers to pinpoint delays under their control.

Currently, BTS has an open docket 28522, which requests comments on how the DOT can improve this data collection. Specifically, should the DOT collect additional information regarding tarmac delays when the flight returns to the airport gate, when the flight is diverted or when the flight is cancelled. After the comments are reviewed, the DOT will issue a notice of proposed rulemaking, if necessary, and a new Information Collection Package will be sent to OMB.

The Confidential Information Protection and Statistical Efficiency Act of 2002 (44 U.S.C. 3501), requires a statistical agency to clearly identify information it collects for non-statistical purposes. BTS hereby notifies the respondents and the public that BTS uses the information it collects under this OMB approval for statistical and non-statistical purposes. Purposes include, but are not limited to, publication of both respondent's identity and its data, submission of the information to agencies outside BTS for review, analysis and possible use in regulatory and other administrative matters.

Issued in Washington, DC, on August 29, 2007.

Marianne Seguin,

Acting Assistant Director, Airline Information, Bureau of Transportation Statistics.

[FR Doc. E7–17497 Filed 9–4–07; 8:45 am]

BILLING CODE 4910–FE–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

August 28, 2007.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 11000, 1750 Pennsylvania Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before October 5, 2007 to be assured of consideration.

Bureau of Engraving and Printing (BEP)

OMB Number: 1520–XXXX.

Type of Review: New.

Title: Redesigned Currency, Benchmark Survey.

Description: The Bureau of Engraving and Printing requests approval to

conduct a series of information collection activities with the public in support of its public education program regarding the introduction of redesigned currency. These collections will include: A survey used to establish baseline measures of awareness of currency changes, confidence in the currency and authentication behavior, and subsequent surveys to evaluate changes in these measures; a survey to evaluate potential messages designed to encourage the public to examine and learn currency security features; a survey to evaluate potential taglines that will help call attention to new security features while maintaining confidence in U.S. currency; and, a survey to test draft materials to be developed in support of the program. The collection will also include in-depth interviews with bank tellers and others who frequently conduct cash transactions as part of their job, to identify special needs and tools for their use.

Respondents: Individuals or households.

Estimated Total Burden Hours: 800 hours.

Clearance Officer: Pamela V. Grayson, (202) 874–2212, Bureau of Engraving and Printing, 14th & C Street, SW., Washington, DC 20228.

OMB Reviewer: Alexander T. Hunt, (202) 395–7316, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

Robert Dahl,

Treasury PRA Clearance Officer.

[FR Doc. E7–17467 Filed 9–4–07; 8:45 am]

BILLING CODE 4840–01–P

Corrections

Federal Register

Vol. 72, No. 171

Wednesday, September 5, 2007

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

45 CFR Part 2551

RIN 3045–AA44

National Service Criminal History Checks

Correction

In rule document E7–16681 beginning on page 48574 in the issue of Friday, August 24, 2007, make the following corrections:

§ 2551.28 [Corrected]

1. On page 48583, in the second column, in § 2251.28(a), in the fourth and fifth lines, ''the effective date of this regulation'' should read ''November 23, 2007''.

2. On the same page, in the same column, in § 2251.28(b), in the fourth and fifth lines, ''the effective date of this regulation'' should read ''November 23, 2007''.

[FR Doc. Z7–16681 Filed 9–4–07; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 53, 54 and 301

[REG–142039–06; REG–139268–06]

RIN 1545–BG18; 1545–BG20

Excise Taxes on Prohibited Tax Shelter Transactions and Related Disclosure Requirements; Disclosure Requirements With Respect to Prohibited Tax Shelter Transactions; Requirement of Return and Time for Filing

Correction

In proposed rule document E7–12902 beginning on page 36927 in the issue of Friday, July 6, 2007, make the following corrections:

1. On page 36927, in the second column, in the first paragraph, ''§§'' is corrected to read ''sections'' wherever it appears.

2. On the same page, in the same paragraph, ''§'' is corrected to read ''section'' wherever it appears.

3. On the same page, in the third column, in the second paragraph, in the 14th line, ''1,250'' should read ''1250''.

4. On the same page, in the same column, the small table following the second paragraph to read as follows:

Recordkeeping	6 hr., 13 min.
Learning about the law or the form	4 hr. 28 min.
Preparing, copying, assembling, and sending the form to the IRS	4 hr. 46 min.

4. On the same page, in the same column, in the sixth line from the bottom of the page, ''§'' is corrected to read ''section''.

5. On the same page, in the same column, in the fifth line from the bottom of the page, ''§§'' is corrected to read ''sections''.

6. On page 36928, in the first column, in the 17th line, ''§'' should read ''section''.

7. On the same page, in the same column, in the 20th line, ''§'' should read ''section''.

8. On the same page, in the same column, under the heading ''*Covered Tax-Exempt Entities*'', ''§'' is corrected to read ''section'' wherever it appears.

9. On the same page, in the same paragraph, in the third line ''§§'' is corrected to read ''sections''.

10. On the same page, in the same column, in the last line of the column, ''§'' should read ''section''.

11. On the same page, in the second and third columns, ''§'' should read ''section'' wherever it appears.

12. On the same page, in the same column, in the 18th line, ''§§'' should read ''sections''.

13. On page 36929, in the first and second columns, ''§'' should read ''section'' wherever it appears.

§ 53.4965–3 [Corrected]

14. On page 36932, in the second column, in § 53.4965–3(a), in the third line, ''*means*'' should read ''means''.

§ 53.4965–8 [Corrected]

15. On page 36937, in the first column, in § 53.4965–8(f), in Example 1, in paragraph (i), in the last line, ''§ 601.601(d)(2)(ii)(b)'' should read ''§ 601.601(d)(2)(ii)(*b*)''.

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 411 and 424

Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III); Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411 and 424

[CMS–1810–F]

RIN 0938–AK67

Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)

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

ACTION: Final rule.

SUMMARY: This final rule is the third phase (Phase III) of a final rulemaking amending our regulations regarding the physician self-referral prohibition in section 1877 of the Social Security Act (the Act). Specifically, this rule finalizes, and responds to public comments regarding, the Phase II interim final rule with comment period published on March 26, 2004, which set forth the self-referral prohibition and applicable definitions, interpreted various statutory exceptions to the prohibition, and created additional regulatory exceptions for arrangements that do not pose a risk of program or patient abuse (69 FR 16054).

In general, in response to public comments, in this Phase III final rule, we have reduced the regulatory burden on the health care industry through the interpretation of statutory exceptions and modification of the exceptions that were created using the Secretary's discretionary authority under section 1877(b)(4) of the Act to promulgate exceptions for financial relationships that pose no risk of program or patient abuse.

DATES: *Effective date:* This final rule is effective on December 4, 2007.

FOR FURTHER INFORMATION CONTACT: Joanne Sinsheimer, (410) 786–4620. Lisa Ohrin, (410) 786–4565.

SUPPLEMENTARY INFORMATION: To help readers locate information in this final rule, we are providing the following Table of Contents.

I. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain ''designated health services'' (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. The current version of section 1877 of the Act, which applies to referrals for 11 DHS, has been in effect and subject to enforcement since January 1, 1995.

This is Phase III of a final rulemaking under section 1877 of the Act. Proposed regulations were published in the **Federal Register** on January 9, 1998 (63 FR 1659). Phase I of the final rulemaking was published in the **Federal Register** on January 4, 2001 (66 FR 856) (''Phase I'') as a final rule with comment period, and Phase II of the final rulemaking was published in the **Federal Register** on March 26, 2004 (69 FR 16054) (''Phase II'') as an interim final rule with comment period. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published on April 6, 2004 (69 FR 17933).

Except for two provisions, the regulations published in Phase I became effective on January 4, 2002. We delayed the effective date of § 424.22(d), relating to home health services until April 6, 2001 (66 FR 8771.) We also delayed the effective date of the final sentence of § 411.354(d)(1) relating to the definition of ''set in advance'' until the publication of Phase II; ultimately, it never became effective. The regulations in Phase II became effective on July 26, 2004.

Phase I Covered—

- Sections 1877(a) and 1877(b) of the Act (the general prohibition against physician self-referral and the exceptions applicable to both ownership and compensation arrangements);

- The statutory definitions at section 1877(h) of the Act;
- Certain additional regulatory definitions; and
- A number of new regulatory exceptions promulgated using the Secretary's authority under section 1877(b)(4) of the Act.

Phase II Covered—

- All provisions of section 1877 of the Act;
- Additional regulatory definitions;
- Additional new regulatory exceptions issued pursuant to the Secretary's authority under section 1877(b)(4) of the Act; and
- Responses to the public comments on the January 1998 proposed rule and the Phase I regulations.

This Phase III final rule responds to comments on Phase II and, thus, addresses the entire regulatory scheme. In developing Phase III of this rulemaking, we have carefully considered the history and structure of section 1877 of the Act, as well as the comments to the Phase II interim final rule. As with Phase I and Phase II, we believe that Phase III of this rulemaking addresses many of the industry's primary concerns, is consistent with the statute's goals and directives, and protects beneficiaries of Federal health care programs. In particular, we have attempted to preserve the core statutory prohibition, while providing sufficient flexibility to minimize the impact of the rule on many common business arrangements. We have endeavored to simplify the rules and provide additional guidance in response to comments, as well as to reduce any undue burden on the regulated community by modifying exceptions created using the Secretary's authority under section 1877(b)(4) of the Act to promulgate additional exceptions regarding financial relationships that pose no risk of program or patient abuse. As we did in Phase II, in evaluating our regulatory options, we have applied the same criteria that we discussed in detail in the Phase I rule (66 FR 859–863, 69 FR 16056.)

The reasons for dividing the rulemaking into Phases I and II are explained in Phase I (66 FR 859–860). The reason for this Phase III final rule is explained in Phase II (69 FR 16055–16056) and in this preamble. Phases I, II, and III of this rulemaking are intended to be read together as a unified whole. Phase I contains a legislative and regulatory history of the physician self-referral law, which is not repeated here (66 FR 857–859). Unless otherwise expressly noted, to the extent the preamble in Phase III uses different language to describe a concept addressed in Phase I or Phase II, our intent is to elucidate that discussion, not to change its scope or meaning. For clarity and ease of access for the general public to the entire set of physician self-referral regulations, we are republishing in its entirety in this Phase III final rule the regulatory text for §§ 411.350 through 411.361 (omitting §§ 411.370 through 411.389 relating to advisory opinions, which were the subject of a separate rulemaking and remain unchanged, except for a technical correction to § 411.370 discussed below in section XIII). Please note that, for ease of reference, the regulatory text for § 411.357 includes paragraphs (v) and (w) relating to the exceptions for arrangements involving donations of electronic prescribing and electronic health records technology, respectively. Those two exceptions were proposed and finalized in a separate rulemaking (70 FR 59182, 71 FR 45140.)

This Phase III preamble is generally organized to track the statute and current regulations. We first address the definitions (although certain key definitions, such as ''isolated transaction,'' are addressed in the discussions of the exceptions to which they mainly relate), then the general prohibition, then the exceptions. Summary discussions are intended to aid the reader in understanding the regulations. More detailed discussions of particular points are included in the responses to public comments for each topic.

II. General Comments

A. General

Comment: We received numerous comments regarding both ownership and compensation arrangements in which the commenter requested confirmation that the particular arrangement described in the comment met the requirements of an exception and, thus, did not violate section 1877 of the Act.

Response: In this final rule, we provide guidance with respect to the provisions of Phase I and Phase II. When possible, we respond to commenters' specific inquiries regarding compliance with the physician self-referral law. However, several of the inquiries failed to provide sufficient facts to enable us to evaluate or respond to the inquiry. Moreover, we consider several other inquiries to be in the nature of a request for a binding opinion, which, as provided in § 411.386, can be made only through the issuance of a formal advisory opinion.

B. Compliance With the Anti-Kickback Statute

Comment: Numerous commenters objected to the inclusion of the requirement that arrangements must not violate the Federal anti-kickback statute (section 1128B(b) of the Act; 42 U.S.C. 1320a–7b(b), hereinafter referred to as the anti-kickback statute), which appears in the regulatory exceptions created pursuant to the Secretary's authority under section 1877(b)(4) of the Act. According to the commenters, the condition is unnecessary and undercuts our efforts to create ''bright lines.''

Response: We disagree with the commenters for the reasons set forth in Phase I (66 FR 863) and Phase II (69 FR 16108). Wherever possible, we have attempted to create bright-line rules. However, given the limitations on our regulatory authority under section 1877(b)(4) of the Act, inclusion of the anti-kickback statute condition is necessary to ensure that the exceptions promulgated under that authority do not pose a risk of program or patient abuse. Moreover, because parties' arrangements must not violate the anti-kickback statute irrespective of whether they satisfy the other requirements of an exception, any additional burden associated with the requirement is minimal.

Comment: Two commenters suggested that the exceptions under the physician self-referral law and safe harbors under the anti-kickback statute should more closely parallel each other. The first commenter stated that, without parallel safe harbors under the anti-kickback statute and exceptions to the physician self-referral law, the physician self-referral law exceptions will be underutilized and ineffective. The second commenter suggested that an arrangement that meets an exception under the physician self-referral law should be deemed to be within a safe harbor under the anti-kickback statute.

Response: We addressed the issue raised by the first commenter in Phase II (69 FR 16115). As explained in detail there, we do not believe it is feasible to except financial relationships solely because they fit in an anti-kickback statute safe harbor. The second commenter's suggestion is outside the scope of this rulemaking and our authority. We note that several of the regulatory exceptions under the physician self-referral law do, in fact, correspond to safe harbors issued by the Office of Inspector General (OIG). For example, the exceptions for the donation of electronic prescribing items and services (§ 411.357(v)) and electronic health records software and

information technology and training services (§ 411.357(w)) correspond to safe harbors issued by the OIG. In addition, the exceptions for referral services and obstetrical malpractice insurance subsidies in § 411.357(q) and (r), respectively, mirror anti-kickback statute safe harbors.

Comment: One commenter asserted that the exceptions in § 411.357(q) and (r) that cross-reference safe harbors relating to referral services and obstetrical malpractice insurance subsidies, respectively, are too narrow. The commenter stated that any arrangement that has received a favorable advisory opinion from the OIG, even if the agreement in question does not fall within a safe harbor, should be permitted under the self-referral law.

Response: Under section 1877(b)(4) of the Act, we may issue additional exceptions (that is, exceptions not specified in the statute) only where doing so would create no risk of program or patient abuse. As noted above, it is not feasible to except financial relationships under section 1877 of the Act solely because they fit in an anti-kickback statute safe harbor, nor would it be feasible or appropriate to do so because an arrangement is the subject of a favorable OIG advisory opinion on a different statute. As we explained in Phase II, in some instances, it is appropriate for us to refer to the criteria in an anti-kickback safe harbor when creating an exception under the physician self-referral law (69 FR 16115).

III. Definitions—§ 411.351

We received public comments only on the specific definitions set out below. In addition to technical changes to several definitions, we are adding definitions for ''downstream contractor,'' ''physician organization,'' and ''rural area'' and modifying the definitions of ''fair market value,'' and '' 'incident to' services.'' The new definitions of ''downstream contractor'' and ''physician organization'' are discussed in sections IX.D and VI.B, respectively, below, together with the relevant provisions to which they apply.

A. Employee

We are making no changes to the definition of ''employee'' in this Phase III final rule.

Comment: One commenter asked us to clarify that, in order to qualify as an employee of a group practice, a group practice must exercise control over the employee; that is, the group practice must supply the equipment, personnel, and support necessary for the individual to provide the service, and the group practice must control how the work is done and have hiring and firing authority over the individual providing services. The commenter asked for clarification on this issue out of concern regarding arrangements in which a group practice ''hires'' an individual as a part-time employee of the group practice but, in reality, exercises no control over the individual.

Response: As set forth in section 1877(h)(2) of the Act and the definition of ''employee'' at § 411.351, an individual is considered an ''employee'' for purposes of the physician self-referral prohibition if the individual is considered an employee under the common law rules applicable to determining the employer-employee relationship, as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986. We agree with the commenter that the actual conduct of the relationship is determinative. To determine whether an employer-employee relationship exists, the various factors, including those regarding supervision, used by the Internal Revenue Service (IRS) to determine employee status apply. Whereas the receipt of a W–2 from an entity and the written terms of the arrangement are relevant, neither controls whether an individual meets the definition of ''employee'' for purposes of the physician self-referral law; rather, the focus is on the actual relationship between the parties.

B. Entity

We are making no substantive changes to the definition of ''entity'' in this Phase III final rule.

Comment: One commenter objected to certain language in the definition of ''entity'' specifying that, in general, a person or entity is considered to be ''furnishing DHS'' if CMS makes payment to that person or entity, either directly, upon assignment on the patient's behalf, or upon reassignment in certain cases. According to the commenter, some arrangements are structured so that referring physicians own entities that lease space, equipment, staff, or management services to entities that furnish DHS, and, in turn, submit claims to Medicare. The commenter suggested that ''entity furnishing DHS'' should be expanded to include entities that derive a substantial amount of their revenues from the provision of services to entities furnishing DHS.

Response: We note that, after the close of the Phase II comment period, the Medicare Payment Advisory Commission (MedPAC), in its March 2005 Report to Congress, recommended that the Secretary ''should expand the definition of physician ownership in the physician self-referral law to include interests in an entity that derives a substantial proportion of its revenue from a provider of designated health services.'' Specifically, MedPAC wrote:

> Physician ownership of entities that provide services and equipment to imaging centers and other providers creates financial incentives for physicians to refer patients to these providers, which could lead to higher use of services. Prohibiting these arrangements should help ensure that referrals are based on clinical, rather than financial, considerations. It would also help ensure that competition among health care facilities is based on quality and cost, rather than financial arrangements with entities owned by physicians who refer patients to the facility.

(*See http://www.medpac.gov/publications/congressional_reports/Mar05_EntireReport.pdf,* at page 170.) We agree with the commenter that arrangements structured so that referring physicians own leasing, staffing, and similar entities that furnish items and services to entities furnishing DHS (also referred to herein as ''DHS entities''), but do not submit claims raise significant concerns under the fraud and abuse laws and would appear contrary to the plain intent of the physician self-referral law. These structures are particularly problematic because referrals by physician-owners of leasing, staffing, and similar entities to a contracting DHS entity can significantly increase the physician-owned entity's profits and investor returns, creating incentives for overutilization and corrupting medical decision-making. We intend to study further the types of arrangements described by the commenter and MedPAC, as well as other types of arrangements, to determine the best approach for addressing them in order to protect against program and patient abuse. We would make any change to address this issue, whether through the definition of ''entity'' or otherwise, in a separate rulemaking that is subject to public comment.

We note that the arrangements described by MedPAC remain subject to the physician self-referral prohibition. In most instances, these structures will constitute indirect compensation arrangements with DHS entities under § 411.354(b) that must satisfy the requirements of the indirect compensation arrangements exception in § 411.357(p). We intend to monitor these arrangements closely for compliance with the physician self-referral law. These arrangements appear

highly suspect under the anti-kickback statute; participants in such arrangements should closely scrutinize the arrangements for compliance with that statute also. Importantly, we note that the indirect compensation arrangements exception in § 411.357(p) includes a requirement that the arrangement not violate the anti-kickback statute.

C. Fair Market Value

In Phase II, we created a ''safe harbor'' provision in the definition of ''fair market value'' at § 411.351 for hourly payments to physicians for their personal services. The safe harbor consisted of two methodologies for calculating hourly rates that would be deemed ''fair market value'' for purposes of section 1877 of the Act. The first methodology requires that the hourly payment be less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market. The second methodology requires averaging the 50th percentile national compensation level for physicians in the same specialty, using at least four of six specified salary surveys, and dividing the result by 2,000 hours to establish an hourly rate. If the relevant physician specialty does not appear in one of the recognized surveys, the parties must use the survey's reported compensation for general practice in order to be within the safe harbor. We emphasized that use of the safe harbor was entirely voluntary and that parties may establish fair market value through other methods. We received a large number of comments questioning the new safe harbor.

Comment: Several commenters disliked the compensation survey methodology. In general, the commenters believed that the methodology was too prescriptive, and they urged more flexibility. Commenters noted that at least one of the listed surveys no longer exists, and that another is out of date. Another commenter stated that many of the survey companies will not sell their surveys to hospitals that do not participate in the surveys. According to the commenters, the available surveys are expensive. Another commenter asserted that other surveys, including the American Medical Group Association survey and *Modern Healthcare's* annual compilation of surveys, provide similar information at less expense. Several commenters objected to the use of national averages, because the national average masks significant regional differences in physician compensation.

Some commenters suggested that the compensation survey methodology be modified in other respects. One commenter urged us to expand the fair market value safe harbor to compensation that falls within the 25th to the 75th percentile of physician compensation. Commenters suggested that providers be able to use fewer than four surveys (for example, averaging the 50th percentile of any two surveys). Several commenters suggested that, where specialty-specific data is unavailable, providers should be able to use data from a similar specialty, rather than from general practitioners. According to the commenters, the compensation of physicians in one type of specialty is more similar to the compensation of physicians in other specialties than to the compensation of general practitioners. One commenter asked whether a contract could include a cost of living annual adjustment.

Response: We share the commenters' concerns regarding the availability of the surveys identified in the safe harbor. We are aware that several of the surveys are no longer available (or may not be readily available to all DHS entities and physicians), making it impractical to utilize the safe harbor. In addition, it may be infeasible to obtain information regarding hourly rates for emergency room physicians at competitor hospitals. Therefore, we are not retaining the safe harbor within the definition of ''fair market value'' at § 411.351. We emphasize, however, that we will continue to scrutinize the fair market value of arrangements as fair market value is an essential element of many exceptions.

Reference to multiple, objective, independently published salary surveys remains a prudent practice for evaluating fair market value. Ultimately, the appropriate method for determining fair market value for purposes of the physician self-referral law will depend on the nature of the transaction, its location, and other factors. As we explained in Phase II, although a good faith reliance on an independent valuation (such as an appraisal) may be relevant to a party's intent, it does not establish the ultimate issue of the accuracy of the valuation figure itself (69 FR 16107). Our views regarding fair market value are discussed further in Phase I (66 FR 944) and Phase II (69 FR 16107).

Because we are eliminating the safe harbor, it is unnecessary to address the commenters' specific suggestions for identifying permissible surveys and expanding the range of acceptable physician compensation. With respect to the inquiry regarding cost of living adjustments, we note that contracts for physician services may include an annual salary adjustment, provided that the resulting compensation is fair market value and otherwise complies with an exception.

Comment: A large number of nephrologists and groups representing nephrologists complained that the application of the safe harbor to their compensation for medical director duties at renal dialysis centers is inappropriate, especially given that the physician self-referral prohibition does not apply to dialysis services for which payment is made under the ESRD composite rate. According to the commenters, the hourly rate under the safe harbor would not adequately compensate dialysis facility medical directors for the full array of their skills and services. Several commenters expressed concern that, notwithstanding the voluntary nature of the safe harbor, the methodology would become the preferred valuation methodology to the detriment of physicians.

Response: For the reasons noted in the preceding response, we have eliminated the fair market value safe harbor in this Phase III final rule. With respect to existing arrangements, nothing in the physician self-referral regulations required use or application of the fair market value safe harbor; it was a wholly voluntary provision. Moreover, a physician's compensation arrangement with a dialysis facility implicates section 1877 of the Act only to the extent that the arrangement creates a direct or indirect financial arrangement with an entity that furnishes DHS, such as a dialysis facility that furnishes DHS not covered by the ESRD composite rate or a hospital that provides dialysis (66 FR 923–924).

Comment: A number of commenters complained that the fair market value safe harbor methodology based on local hourly rates for emergency room physician services creates significant risk under the antitrust laws.

Response: We have eliminated the fair market value safe harbor for payments to physicians.

Comment: Two commenters asked us to comment on other valuation methodologies.

Response: Nothing precludes parties from calculating fair market value using any commercially reasonable methodology that is appropriate under the circumstances and otherwise fits the definition at section 1877(h) of the Act and § 411.351. Ultimately, fair market value is determined based on facts and

circumstances. The appropriate method will depend on the nature of the transaction, its location, and other factors. Because the statute covers a broad range of transactions, we cannot comment definitively on particular valuation methodologies. We refer the commenter to previous discussions in Phase I and Phase II regarding valuation methodologies (66 FR 944–945, 69 FR 16107).

Comment: One commenter wanted confirmation that a fair market value hourly rate could be used to compensate physicians for both administrative and clinical work. Another commenter asked whether the rate could be used to determine an annual salary.

Response: A fair market value hourly rate may be used to compensate physicians for both administrative and clinical work, provided that the rate paid for clinical work is fair market value for the clinical work performed and the rate paid for administrative work is fair market value for the administrative work performed. We note that the fair market value of administrative services may differ from the fair market value of clinical services. A fair market value hourly rate may be used to determine an annual salary, provided that the multiplier used to calculate the annual salary accurately reflects the number of hours actually worked by the physician.

D. ''Incident to'' Services

Under section 1877 of the Act, group practices are permitted to pay profit shares and productivity bonuses to their physicians in ways that other DHS entities cannot. Unlike other DHS entities, the statute permits group practices to pay a physician in the group a share of the overall profits of the group, or a productivity bonus based on services personally performed or services ''incident to'' such personally performed services, provided that the profit share or bonus is not determined in any manner that is directly related to the volume or value of the physician's referrals. At § 411.351, we define ''incident to'' services to mean those services that meet the requirements of section 1861(s)(2)(A) of the Act, the ''incident to'' billing rule in § 410.26, and the relevant manual provisions, as those provisions may be amended or replaced from time to time, all of which set forth coverage criteria for ''services and supplies'' furnished ''incident to'' a physician's professional service.

In the calendar year (CY) 2002 physician fee schedule final rule published on November 1, 2001 (66 FR 55246), we amended our ''incident to'' billing regulation in § 410.26 to provide that ''incident to'' services and supplies means those services and supplies that are included in section 1861(s)(2)(A) of the Act and that are not specifically listed in the Act as a separate benefit. In the CY 2003 physician fee schedule final rule (67 FR 79966), we clarified that only those services that do not have their own separate and independently listed benefit category may be billed as ''incident to'' a physician service, except as otherwise expressly permitted by statute (for example, physical therapy services to the extent authorized under section 1862(a)(20) of the Act) (67 FR 79994). Consequently, diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests, all of which comprise a single benefit category under section 1861(s)(3) of the Act, may not be billed as ''incident to'' services under section 1861(s)(2)(A) of the Act. Thus, under section 1877 of the Act, a group practice physician may not receive a productivity bonus if the bonus is calculated based on such diagnostic tests, unless the physician personally performed the tests. Moreover, the bonus cannot be related directly to the volume or value of DHS referrals. We discuss the treatment of ''incident to'' services in further detail in section IV below.

Given our intent to conform the physician self-referral regulations as much as possible to existing Medicare coverage and payment rules, we did not intend in Phase I or Phase II to distinguish between ''services'' and ''supplies'' furnished ''incident to'' a physician's professional services. Accordingly, as discussed in more detail in section IV of this preamble, we are revising the definition of '' 'incident to' services'' at § 411.351 to clarify that the term includes both services and supplies (such as drugs) that meet the applicable requirements set forth in section 1861(s)(2)(A) of the Act, § 410.26 of our regulations, and relevant manual provisions. We are also making a minor revision to make clear that the definition covers the terms '' 'incident to' services'' and ''services 'incident to' '' for purposes of these regulations.

Comment: A commenter asserted that our interpretation in the CY 2003 physician fee schedule final rule as to what services qualify as ''incident to'' services (67 FR 79993–79994) is inconsistent with a previous interpretation we made in the CY 2002 physician fee schedule final rule (66 FR 55268). The commenter contends that ''incident to'' services may include separately listed and independent services, such as diagnostic tests. The commenter contends that our application of the ''incident to'' billing rules in the physician self-referral context effectively prohibits group practice physicians from receiving a share of the group's overall profits or a productivity bonus based on diagnostic tests that were directly supervised by the physician or a member of his or her group practice. The commenter requested that we amend the definition of ''incident to'' at § 411.351 to cover any services, including services that are listed separately and independently (such as diagnostic tests), that are directly supervised by the physician or a physician in the group practice, provided that they meet all of the other requirements under the ''incident to'' billing rules. According to the commenter, this interpretation appears consistent with the Congress' intent under section 1877 of the Act to favor group practice physicians with respect to the distribution of profits and productivity bonuses.

Response: We are not amending the definition of ''incident to'' services at § 411.351 as suggested by the commenter. We believe it would be confusing to define ''incident to'' services differently for physician self-referral purposes than for billing purposes. As we stated in Phase I, we intend to interpret the physician self-referral law in a manner that conforms to existing Medicare coverage and payment rules (66 FR 859). We specifically noted in Phase I (66 FR 909) and in the Phase II definition of ''incident to services'' (69 FR 16128) that the ''incident to'' services on which group practice physicians could be compensated must comply with existing billing requirements as they may be amended from time to time.

We do not believe that our ''incident to'' billing rule in § 410.26 is inconsistent with the language of section 1877(h)(4)(B)(i) of the Act. Although ''incident to'' services are referrals for purposes of section 1877 of the Act, we believe that the Congress intended that these services nonetheless may be considered when calculating a physician's productivity bonus. For those services that are appropriately billed ''incident to'' under current Medicare rules, the group practice physician to whose personally performed services the ''incident to'' services are incidental (that is, the ordering physician) may be paid a productivity bonus or profit share consistent with the special rules for such compensation set forth in § 411.352(i).

As we discussed in the CY 2003 physician fee schedule final rule, we interpret § 410.26(a)(7) literally; that is, ''incident to'' services and supplies

covered under section 1861(s)(2)(A) of the Act means services and supplies not having their own independent and separately listed statutory benefit category (67 FR 79994.) The commenter provided the example of diagnostic tests performed under the direct supervision of a physician and meeting the requirements under the ''incident to'' billing rules. Regardless of the physical possibility of diagnostic tests being performed under the direct supervision of a physician and meeting the requirements of certain billing rules, because these services have an independent and separately listed statutory benefit category (section 1861(s)(3) of the Act), they cannot be billed as ''incident to'' a physician service. (We note that we are deleting § 411.355(a)(3) because it is redundant and incorrectly suggests that diagnostic tests may be billed as ''incident to'' services.)

E. Physician in the Group Practice

We are modifying the definition of ''physician in the group practice'' to clarify that an independent contractor physician must furnish patient care services for the group under a contractual arrangement *directly* with the group practice.

Comment: A commenter asked that the definition of ''physician in the group practice'' be revised to delete the condition that a physician who is an independent contractor of a group practice is considered to be in the group practice only when he or she is performing services on the group practice's premises. The commenter noted that section 952 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) revised the reassignment provisions in section 1842(b)(6) of the Act to permit independent contractor physicians to reassign their claims to a group practice for services performed off-premises (§ 424.80(b)(2)).

Response: Section 1842(b)(6) of the Act generally prohibits Part B payment to any person or entity other than the beneficiary who received the service or the physician or other supplier who furnished the service. This section of the Act also enumerates specific exceptions, known as the reassignment exceptions, to this general rule. Prior to section 952 of the MMA, we were prohibited from making payment to an entity that received reassigned payments from a contractor physician or other contractor supplier, unless the physician or other supplier performed the service at issue on the premises of the entity billing for the service. Section 952 of the MMA amended section 1842(b)(6) of the Act, so that we are allowed to make payment to an entity that has received reassigned payments pursuant to a contractual arrangement, provided that the contractual arrangement meets the program integrity and other safeguards that the Secretary may determine are appropriate. Thus, although section 1842(b)(6) of the Act grants us general authority to honor certain reassignments made pursuant to a contractual arrangement, it does not require us to honor those we believe are potentially abusive. We note that section 952 of the MMA does not apply exclusively to arrangements with group practices, and, therefore, retains meaning in the context of reassignments between other parties. For these reasons, we do not believe that section 952 of the MMA requires us to change our definition of ''physician in the group practice'' so that an independent contractor physician qualifies as a ''physician in the group practice'' irrespective of whether he or she is performing services on or off the group practice's premises. We draw attention to § 424.80(a), which, in implementing section 952 of the MMA, we amended to state that nothing in § 424.80 relieves a party's obligations under certain other rules, including the physician self-referral rules.

We continue to believe that it is appropriate to consider an independent contractor physician a ''physician in the group practice'' only when he or she is performing services in the group practice's facilities and, thus, has a clear and meaningful nexus with the group's medical practice. The term ''physician in the group practice'' is central to the definition of a group practice and significant for purposes of two important exceptions in section 1877 of the Act: The physician services exception and the in-office ancillary services exception. These exceptions enable physicians to make referrals for DHS within their group practices provided that certain requirements are satisfied. Accordingly, the strong nexus with a group practice created by the requirement that an independent contractor physician practice in a group practice's facilities ensures that the physician is truly practicing ''in the group.''

Comment: Two commenters expressed the need for clarification of the requirements for qualification as a ''physician in the group practice.'' These commenters asserted that a ''physician in the group practice'' is permitted to furnish only *supervision* services (which are not separately reimbursed by Medicare), and that any services for which a group practice actually bills Medicare must be provided by a *member* of the group. The commenters requested that we confirm their interpretation of the rules regarding billing for services of physicians in a group practice and members of a group practice. In the alternative, the commenters suggested that we require that any separately-billable services furnished by a ''physician in the group practice'' be provided in the same building where the group practice provides its full range of services, thus prohibiting a ''physician in the group practice'' from providing services in a centralized building. According to the commenters, this change would ensure that independent contractor physicians have a sufficient nexus to the group practice to justify the group's utilization of the in-office ancillary services exception.

Response: The commenters are mistaken that, as defined at § 411.351, a ''physician in the group practice'' (who can be either a member of the group or an independent contractor) may furnish only non-billable supervision services. The definition makes clear that a ''physician in the group practice'' can include an independent contractor who is ''furnishing patient care services.'' ''Patient care services'' is defined at § 411.351 to encompass a broad range of billable and non-billable services.

In order to qualify as a ''group practice'' under § 411.352, only members of the group practice (and not independent contractor physicians in the group practice) are required to furnish ''substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment and personnel.'' In other words, an independent contractor ''physician in the group practice'' may furnish billable services, and may furnish services—in the group practice's facilities—that comprise less than the full range of the patient care services that he or she usually furnishes. This enables a group practice to hire, on a contract basis, a specialist or other physician without jeopardizing the group's ability to qualify as a group practice and utilize the in-office ancillary services exception, even if the contracted physician works for several physician practices or facilities. We note that qualifying as a group practice is not in and of itself sufficient to comply with the physician self-referral rules, and that use of the in-office ancillary services exception requires compliance with all of the conditions of that exception.

Under our regulations, an independent contractor physician is a ''physician in the group practice'' only when he or she is performing services in the group practice's facilities. We are concerned about reports that some group practices purport to rely on the in-office ancillary services exception in § 411.355(b) when they: (1) Nominally comply with the centralized building requirements in § 411.355(b)(2)(ii) and (b)(2)(iii); (2) contract with independent contractor physicians to furnish or supervise services in the centralized building as ''physicians in the group practice''; (3) accept reassignment of the right to payment from those physicians; and (4) realize profits based on the services they refer to the independent contractor ''physicians in the group practice'' stationed in the centralized building. In the physician fee schedule proposed rule for CY 2007, we proposed changes to our reassignment rules and to the definition of ''centralized building'' to address potentially abusive arrangements (71 FR 48981, 49054–49057). We are reviewing the public comments to our proposal and intend to issue a final rulemaking on this subject.

Comment: One commenter noted that the definition of ''member of the group'' at § 411.351 specifically excludes leased employees who do not meet the definition of an ''employee'' at § 411.351. The commenter questioned whether a leased employee who does not meet the definition of an employee may nevertheless meet the definition of a ''physician in the group practice.'' The commenter noted that an independent contractor physician may be a ''physician in the group practice'' and asserted that there does not appear to be any distinction between an independent contractor and a leased employee who does not meet the definition of an ''employee'' that would justify excluding the latter type of individual from being a ''physician in the group practice.''

Response: The definition of ''physician in the group practice'' clearly encompasses only members (that is, owners and employees) and independent contractors. We are not persuaded to include other types of employment relationships (such as arrangements involving a group practice ''leasing'' or borrowing a physician who is an employee or contractor of some other entity. In order to fit within the definition of ''physician in the group practice,'' an independent contractor must have ''a contractual arrangement with the group practice.'' We interpret this to require that the contractual arrangement be directly between the group practice and the independent contractor physician, and not between the group practice and another entity, such as a staffing company. We are expressly incorporating this interpretation into the regulations by modifying the definition of ''physician in the group practice'' at § 411.351.

Group practices receive favorable treatment under the physician self-referral law with respect to physician compensation. Accordingly, we believe that, in order to qualify as a group practice and receive such favorable treatment, the group practice's physicians must have a strong and meaningful nexus to the group practice. An independent contractor in direct contractual privity with a group practice has such a nexus; employees leased from other entities do not. We believe this justifies excluding a leased employee from being a ''physician in the group practice,'' contrary to the commenter's assertion that there is no distinction between an independent contractor and a leased employee. Moreover, we are concerned about potentially abusive arrangements, such as a situation in which a physician is employed by (and receives one W–2 from) a staffing company that leases the physician to numerous group practices, none of which has to enter into an individual contract with the physician but all of which can consider the physician a ''physician in the group practice'' with the attendant benefits of such categorization.

F. Radiology and Certain Other Imaging Services and Radiation Therapy

In Phase II, we defined ''radiology and certain other imaging services'' to exclude radiology procedures that are integral to the performance of a nonradiological medical procedure and performed during the nonradiological procedure, or immediately following the nonradiological procedure when necessary to confirm placement of an item placed during the nonradiological procedure (69 FR 16103). We declined to include nuclear medicine in the DHS category of ''radiology and certain other imaging services,'' but stated that we would continue to study the issue. One commenter stated that it disagreed with our decision. Based on this comment and further study, in the CY 2006 physician fee schedule proposed rule, we proposed to include diagnostic nuclear medicine services within the meaning of ''radiology and certain other imaging services,'' and to include therapeutic nuclear medicine services within the meaning of ''radiation therapy and supplies'' (70 FR 45854–45856). We adopted our proposal in the CY 2006 physician fee schedule final rule (70 FR 70283–70289), effective January 1, 2007.

We are making no changes to the definition of ''radiology and certain other imaging services'' in this Phase III final rule.

Comment: One commenter noted that, in Phase II, we specifically declined to exclude ophthalmic A-scans and B-scans from the definition of ''radiology and certain other imaging services'' (69 FR 16103). The commenter disagreed with our conclusion, particularly with respect to A-scans. The commenter stated that the applicable standard of care dictates that A-scans are integral to cataract and other refractive surgeries and that they are not diagnostic in nature because they guide *how* surgery will be performed, not *whether* surgery will be performed. According to the commenter, although the scan is not done during the operation, it is an integral part of the surgery and raises little risk of abuse or overutilization because it will be done only if cataract surgery has already been prescribed.

Response: An A-scan involves the transmission of high-frequency sound waves through the eye and the measurement of their reflection from ocular structures. An A-scan provides a one-dimensional picture, most commonly used to measure the eye length and provide the data needed to calculate the power of the optical correction of the intraocular lens implant for cataract surgery. A B-scan, which is a two-dimensional cross section view of the eye, is used if the view inside the eye is obstructed by blood, an extremely dense cataract, or other cloudy media.

The definition of ''radiology and certain other imaging services'' at § 411.351 does not include radiology procedures that are integral to the performance of a nonradiological medical procedure and performed: (1) During the nonradiological medical procedure, or (2) immediately following the nonradiological medical procedure when necessary to confirm placement of an item placed during the nonradiological medical procedure. The commenter correctly states that often an A-scan (and a B-scan, as appropriate) is a pre-operative procedure performed prior to cataract surgery (which is a scheduled elective surgery). These scans are not performed during or just after cataract surgery. A-scans and B-scans are included in the definition of ''radiology and certain other imaging services'' because, even though they are integral to the performance of a nonradiological medical procedure, they are not performed during the nonradiological medical procedure or

immediately following it to confirm placement of an item placed during the nonradiological medical procedure. However, in the CY 2008 Outpatient Prospective Payment System notice of proposed rulemaking, we proposed to exclude from the definition of ''radiology and certain other imaging services'' at § 411.351 radiology procedures that are ''covered ancillary services'', as defined at § 416.164(b) of this chapter for purposes of the revised ASC payment system. The term ''covered ancillary services'' includes certain radiology services that are integral to, and performed on the same day as, a covered ambulatory surgical procedure.

Comment: One commenter stated that it welcomed the exclusion from the definition of ''radiology and certain other imaging services'' of radiology services performed immediately after nonradiology services. The commenter asserted that it is standard protocol to order a CT scan in the aftermath of prostate brachytherapy in order to ensure that the radioisotopes have been placed properly. The commenter asserted that, although some may prefer to perform this service immediately after the procedure, it is better from a clinical standpoint to wait several weeks because the additional time allows for the prostate to become less swollen, thereby enabling the physician to determine more accurately whether the seeds were placed correctly. Therefore, the commenter suggested that we expand the exclusion from the definition to also include a CT scan taken within 6 weeks after the prostate brachytherapy to confirm proper placement of the isotopes.

Response: We decline to adopt the commenter's proposal. As we stated in Phase I, where the radiology procedure is performed after the nonradiology procedure (as opposed to radiology procedures integral to and performed during a nonradiological procedure), referring physicians have discretion in choosing the entity that provides the radiology service independent of the entity providing the nonradiology procedure (66 FR 929). In Phase II, we excluded from the definition of ''radiology and certain other imaging services'' radiology procedures performed immediately after the nonradiology procedure in order to confirm placement of an item because we believed there would be no risk of program or patient abuse by doing so (69 FR 16103). Where a radiology procedure is not performed *immediately* after the nonradiology procedure to confirm placement of an item, we believe there is a risk that the referring physician may direct referrals to an entity with which he or she has a financial interest, the very conduct addressed by the statute. As we noted in Phase II, depending on the facts and circumstances, exceptions, such as the in-office ancillary services exception in § 411.355(b) or the rural provider exception in § 411.356(c)(1), may apply to referrals for radiology services furnished before or after the nonradiology procedure (69 FR 16103).

We note also that, depending on the facts and circumstances, CT scans or other imaging ordered in the aftermath of prostate brachytherapy may qualify as ''necessary and integral'' ancillary services so as to come within the consultation exclusion from the definition of ''referral.'' We question whether a CT scan or other imaging performed as late as 6 weeks after the brachytherapy would be ''necessary and integral'' to the brachytherapy, but decline to say that such a CT scan or other imaging could never be ''necessary and integral'' to the original procedure (and, thus, not be considered a ''referral'' for purposes of the physician self-referral law); rather, the specific facts and circumstances control.

G. Referral

Section 1877(h)(5)(c) of the Act defines ''referral'' as a request by a physician for an item or service for which payment may be made under Medicare Part B, including a request for a consultation and any DHS ordered or performed by the consulting physician or under the supervision of the consulting physician, and the request or establishment of a plan of care by a physician that includes the furnishing of DHS, with certain exceptions for a small subset of services provided or ordered by pathologists, diagnostic radiologists, and radiation oncologists in accordance with a consultation requested by another physician.

In Phase I, we defined ''referral'' to exclude services personally performed by a physician who ordered the services, but to include DHS provided by the physician's employees or contractors or by other members of the physician's group practice (66 FR 871–872). In Phase II, we confirmed that a ''referral'' includes services performed by others ''incident to'' the physician's services (69 FR 16063). Phase II also clarified that the definition of ''referral'' excludes referrals for necessary and integral DHS ordered and appropriately supervised by a radiation oncologist pursuant to a consultation (69 FR 16065).

We received several comments addressing the issue of services performed by a physician's employees that are ''incident to'' the physician's personally-performed services. Other comments addressed the exclusions from the definition of ''referral'' for certain DHS requested by radiologists, pathologists, and radiation oncologists pursuant to a consultation. We are making no changes to the definition of ''referral'' in this Phase III final rule.

Comment: Several commenters requested clarification of the statement in Phase II regarding whether there is a ''referral'' when antigens are prepared and furnished by a physician, or whether there is a ''referral'' when a physician refills an implantable pump (69 FR 16063). The response in Phase II appeared, in the commenters' view, to indicate that, if a physician personally prepares and furnishes antigens or personally refills an implanted pump for a patient, there is no ''referral'' for purposes of the physician self-referral statute. From this statement, the commenter concluded that the physician could bill for these DHS without consideration as to whether the referrals satisfy the requirements of an exception.

Response: In Phase II, we stated that the definition of ''referral'' excludes services personally performed or provided by the referring physician, but specifically includes any services performed or provided by anyone else (69 FR 16063). This interpretation is codified in the definition of ''referral'' at § 411.351. It is possible for a physician to order and personally furnish antigens to a patient and to order a refill for, and personally refill, an implantable pump. In such instances, there would be no ''referral'' for a designated health service, and no exception is needed.

We note that the furnishing of durable medical equipment (DME) and supplies by a referring physician requires a different analysis than the mere refilling of an implantable pump. There are few, if any, situations in which a referring physician would personally furnish DME and supplies to a patient, because doing so would require that the physician himself or herself be enrolled in Medicare as a DME supplier and personally perform all of the duties of a supplier as set forth in the supplier standards in § 424.57(c).

DME suppliers are entities that provide services under the specific Part B benefit for the provision of medical equipment and supplies for use in the patient's home. These entities must be enrolled with the appropriate Medicare contractor as a DME supplier and must meet all of the professional supplier standards and quality standards that we require through regulations and

administrative or program instructions. The enrollment requirements and professional supplier standards are not waived in those situations in which a physician furnishes DME directly to the patient. The services to be personally performed by the physician would include, but not be limited to, the following, as appropriate—

- Personally fit the item for the beneficiary;
- Provide necessary information and instructions concerning use of the DME;
- Advise the beneficiary that he or she may either rent or purchase inexpensive or routinely purchased DME;
- Explain the purchase option for capped rental DME;
- Explain all warranties;
- (Usually) deliver the DME to the beneficiary at home; and
- Explain to the beneficiary at the time of delivery how to contact the physician in his or her capacity as a DME supplier by telephone.

A referring physician claiming to provide DME personally would need to maintain adequate documentation to establish that the physician personally performed these and other required DME supplier activities. All of these supplier requirements would need to be satisfied in order for a physician to be considered to be providing personally DME items and supplies. This is true for all DME furnished by a physician, including, for example, continuous positive airway pressure (CPAP) equipment. We believe that it is highly unlikely that a referring physician would meet the criteria for personally performed services when dispensing CPAP or other DME equipment. Thus, the dispensing of CPAP equipment by a physician would almost always constitute a ''referral'' for purposes of the physician self-referral statute, as would the dispensing of CPAP equipment by anyone else affiliated with the referring physician, such as a nurse or physician assistant. We note that CPAP equipment is DME that does not qualify for the in-office ancillary services exception.

Comment: One commenter suggested that a ''referral'' should not include ''incident to'' services requested by a physician and performed by an employee or contractor, unless the services are performed by an employee or contractor who is licensed to provide the services without physician supervision and who could otherwise bill separately for the services. The commenter also requested that we provide further education to physicians on how these ''incident to'' services would fit into the in-office ancillary services exception.

Response: The commenter provided no support for its suggestion, nor did the commenter explain why the in-office ancillary services exception does not provide adequate protection under the circumstances described. We decline to change our interpretation of ''referral'' as requested by the commenter. As we stated in Phase II:

> We are adhering to our original determination that ''incident to'' services performed by others, as well as services performed by a physician's employees, are referrals within the meaning of section 1877 of the Act. * * * As a practical matter, although ''incident to'' services and employee services are included in the definition of ''referrals'' for purposes of section 1877 of the Act, many of those referrals will fit in the in-office ancillary services [exception] or another exception.

(69 FR 16063.) We continue to conclude that requests for DHS performed by a physician's employees or independent contractors are ''referrals'' within the meaning of the physician self-referral prohibition, although these referrals may satisfy the requirements of an exception, including the in-office ancillary services exception in § 411.355(b).

Comment: Several commenters pointed out that, although we stated in Phase II that we were expanding the consultation exclusion to protect ancillary services that were necessary and integral to the provision of radiation therapy, the regulation text did not include any language to that effect (69 FR 16065). One commenter requested that the regulatory definition be amended to conform to the preamble discussion. Another commenter complained that the expansion of the consultation exclusion to include ancillary services that are necessary and integral to radiation oncology would increase utilization and Federal health care program costs and defeat the purposes of section 1877 of the Act. Two commenters, one representing brachytherapy providers, requested that interventional radiologists be permitted to provide diagnostic imaging services that are necessary and integral to their procedures.

Response: In Phase II, we intended to revise the definition of ''referral'' at § 411.351 to exclude from the definition ancillary services that are necessary and integral to the provision of radiation therapy, but inadvertently neglected to amend the regulatory text. In the CY 2006 physician fee schedule final rule published November 21, 2005, we made a technical correction that modified the language in paragraph (2) of the definition of ''referral'' at § 411.351 to clarify that ancillary services necessary for and integral to the provision of radiation therapy are also protected by the consultation provision (70 FR 70330). We believe that the clarification was necessary to effectuate the statutory exclusion, and that it is sufficiently narrow to prevent abuse. No additional change is needed.

We do not believe that it is appropriate to exclude from the definition of ''referral'' ancillary testing necessary and integral to interventional radiology procedures performed as a result of a consultation. Interventional radiologists perform minimally invasive procedures using imaging for guidance. Examples of these procedures include angiography, angioplasty, biopsy, stenting, cryotherapy, and embolization. Because it is our understanding that interventional radiology is surgical in nature, we believe that any necessary and integral services would be ancillary to a surgical procedure, rather than to a radiology procedure. Thus, the consultation provision would not apply. Depending on the facts and circumstances, diagnostic imaging services performed by interventional radiologists may fit within the exclusion from the definition of ''radiology and certain other imaging services'' for radiology procedures that are integral to the performance of a nonradiological medical procedure and performed during the procedure or immediately following the procedure to confirm placement of an item placed during the procedure.

Comment: One commenter asked us to clarify whether the consultation exclusion for radiation oncologists in the definition of ''referral'' at § 411.351 protects radiation oncology services personally performed by the radiation oncologist or by a radiation oncologist in the same group practice. The commenter noted that Phase II expanded the consultation exclusion from the definition of ''referral'' to permit radiation therapy requested by a radiation oncologist to be performed by or under the supervision of the radiation oncologist, or under the supervision of a radiation oncologist in the same group practice (69 FR 16131). The commenter stated that, read literally, the exclusion from the definition of ''referral,'' as amended, would allow a radiation oncologist in the consulting radiation oncologist's group practice to supervise the radiation therapy, but not to perform it.

Response: The commenters' reading of the definition of ''referral'' at § 411.351 is correct. The consultation exclusion for radiation oncologists in

the definition of ''referral'' protects only radiation oncology services personally performed or supervised by the radiation oncologist or services supervised by a radiation oncologist in the same group practice. Requests by a pathologist for clinical diagnostic laboratory tests and pathological examination services and requests by a radiologist for diagnostic radiology services are treated similarly.

Comment: Several commenters asked that we expand the consultation provision to include ''walk-in'' patients (that is, patients who are seen by a physician without having been referred to that physician by another physician), as well as patients referred by other physicians. According to the commenters, there is no reason these patients are more likely to receive unnecessary treatment.

Response: We decline to make the change suggested by the commenters. We believe that walk-in patients for pathology, radiology, and radiation oncology are not common. Moreover, the fact that a patient ''walks in'' to a physician's office (whether a pathologist, radiologist, radiation oncologist, or other type of physician) is not determinative under the physician self-referral law with respect to DHS referrals made by the physician whose services are sought by the walk-in patient. Thus, even if a patient initially self-refers to a pathologist, radiologist, or radiation oncologist, subsequent orders of items or services by the pathologist, radiologist, or radiation oncologist are referrals of DHS. Moreover, these referrals are subject to potential overutilization or other abuse.

As we noted in Phase I (66 FR 874), the Congress regarded the specialists excepted under the definition of ''consultation'' as physicians who were not initiating a referral for services, but merely implementing the request of another physician who has already determined that the patient is likely to need the specialist's services. In these situations, the Congress indicated its belief that overutilization would not be likely. As we noted in Phase II (69 FR 16064), the statutory consultation exception ''creates a narrow exception for a small subset of services provided or ordered by certain specialists in accordance with a consultation requested by another physician.'' The additional protection against overutilization of diagnostic radiology, pathology, and radiation therapy services implicit when a radiologist, pathologist, or radiation oncologist merely implements a determination made by another physician that the patient is likely to need the specialist's services (and those services meet the requirements of a consultation) are not present in the case of a patient who ''walks in'' for these services.

We are mindful that services provided to walk-in patients will not meet the definition of ''consultation,'' and any subsequent DHS will, therefore, be the subject of a referral by the pathologist, radiologist, or radiation oncologist. Depending on the circumstances, these referrals may satisfy the requirements of an exception to the prohibition on physician self-referral. As noted in Phase II in response to similar concerns about self-referred patients (69 FR 16066), changes made to the in-office ancillary services exception in Phase II should, in many circumstances, enable DHS referrals for self-referred patients to fit in that exception.

Comment: Several commenters requested that we clarify that the consultation exclusion covers the technical component of DHS ordered by hospital-based pathologists and radiologists pursuant to a consultation. Another commenter suggested that DHS ordered by anesthesiologists pursuant to a consultation should also be excluded from the definition of a referral.

Response: We have previously considered the first issue and continue to believe that, where a physician orders the technical component of a designated health service (for example, an x-ray) and someone other than the physician performs the technical component, there is a referral to which section 1877 of the Act applies (66 FR 871, 69 FR 16063). However, the commenters are correct with respect to the technical component of a designated health service ordered by a hospital-based pathologist, radiologist, or radiation oncologist, if the requirements of the consultation exclusion otherwise apply. Specifically, the technical components of DHS ordered by these types of physicians pursuant to a consultation are subject to the consultation exclusion from the definition of a ''referral'' at § 411.351.

With respect to extending the consultation provision to DHS ordered by anesthesiologists, we note that the statutory exception is limited to pathologists, radiologists, and radiation oncologists who meet certain criteria. We do not have the authority to extend the statutory consultation exception in the definition of ''referral'' to specialists other than those enumerated by the Congress. Moreover, we are not persuaded that any special regulatory exception is warranted for DHS referrals made by an anesthesiologist to an entity with which he or she (or his or her immediate family member) has a financial relationship. Depending on the circumstances, anesthesiologist referrals for DHS may qualify for an existing exception, including, for example, the exception for personal service arrangements or the exception for *bona fide* employment relationships.

Comment: One commenter asked that the consultation exclusion from the definition of ''referral,'' which, according to the commenter, protects tests performed by other pathologists, radiologists, or radiation oncologists in the same group practice, be expanded to protect services furnished by physicians who are employees of the same entity, such as a hospital. The commenter gave the example of a hospital-employed radiologist who receives an order for diagnostic services and subsequently directs a second radiologist employed by the same hospital to perform the services. According to the commenter, there is no possibility of abuse in this situation, and the change is necessary to permit hospital-employed pathologists, radiologists, and radiation oncologists to provide coverage for each other.

Response: We do not agree that an expansion of the consultation exception is warranted. Where physicians have a common hospital employer that bills for the technical components of a test (that is, the hospital is the DHS entity), the hospital and the referring physicians may avail themselves of the exception for *bona fide* employment relationships in § 411.357(c). With respect to any professional component of the services that are DHS, the hospital should be able to bill pursuant to a reassignment (which would make the hospital the DHS entity), and the arrangement could be structured to satisfy the requirements of the exception for *bona fide* employment relationships.

H. Rural Area

The term ''rural area'' is used throughout the physician self-referral regulations. For ease of reference and to simplify the regulations, we are moving the definition to § 411.351. For physician self-referral purposes, we are defining ''rural area'' as an area that is not an urban area as defined at § 412.62(f)(1)(ii). The definition is consistent with the definition in the statutory exception for rural providers at section 1877(d)(2) of the Act.

IV. Group Practice—§ 411.352

The determination of which organizations qualify as group practices for purposes of section 1877 of the Act is critical for several exceptions, including the in-office ancillary services exception. In addition, section 1877 of the Act allows group practices more flexibility in compensating physicians

(for example, only group practice physicians may be compensated in a manner that takes into account services furnished ''incident to'' a physician's personally performed services).

Phase I addressed the requirements for qualification as a group practice under section 1877(h)(4) of the Act. (The regulatory requirements appear in § 411.352.) Most commenters commended the changes made in Phase I. In Phase II, we made several minor changes to § 411.352.

This Phase III final rule makes one minor change to § 411.352 to reflect more closely the statutory scheme and our original intent in the Phase I final regulation that the ''incident to'' services need not themselves be personally performed by the referring physician: we are changing the parenthetical language in § 411.352(i)(1) to permit a physician in the group to be paid a productivity bonus based on services that he or she has personally performed, or services ''incident to'' such personally performed services or both.

Comment: One commenter asked for confirmation that a separate corporation that is formed by a hospital and that has as its primary purpose being a physician group and employing physicians would meet the single legal entity requirement even if the physicians are divided into different divisions based on specialty.

Response: A separate corporation formed by a hospital to employ physicians can constitute a single legal entity, provided that the specialty divisions are not separate legal entities and the arrangement otherwise satisfies the requirements of § 411.352.

Comment: One commenter asked that we clarify that a medical foundation qualifies as a group practice.

Response: For the reasons noted in Phase I (66 FR 902–903) and Phase II (69 FR 16077), including those discussed below, we do not believe it is feasible to make a blanket determination that all medical foundations qualify as group practices. Moreover, we see no need to revisit the requirements for qualification as a group practice under § 411.352 or the discussion in Phase II regarding whether a foundation can meet those requirements.

The commenter has failed to convince us that many typical foundation-model practice arrangements satisfy the requirements for qualification as a group practice. Section 1877(h)(4)(A) of the Act defines ''group practice'' to include, *inter alia*, two or more physicians legally organized as a foundation. In one common variation of a foundation-model arrangement, it is the foundation, and not the physicians, that owns the medical practice; thus, the *physicians* are not legally organized as a ''foundation'' as that term is used in section 1877(h)(4)(A) of the Act. Instead, the *foundation* owns and operates all elements of the practice. However, because it cannot provide physician services, the foundation employs or contracts with physicians to furnish patient care services (66 FR 902.) In States in which a foundation (or other corporation) may provide physician services, a medical foundation may be a group practice if all of the group practice requirements are satisfied.

As we noted in Phase II, if a particular foundation-model arrangement meets the single legal entity test (and has at least two physician employees), it may qualify as a group practice under § 411.352 and use the in-office ancillary services exception in § 411.355(b), provided that all other requirements of § 411.352 and the in-office ancillary services exception are met (69 FR 16077).

Comment: Two commenters inquired about the application of the indirect compensation arrangements exception and personal service arrangements exception to foundation-model practices. One commenter questioned whether foundation-model structures create indirect compensation arrangements between referring physicians and the DHS entity that owns the foundation, thus implicating the indirect compensation arrangements exception requirements.

Response: With respect to the application of the indirect compensation arrangements exception and personal service arrangements exception to arrangements involving medical foundations, we reiterate that an arrangement need not satisfy the requirements of a *specific* exception to comply with the physician self-referral rules. An entity may rely on any exception that an arrangement satisfies (66 FR 916, 919; 69 FR 16086.) With the new ''stand in the shoes'' provision (discussed below in section VI.B), many arrangements involving foundation-model structures may be deemed to be direct compensation arrangements and potentially qualify for the personal service arrangements exception. Whether a particular arrangement constitutes an indirect compensation arrangement pursuant to § 411.354(c) will continue to depend on the specific facts and circumstances of the arrangement.

Comment: One commenter asserted that a ''typical'' medical foundation arrangement is structured as follows: a nonprofit medical foundation owns and operates a nonprofit health care clinic and contracts with a medical group (organized as a professional corporation) to provide the professional services of the group's employed physicians at the foundation's clinic. The medical foundation pays the group aggregate compensation that is then divided among the group's physicians. The commenter inquired whether the medical group can qualify as a group practice within the meaning of the physician self-referral rules if the medical foundation bills and collects for the professional services of the medical group using a provider number assigned to the foundation.

Response: As we observed in Phase II (69 FR 16077), foundation-model physician practices exist in a variety of forms, depending on jurisdiction and other factors; therefore, it is difficult to generalize about these arrangements. Nothing in the physician self-referral regulations precludes a foundation-model physician practice from qualifying as a ''group practice'' if it can satisfy every element of the requirements in § 411.352.

The fact that a medical foundation bills and collects for the professional services of the physicians in the medical group who provide services at the foundation's clinic using a billing number assigned to the foundation rather than a billing number assigned to the group does not necessarily disqualify the medical group from satisfying the requirements of § 411.352. However, the fact that professional services of members of the medical practice are billed by the foundation using a billing number assigned to the foundation pursuant to a reassignment may affect the ability of the medical practice to satisfy the ''substantially all'' test in § 411.352(d), which requires that substantially all (that is, at least 75 percent) of the patient care services of the physicians who are members of the group practice (for example, owners or employees) are provided through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group. Where professional services are provided to a foundation clinic pursuant to a services contract between the group practice and the foundation, a group practice may count such services as services the physician provides through the group. For further explanation of the ''substantially all'' test, see 66 FR 904–905 and 69 FR 16079.

We note that, if a foundation-model practice qualifies as a group practice under § 411.352, the practice may be able to use the physician services or in-office ancillary services exceptions for

DHS referrals where the group practice is the entity furnishing the DHS (that is, where the DHS are billed under the group practice's billing number, not the foundation's billing number). Referrals of DHS billed by the foundation would not qualify for these exceptions.

Comment: One commenter asserted that faculty practice plans should be entitled to the same treatment as group practices with respect to methodologies for compensating the plan physicians. According to the commenter, the inclusion of faculty practice plans as entities eligible under the statutory definition of ''group practice'' in section 1877(h)(4)(A) of the Act evidences the Congress's intent that faculty practice plans be treated as group practices. The commenters asserted that the failure to include faculty practice plans as group practices disadvantages physicians in academic practice.

Response: Nothing in the regulations prevents a faculty practice plan from qualifying as a group practice if it can satisfy the conditions in § 411.352 (66 FR 917). If these conditions are satisfied, the faculty practice plan may avail itself of the physician services exception in § 411.355(a) and the in-office ancillary services exception in § 411.355(b) for DHS referrals within the faculty practice plan, as well as the special rule for productivity bonuses and profit shares in § 411.352(i). We note that neither the physician services exception, nor the in-office ancillary services exception, would protect referrals by faculty practice plan physicians to other components of an academic medical center, such as the affiliated hospital. In such circumstances, the academic medical center services exception may be useful.

Comment: One commenter asked for clarification of the unified business test requirement that a group practice have centralized decision-making by a body representative of the group practice and its application to a nonprofit corporation. Under IRS rules, a majority of the board of a tax-exempt, nonprofit corporation must be composed of disinterested representatives of the community. The commenter suggested that, in these situations, the individuals that are representative of the group practice should not have to constitute a majority of the board.

Response: The regulations in § 411.352(f)(1)(i) require that the decision-making body be representative of the group practice and that the decision-making body, not the group practice, maintain effective control over the group's assets and liabilities. Nothing in the regulations requires that a majority of the decision-making body be physicians (although this might be a reasonable and prudent way to ensure fair representation). In Phase II, we noted that ''there must be substantial 'group level' management and operation,'' but did not prescribe any particular process (69 FR 16080). Nothing in the regulations would preclude a tax-exempt, nonprofit group practice with a majority of its board composed of disinterested representatives of the community from satisfying the requirements of § 411.352(f)(1)(i) if the board maintains effective control over the group's assets and liabilities and is representative of the group practice.

Comment: Several commenters requested confirmation that a group practice can compensate its members (including employed physicians) and ''physicians in the group practice'' by directly taking into account the volume and value of items and services that are provided ''incident to'' the physicians' professional services. Commenters questioned the interplay between language in § 411.352(g) that prohibits group members from receiving any compensation based directly or indirectly on the volume or value of referrals by the physician and the special rule for productivity bonuses and profit shares in § 411.352(i), which provides:

> A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services that he or she has personally performed (including services ''incident to'' those personally performed services as defined [at] § 411.351), provided that the share or bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.

Response: The ''volume or value of referrals'' provision in § 411.352(g) (section 1877(h)(4)(A)(iv) of the Act) describes a ban, for purposes of the group practice definition, on compensating members of the group practice in any way that relates directly or indirectly to the volume or value of their DHS referrals. Notwithstanding this restriction, the ''special rule'' in § 411.352(i) (section 1877(h)(4)(B)(i) of the Act) permits group practices to compensate their physicians using profit shares and productivity bonuses that indirectly relate to DHS referrals without jeopardizing their ability to qualify as a group practice.

Specifically, in order to qualify as a group practice, a physician practice may not compensate a physician who is a member of the practice *directly or indirectly* based on the volume or value of referrals by the physician. However, under the special rule for profit shares and productivity bonuses, a group practice may pay a physician in the group practice a share of overall profits of the group provided that the share is not determined in any manner that is *directly* related to the volume or value of referrals of DHS by the physician. A group practice may also pay a physician in the group practice a productivity bonus based on services that the physician has personally performed or services ''incident to'' such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.

With respect to productivity bonuses based on ''incident to'' services, we stated in Phase I (66 FR 909) our view that group practice physicians can receive compensation directly related to the physician's personal productivity and to services incident to the physician's personally performed services. We noted that the services would have to comply with the requirements of section 1861(s)(2)(A) of the Act and section 2050 of the Carriers Manual (now section 60.1 of the CMS Internet–only Manual, publication 100–02, Medicare Benefit Policy Manual, Chapter 15 (Covered Medical and Other Health Services)) or other HHS rules and regulations affecting ''incident to'' billing. That is, the services would have to be directly supervised by the physician under the ''incident to'' billing rules (the physician must be present in the office suite and immediately available). We believe that this heightened supervision requirement provides some assurance that the ''incident to'' DHS would not be the primary incentive for a self-referral. In Phase II, we reaffirmed this interpretation and indicated that we were revising the regulations to make clear that productivity bonuses can be based directly on ''incident to'' services that are incidental to a physician's personally performed services (69 FR 16080).

Based on comments to the Phase II rule, we believe additional regulatory text refinement is warranted. Accordingly, we have revised § 411.352(i) to read:

> A physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group may be paid a productivity bonus based on services that he or she has personally performed (or services ''incident to'' such personally performed services), provided that the bonus is not determined in any manner that is

directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services ''incident to'' the physician's personally performed services).

The revised regulatory text makes clear that productivity bonuses can be based directly on ''incident to'' services that are incidental to the physician's personally performed services, even if those ''incident to'' services are otherwise DHS referrals (for example, physical therapy or outpatient prescription drugs). The productivity bonus cannot be directly related to any other DHS referrals, such as diagnostic tests or hospital admissions. We note that in Phase II (69 FR 16080), we also indicated that overall profit shares could relate directly to ''incident to'' services. Upon further reflection, we have concluded that this interpretation is inconsistent with the clear statutory language, which includes ''incident to'' services only in the context of productivity bonuses, and with our Phase I interpretation (66 FR 908–909). Thus, we are withdrawing our statement in Phase II at 69 FR 16080 with respect to overall profit shares and ''incident to'' services. Because an overall profit share under § 411.352(i)(2) means the aggregation of profits derived from DHS of the group as a whole or of a component of at least five physicians, an overall profit share will necessarily include profits from DHS that are billed as ''incident to'' services (66 FR 876,909). Under this Phase III final rule, profits must be allocated in a manner that does not relate directly to DHS referrals, including any DHS that is billed as an ''incident to'' service. We note that the regulations provide a number of methods that satisfy this requirement.

Comment: One commenter requested clarification that ''incident to'' drugs may be factored directly into productivity bonuses, given that § 411.352(i) speaks only of ''services'' and not ''items.''

Response: A physician in a group practice may be paid a productivity bonus based on services and supplies furnished ''incident to'' a physician's personally performed services. We defined '' 'incident to' services'' at § 411.351 to mean those services that meet the requirements of section 1861(s)(2)(A) of the Act and § 410.26 of our regulations, both of which set forth coverage criteria for ''services and supplies'' furnished incident to a physician's professional services. Given our intent to conform the physician self-referral regulations as much as possible to existing Medicare coverage and payment rules, we did not intend in Phase I or Phase II to distinguish between ''services'' and ''supplies'' furnished incident to a physician's professional services. Accordingly, we are revising the definition of '' 'incident to' services'' at § 411.351 to clarify that the term includes both services and supplies (such as drugs) that meet the applicable requirements set forth in section 1877(h)(4)(B)(i) of the Act and § 410.26 of our regulations.

Comment: One commenter stated that many group practices, in order to avoid taxes, do not allocate ''profits'' to their members, but distribute ''bonuses.'' The commenter asked if the group practice has complied with § 411.352(i) if it calculates its ''bonuses'' in a manner that complies with the profit-sharing requirements.

Response: A group practice may compensate physicians with overall profit shares or productivity bonuses, or some combination of the two, provided that the allocation methodology complies with § 411.352(i)(2) or (i)(3), respectively. Whether the characterization of funds distributed to physicians as ''bonuses'' rather than ''profits'' meets IRS rules is outside the scope of this rulemaking.

Comment: A commenter requested that the minimum size of a group practice component for purposes of profit-sharing under § 411.352(i)(2) be fewer than the current requirement of at least five physicians where the grouping constitutes an identifiable specialty or practice focus within the group practice. According to the commenter, one of every four orthopedic groups has two or three physicians, and many larger groups have subspecialties of fewer than five members.

Response: We stated in Phase I (66 FR 908) and Phase II (69 FR 16080–16081) that we saw no reason to reduce the minimum number of physicians in a component for profit-sharing purposes. We maintain this position. Our concern remains that smaller components increase the risk of overutilization of DHS and other abuse by strengthening the ties between an individual physician's compensation and his or her referrals. Setting the minimum number of physicians in a group practice component at five reduces the likelihood that a physician will be directly compensated for his or her own referrals.

V. Prohibition on Certain Referrals by Physicians and Limitations on Billing—§ 411.353

Section 411.353 sets out the basic prohibition on physician self-referral under section 1877 of the Act. Two provisions, § 411.353(e) and § 411.353(f), address the potentially harsh results from inadvertent violations of the prohibition. Section 411.353(e), which was added in Phase I, provides that payment may be made to an entity that submits a claim to Medicare for DHS if the entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who referred the DHS to the entity, provided that the claim otherwise complies with all applicable Federal laws and regulations. Section 411.353(f), which was added in Phase II, permits DHS entities to submit claims and receive payment for DHS furnished during certain instances of temporary noncompliance. Specifically, § 411.353(f) permits DHS entities to submit claims and receive payment for such claims if: (1) The arrangement had been in full compliance with an applicable exception for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant; (2) the financial relationship fell out of compliance for reasons beyond the entity's control and the entity promptly moved to address the noncompliance; and (3) the financial relationship does not violate the anti-kickback statute and complies with all applicable Federal and State laws, rules, and regulations. Section 411.353(f) applies only to DHS furnished during the time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant. We specified that an entity could not use the exception in § 411.353(f) more than once every 3-years with respect to the same referring physician, and the provision could not be used if the exception with which the financial relationship previously complied was either § 411.357(k) or (m) (regarding nonmonetary compensation and medical staff incidental benefits, respectively). In general, commenters welcomed the protections of § 411.353(e) and (f), but asked that they be broadened. We are making no substantive changes to § 411.353(e) or (f) in this Phase III final rule.

Comment: Some commenters asked for clarification regarding how long a DHS entity would be precluded from submitting claims for DHS referred by a physician with whom the DHS entity had a financial relationship that failed to comply with an exception and for which § 411.353(f) or § 411.357(f) either may not be applicable or may not

provide what the commenters believed would be sufficient protection.

Response: The statute provides no explicit limitation on the billing and claims submission prohibition. We are addressing this issue in another rulemaking.

Comment: Some commenters objected to our decision not to extend to referring physicians the protection of § 411.353(e) (regarding payments made to an entity that does not have knowledge of the identity of the physician who made the referral for DHS). The commenters acknowledged that a referring physician would not be subject to sanction under section 1877 of the Act unless the physician knowingly caused an improper claim or bill to be submitted (or knowingly engaged in a circumvention scheme). The commenters were concerned, however, that the referring physician who had no such intent could nevertheless be subject to liability under the civil False Claims Act, 31 U.S.C. 3729.

Response: Liability under the civil False Claims Act requires that the violator act knowingly. Only a physician who knowingly causes the submission of a bill or claim for a service for which payment may not be made under section 1877 of the Act would be subject to sanction under the civil False Claims Act for such conduct. Similarly, as the commenters' observe, a referring physician would not be subject to sanction under section 1877(g) of the Act unless the physician knowingly causes an improper claim or bill to be submitted (or knowingly engages in a circumvention scheme). Accordingly, we are not expanding the provision as suggested by the commenters.

Comment: Several commenters asked that we extend for a longer period of time the 90-day window in § 411.353(f)(2), which permits a physician and DHS entity that are parties to an arrangement that no longer satisfies the requirements of an exception to refer and submit claims, respectively, for DHS. Some commenters asked that the window run from the date of noncompliance until 30 or 90 days after the date on which the noncompliance was discovered. Commenters asserted that the other requirements of the exception, namely that the arrangement had to have been in compliance with an exception for at least 180-consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant and that the noncompliance was due to actions beyond the control of the DHS entity, were sufficient to protect against possible program or patient abuse. One commenter suggested that the expanded noncompliance window be conditioned on the good faith of the DHS entity and the immateriality or inadvertence of the noncompliance. One commenter acknowledged that starting the window from the time of discovery of the noncompliance may provide an incentive for hospitals and physicians to remain ignorant about noncompliant arrangements, but stated that this ''minor'' risk could be mitigated by a condition that would negate the use of the exception if that behavior exists. Another commenter recommended that, in a situation in which an arrangement is out of compliance, but the physician is unable to make referrals due to a disability, active military duty, or some other reason, the time for correcting the noncompliance be tolled until the point at which the physician is again reasonably able to make referrals.

Response: We disagree with the commenters that proposed a ''discovery-based'' rule, as well as with the commenter that recommended that the period in which noncompliance must be corrected be tolled during the time in which (for whatever reason) referrals are not being made. Section 1877 of the Act is intended to deter inappropriate financial relationships through a strict liability regime. A discovery-based rule is contrary to the statutory scheme. Moreover, such a rule creates a perverse incentive not to diligently monitor and enforce compliance. Tolling the time period for rectifying the noncompliance while a physician is unable to make referrals due to disability, military duty, or another reason is not necessary because it is not likely that the parties would violate the physician self-referral statute if no referrals are being made.

The commenters' suggestions would create substantial enforcement problems because it may be difficult to establish the date on which the noncompliance was discovered. Imposing standards regarding the materiality of the noncompliance or the good faith of the parties would present similar enforcement difficulties and would be contrary to the statutory scheme. Finally, we do not believe that extending the noncompliance window in § 411.353(f)(2) beyond the current 90-days is either warranted or necessary. Parties to an arrangement should monitor the continued compliance of the arrangement with the conditions of an applicable exception. We note, however, as discussed below at section IX.D, that we are establishing a 6-month holdover provision for personal service arrangements that otherwise meet the requirements in § 411.357(d). We believe that this provision, along with the holdover provisions already available in the exceptions for the rental of office space and equipment in § 411.357(a) and (b), should provide adequate relief to parties to arrangements of these types that would otherwise temporarily fall out of compliance with the physician self-referral law.

Comment: A hospital trade association asked that we delete the requirement in § 411.353(f)(1)(ii) that the noncompliance be due to reasons beyond the entity's control. Several commenters sought clarification as to what actions were beyond the control of the DHS entity. Two commenters asked whether a physician's failure to sign promptly a written contract that the hospital had sent in a timely manner and that otherwise complied with the personal service arrangements exception would be considered beyond the hospital's control. One commenter asked whether, in evaluating the failure to continue to satisfy the requirements of an exception, it made a difference that the hospital needed the services immediately, such as for on-call coverage. Specifically, the commenter gave the example of the provision of needed on-call coverage services prior to the formal execution of a written agreement for those services. Another commenter suggested that we clarify that an arrangement is eligible for the temporary noncompliance exception if it falls out of compliance with an exception due to the actions of a third party, such as the actions of the government through a change in the regulations or the removal of a Health Professional Shortage Area (HPSA) designation of an area for purposes of the physician retention exception.

Response: We discussed in detail the application of the temporary noncompliance exception in Phase II (69 FR 16057.) We are not repeating that explanation here. With respect to the inquiry regarding on-call coverage for which there is an immediate need, we reiterate that the DHS entity may avail itself of the temporary noncompliance exception only when the arrangement was in full compliance with an exception to the physician self-referral law under § 411.355, § 411.356, or § 411.357 prior to the temporary noncompliance. In the example provided by the commenter, the arrangement was never in compliance with the law, and therefore the temporary noncompliance exception would be unavailable to the DHS entity. With respect to the second commenter's example regarding noncompliance occurring due to loss of a HPSA designation, as we noted in Phase II,

such noncompliance would be considered beyond the entity's control (69 FR 16057). With respect to other instances of noncompliance caused by third parties, a determination of whether such noncompliance was beyond the entity's control would have to be made on a case-by-case basis. Finally, we do not believe it necessary or practical to give specific guidance on documentation of the steps taken to rectify temporary noncompliance. Entities should maintain adequate and contemporaneous documentation of all financial relationships with referring physicians, including—

- The terms of each arrangement;
- Whether and how an arrangement fell out of compliance with an exception;
- The reasons for the arrangement falling out of compliance;
- Steps taken to bring the arrangement into compliance;
- Relevant dates; and
- Similar information.

Comment: Two commenters recommended eliminating the requirement in § 411.353(f) that the arrangement must have been in compliance with an applicable exception for 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant. According to the commenter, the program is adequately protected by the requirement that the noncompliance had to occur for reasons beyond the entity's control.

Response: For the reasons noted in Phase II, we are retaining the requirement that the arrangement must have been in compliance with an exception under § 411.355, § 411.356, or § 411.357 for 180 consecutive calendar days (69 FR 16057). We continue to believe that the requirement is necessary to ensure that the temporary noncompliance exception is not subject to abuse.

Comment: A commenter recommended that enforcement officials exercise their discretion by declining to pursue minor and technical violations. Another commenter stated that we should consider adding an exception that would permit physicians to refer for DHS and DHS entities to submit and receive payment for DHS claims if, in our sole discretion, there was no abuse. The commenter suggested that such an exception should be available only after: (1) receipt by the entity of a favorable advisory opinion; or (2) a voluntary disclosure by the entity or upon audit or investigation by the government.

Response: The physician self-referral law is a strict liability statute, and we therefore do not have authority to waive the nonpayment sanction under the statute for ''minor'' and ''technical'' violations, or violations stemming from non-abusive arrangements. We lack the statutory authority to promulgate the exception suggested by the commenter, but we are open to creating additional regulatory exceptions that pose no risk of program or patient abuse.

VI. Financial Relationship, Compensation, and Ownership or Investment Interest—§ 411.354

Section 411.354 defines the financial arrangements that are subject to the statutory prohibition. The section defines direct and indirect ownership and investment interests, and direct and indirect compensation arrangements. The section also establishes a number of rules governing various aspects of compensation arrangements.

In Phase I, we established a three-part, ''bright line'' test for defining an ''indirect compensation arrangement'' that incorporates a knowledge element. To satisfy the knowledge element, a DHS entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with or otherwise reflects the volume or value of referrals or other business generated for the DHS entity. Phase I established a corresponding new exception for indirect compensation arrangements. By (1) defining the universe of ''indirect compensation arrangements'' that potentially trigger disallowance of claims and penalties, and (2) creating an exception for the subset of ''indirect compensation arrangements'' that would *not* trigger disallowance or penalties, we structured the treatment of indirect compensation arrangements under section 1877 of the Act to parallel closely the treatment of direct compensation arrangements.

Phase I also established several special rules applicable to certain key requirements in the various definitions and exceptions related to compensation arrangements, including when an arrangement was ''set in advance'' and whether time-based or unit-based compensation methodologies took into account ''the volume or value'' of referrals or ''other business generated between the parties.'' Finally, Phase I established that, in some limited instances, it is permissible for an employer, managed care organization, or entity with which a physician contracts to require a physician to refer to a particular DHS entity as part of certain compensation arrangements.

Phase II addressed concerns raised by commenters regarding the Phase I definitions of the various types of financial relationships. The modifications set forth in Phase II included—

- Clarifying the meaning of direct and indirect ownership and affirming that, absent unusual circumstances, common ownership of an entity does not create an ownership interest by one common investor in another (69 FR 16061);
- Clarifying the relationship between the ''indirect compensation arrangement'' definition and the ''volume or value'' and ''other business generated'' standards (69 FR 16061);
- Revising the definition of ''referring physician'' at § 411.351 to provide that a referring physician is treated as ''standing in the shoes'' of his or her wholly-owned professional corporation (PC) (69 FR 16125).

We also solicited comments on whether to permit a physician to ''stand in the shoes'' of a group practice of which he or she is a member (69 FR 16060). (Our response to comments on this issue is set forth in detail below in section VI.B of this preamble.)

In response to Phase II, we received comments regarding aspects of the ownership provisions. Most comments, however, related to various aspects of the ''indirect compensation arrangement'' definition and the related exception.

We are making two substantive and several minor changes to § 411.354. First, we are revising the regulation text in § 411.354(b)(3)(v) to provide that an ownership or investment interest does not include a security interest in the equipment of a hospital held by a physician who both sold the equipment to the hospital and financed its purchase through a loan to the hospital. (However, such transactions will create compensation arrangements.) Second, we are amending the regulations in § 411.354(c) to add a ''stand in the shoes'' provision under which referring physicians will be treated as ''standing in the shoes'' of their group practices (and certain other physician organizations) for purposes of applying the rules that describe direct and indirect compensation arrangements in § 411.354. As explained in greater detail below in response to comments, this change will reduce the risk of fraud and abuse by closing an unintended loophole in the definition of ''indirect compensation arrangement'' (by deeming more arrangements to be direct compensation arrangements) and will ease compliance by simplifying the analysis of many arrangements. This revised approach is conceptually an extension of the Phase II rule that treated referring physicians as standing

in the shoes of their professional corporations.

In addition, we are making non-substantive changes to clarify that we do not interpret ''otherwise reflects'' and ''takes into account'' (with respect to referrals and as these terms are used in certain exceptions) as having separate and different meanings. That is, the terms were used interchangeably in Phase II, and we have made conforming changes for consistency. Other changes are discussed below.

A. Ownership

Comment: One commenter stated that secured loans should not automatically create an ownership or investment interest in the entity granting the security interest (absent other indicia of ownership such as voting or other governance rights, profit participation, etc.). For example, a contract for a physician's sale of equipment to a hospital on an installment payment basis will commonly include a security interest in the equipment in case of nonpayment. According to the commenter, under the Phase II rule, such a security interest would create an ownership interest in part of a hospital, and thus create a prohibited financial relationship (69 FR 16063). The commenter believed that this interpretation is at odds with our indication in Phase II that a one-time sale using installment payments that are protected by a security interest could be eligible for the isolated transactions exception in § 411.357(f). The commenter asserted that this type of arrangement should instead be viewed as a compensation arrangement, potentially qualifying for the isolated transactions exception. The commenter referenced our Phase II remarks with respect to the types of transactions that qualify for the protection of the exception for isolated transactions at § 411.357(f) (69 FR 16098).

Response: In Phase II, we indicated that loans or bonds secured by, or otherwise linked to, a particular piece of equipment or the revenue of a department or other discrete hospital operations would be considered an ownership interest in part of a hospital (69 FR 16063). We also stated that a one-time sale of property (which could be equipment), using installment payments that are appropriately secured, for example by a security interest taken in the property, could qualify for the isolated transactions exception in § 411.357(f) if all other requirements of the exception are satisfied (69 FR 16098). After reconsidering the issue, we do not believe that the Congress intended a security interest taken by a physician in equipment sold to a hospital and financed by a loan from the physician to the hospital to create an ownership or investment interest in the hospital's property or a portion of the hospital's property (subject to a contrary provision in the security instrument or agreement of the parties). Instead, such a transaction is more appropriately analyzed as a compensation arrangement that must satisfy the requirements of an applicable exception if the physician-seller refers DHS to the hospital-purchaser. We have modified § 411.354(b)(3), accordingly. We continue to believe that loans or bonds secured by, or otherwise linked to, the revenue of a department or other discrete hospital operations would be considered an ownership interest in a part of a hospital. Such interests would not qualify for protection under the whole hospital exception in § 411.356(c)(3).

Comment: A commenter objected to the treatment of bonds as an ownership interest in § 411.354(b)(1) and suggested that there should be an exception for bonds issued by a tax-exempt entity that has a non-participatory interest. For example, an ownership interest should not include a bond issued by a tax-exempt entity if interest is not calculated on the earnings of the institution.

Response: Section 1877 of the Act includes as a ''financial relationship'' both ownership *and* investment interests, except for those specifically excluded under sections 1877(c) and (d) of the Act. Section 1877 of the Act provides that ownership or investment interests can be through equity, debt, or other means. Because bonds are an investment interest based on debt, the purchase of bonds (regardless of whether the issuing entity is tax-exempt) creates an ownership or investment interest for purposes of the physician self-referral law.

Comment: One commenter stated that some physicians were interpreting improperly the language in the Phase I preamble regarding the exclusion of any interest in a retirement plan from the definition of ''ownership or investment interest'' in § 411.354(b)(3). According to the commenter, some physicians are using retirement plans to purchase DHS entities to which they refer patients for DHS. The commenter requested clarification of our position.

Response: We agree with the commenter that the purchase of ownership interests in DHS entities by physicians through their retirement funds is inconsistent with the statutory intent. In addition to the information provided by this commenter, we have heard anecdotally that some physicians are purchasing ownership interests in DHS entities through their retirement plans. In the CY 2008 Physician Fee Schedule notice of proposed rulemaking (72 FR 38122), we proposed revisions to § 411.354(b)(3) to address the issue of ownership in a retirement plan. We may finalize that proposal, or a similar change to the regulation, in a future rulemaking. We caution that, depending on the facts, arrangements involving a DHS entity owned through a physician's retirement plan may be part of an indirect compensation arrangement between the referring physician and the DHS entity (pursuant to § 411.354(c)) that would need to satisfy the requirements of the exception in § 411.357(p) for indirect compensation arrangements. In many cases, the referring physician would receive compensation from the retirement plan that takes into account the referrals to the DHS entity owned by the retirement plan. The arrangements described by the commenter are also problematic under the anti-kickback statute.

Comment: A commenter asked whether a guaranty of a loan constitutes an ownership interest in the debtor and, if so, what exception would be available.

Response: A guaranty does not create an ownership interest, but a guaranty usually creates a compensation arrangement between the guarantor and the debtor.

B. Compensation

Phase II discussed at some length the definition of an indirect compensation arrangement. Some commenters on the Phase II rule requested further clarification, particularly regarding—

- The treatment of an indirect compensation arrangement;
- The relationship between the definition of ''indirect compensation arrangement'' and the exception for indirect compensation arrangements; and
- The relationship between the exception for indirect compensation arrangements and other exceptions.

Many commenters sought clarification regarding the application of the indirect compensation arrangement definition in the context of financial arrangements in which a group practice was interposed between the entity furnishing DHS and the referring physician. According to some commenters, in most of these arrangements, there would not appear to be an indirect compensation arrangement within the meaning of the regulation, because the physician's compensation from the group practice would likely be based on his or her

productivity in the group practice, and not tied to referrals to the DHS entity with which the group practice has a financial arrangement. Other commenters stated that they continued to find the definition difficult to understand and apply.

In Phase II, we specifically solicited comments with respect to whether we should permit physicians to ''stand in the shoes'' of their group practices for purposes of determining whether they have a direct or indirect compensation arrangement with a DHS entity (69 FR 16060). This Phase III final rule includes new provisions in § 411.351 and § 411.354 that address compensation arrangements in which a group practice (or other ''physician organization,'' as newly defined at § 411.351) is directly linked to the physician in a chain of financial relationships between the referring physician and a DHS entity. Under the Phase I and II regulations, such arrangements did not fit in the definition of a direct compensation arrangement (66 FR 868, 69 FR 16059–16060); rather such arrangements would have been analyzed under the as ''indirect compensation arrangements'' under § 411.354(c)(2). If an arrangement meets the definition of an ''indirect compensation arrangement,'' it must comply with the exception for indirect compensation arrangements at § 411.357(p) if the physician refers DHS to the entity.

This approach creates two issues. First, industry representatives have claimed that resorting to the indirect compensation arrangements definition and exception adds an unnecessary step when determining compliance with the physician self-referral prohibition. These parties believe that it would be easier, more efficient, and consistent with the purposes of the physician self-referral law to examine the relationship between the hospital and the group practice for compliance with a physician self-referral exception. They urge that a referring physician should ''stand in the shoes'' of his or her group practice, which acts on behalf of its physician members and contractors. This would, in turn, enable the parties to analyze the arrangement between the DHS entity and the group practice (for example, a lease of office space, personal service arrangement, or fair market value arrangement) under the various direct compensation arrangements exceptions, without using the indirect compensation arrangements definition or exception. We agree.

Second, we are concerned about reports that parties may be construing the definition of an indirect compensation arrangement too narrowly, resulting in determinations that arrangements that involve financial incentives for referring physicians fall outside the ambit of the physician self-referral law. In particular, we are concerned that arrangements between DHS entities and group practices are often viewed as outside the application of the statute. The new ''stand in the shoes'' provisions should close this unintended loophole by treating compensation arrangements between DHS entities and group practices as if the arrangements are with the group's referring physicians. This approach incorporates a commonsense understanding of the relationship between group practices and their physicians. Thus, if a DHS entity leases office space to a group practice, the lease will be deemed to be a direct compensation arrangement with each physician in the group practice, and the lease will need to fit in the exception for rental of office space in § 411.357(a) if the DHS entity wants to submit claims for DHS referrals from those physicians. For purposes of the ''stand in the shoes'' provision, we are including in the definition of ''physician organizations,'' in whose shoes the referring physician will stand, the referring physician's professional corporation, physician practice, or group practice.

Specifically, under the new provision, a physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the DHS entity is his or her physician organization. In addition, for purposes of the definition of ''indirect compensation arrangement,'' a physician will be deemed to stand in the shoes of the physician organization with which he or she has a direct financial relationship (that is, the physician organization with which he or she is directly linked). When a physician stands in the shoes of his or her physician organization, he or she will be deemed to have the same compensation arrangement (with the same parties and on the same terms) as the physician organization has with the DHS entity. We have included language in the regulations in § 411.354(c)(3)(i) to make clear that ''parties'' refers to the physician organization and all of its physician members, employees, and independent contractors. In the preceding example, the arrangement for the rental of office space would need to satisfy all of the requirements of the exception in § 411.357(a), including, for example, the requirement that the rental charges not take into account the volume or value of referrals or other business generated between the parties. The ''parties'' to the arrangement would be the hospital and the group practice, including all members, employees, and independent contractors of the group practice. Thus, if the lease arrangement takes into account referrals or other business generated by the group practice (or any of its physicians) the arrangement will not be protected.

We are mindful that many existing arrangements involving relationships with an interposed physician organization between the DHS entity and the referring physician, like the one discussed in the example above, may have been properly structured to comply with the indirect compensation arrangements exception in § 411.357(p). It is not our intent to require that those arrangements be reexamined and revised to comply with a direct compensation arrangements exception. Except as provided below, as of the effective date of this Phase III final rule, all compensation arrangements must be analyzed under the ''stand in the shoes'' provisions in § 411.354 to determine what type of compensation arrangement exists (direct or indirect) and what corresponding exceptions might be available. However, arrangements that were entered into prior to the *publication* date of this Phase III final rule and that satisfied the requirements of the indirect compensation arrangements exception in § 411.357(p) on the date of the *publication* of this Phase III final rule need not be amended during the original term of the arrangement or the current renewal term (that is, the renewal term the arrangement is in on the date of *publication* of this Phase III final rule) to comply with the requirements of another exception. Those arrangements may continue to use the exception in § 411.357(p) during the original or current renewal term of the agreement as if the ''stand in the shoes'' doctrine does not apply.

We are not making any changes at this time to the treatment of arrangements that, after application of the ''stand in the shoes'' provision, still do not meet the definition of a direct compensation arrangement. Those arrangements will continue to require analysis under the indirect compensation arrangements definition. In other words, arrangements involving an intervening entity other than a physician organization (for example, a chain that runs DHS entity to management company to referring physician) or involving more than one intervening entity (for example, a chain that runs DHS entity to management company to group practice to referring physician) would continue to be

analyzed under the Phase I and II rules for indirect compensation arrangements and the indirect compensation arrangements exception. Although we remain concerned that arrangements that interpose such entities are subject to abuse, we believe that we would benefit from additional public input on the best way to apply a ''stand in the shoes'' rule to these indirect relationships. We note that an arrangement that may not qualify as either a direct or an indirect compensation arrangement for purposes of the physician self-referral statute may still be suspect under the anti-kickback statute.

We believe that this new provision will address the concerns raised in the comments, including comments discussed below in section VI.B, as well as simplify compliance with the physician self-referral regulations generally. Our responses to specific comments are discussed below.

Comment: A number of commenters requested further clarification, for purposes of the indirect compensation arrangement definition, regarding the circumstances under which compensation received by a physician may ''otherwise reflect'' the volume or value of the physician's referrals to an entity furnishing DHS. Specifically, these comments addressed situations in which the physician has a direct financial relationship with an ''intervening entity'' that, in turn, has a direct relationship with the DHS entity to which the physician refers patients for DHS. Several commenters believed that payments by a hospital to a group practice for the recruitment of a physician should not implicate the general prohibition with respect to referrals made by physicians in the group other than the recruited physician, provided that the physicians in the group are not compensated based on the volume or value of their referrals to the hospital making the recruitment payment. Another commenter stated that, if we interpret the ''otherwise reflect'' language to mean that a fixed payment may ''reflect'' the volume or value of referrals if that payment exceeds fair market value, we should state that clearly. However, the commenter noted that such an interpretation would be very problematic, because the volume and value standard is critical to many of the statutory and regulatory exceptions.

Response: First, in Phase II, we clearly stated that fixed compensation (that is, one lump payment or several individual payments aggregated together) can take into account or otherwise reflect the volume or value of referrals (for example, if the payment exceeds the fair market value for the items or services provided) (69 FR 16059). Whether the compensation does, in fact, take into account or otherwise reflect the volume or value of referrals will require a case-by-case determination based on the facts and circumstances.

Many of the commenters' concerns regarding indirect compensation arrangements involving payments to group practices will become moot, given our decision to adopt a ''stand in the shoes'' policy, as described above. Many arrangements will need to satisfy a direct exception, and the group practice's method of compensating a physician will be irrelevant for purposes of determining compliance with an exception.

Comment: Several commenters described financial arrangements between DHS entities and group practices that did not meet the definition of an indirect compensation arrangement. The commenters requested confirmation that, if there is no direct or indirect financial relationship (as defined in the regulations) between a DHS entity and a physician, section 1877 of the Act is not implicated.

Response: Section 1877 of the Act prohibits only referrals from a physician to entities furnishing DHS with which the physician (or an immediate family member) has a financial relationship as defined at § 411.354.

We believe that the commenters' inquiries are addressed by the modifications we are making in this Phase III final rule regarding the treatment of certain compensation arrangements between entities furnishing DHS, group practices, and physicians in those group practices. Specifically, as discussed above, we are adding new provisions in § 411.354 to treat a physician as ''standing in the shoes'' of his or her group practice or physician organization. Conceptually, this new provision has the effect of treating many compensation arrangements that previously would have been treated as indirect compensation arrangements as direct compensation arrangements and requiring them to satisfy the requirements of an exception for direct compensation arrangements. It also has the effect of treating some arrangements that may not previously have met the definition of either a ''direct compensation arrangement'' or an ''indirect compensation arrangement'' as a direct compensation arrangement for which an exception is needed. As many commenters to Phase II recognized, indirect compensation arrangements are clearly subject to the physician self-referral prohibition.

Comment: One commenter sought clarification concerning the interplay between the use of the ''volume or value'' standard in the definition of an indirect compensation arrangement and the exception for indirect compensation arrangements. Specifically, the commenter asked how any indirect compensation arrangement could satisfy the exception's requirement that the arrangement not take into account the volume or value of referrals ''in any manner,'' given that, by definition, the compensation must vary with, or otherwise reflect, the volume or value of referrals.

Response: In Phase II, we responded to a similar comment. In that rule (69 FR 16069), we stated:

> For purposes of determining whether an indirect compensation arrangement exists under the definition at § 411.354(c), the inquiry is whether the aggregate compensation to the referring physician reflects the volume or value of DHS referrals or other business generated by the referring physician, even if individual time-based or unit-of-service based payments would otherwise be permissible (that is, the payments are fair market value at inception and do not vary over the term of the agreement). In short, many time-based or unit-of-service based fee arrangements will involve aggregate compensation that varies based on volume or value of services and thus will be ''indirect compensation arrangements'' under § 411.354(c). However, in determining whether these arrangements fit into the indirect compensation arrangements exception at § 411.357(p), which does not include an aggregate requirement, the relevant inquiry is whether the individual payments are fair market value not taking into account the volume or value of referrals or other business generated by the referring physician (and do not change after inception). In other words, the issue is whether the time-based or unit-of-service based fee is fair market value and not inflated to compensate for the generation of business.

In short, the definition looks to the aggregate compensation (that is, compensation that combines each individual payment under the arrangement), whereas the exception looks at individual payments without aggregating them.

Comment: One commenter asked that we clarify that the conversion of a direct compensation arrangement that does not meet a direct compensation arrangements exception into an indirect compensation arrangement that meets the indirect compensation arrangements exception is not a prohibited circumvention scheme.

Response: We are unclear about the exact nature of the arrangements described by the commenter. If an

arrangement between a referring physician (or immediate family member) and a DHS entity meets the definition of an ''indirect compensation arrangement'' and, in fact, satisfies the requirements of the indirect compensation arrangements exception in § 411.357(p), referrals made between the referring physician (or immediate family member) and the DHS entity are not prohibited. The arrangement must satisfy the exception in operation, not just on the face of the documentation. Efforts to circumvent improperly the statute in any form may evidence improper intent for purposes of the physician self-referral statute, which may be relevant to enforcement actions for civil monetary penalties and false claims if the financial arrangement does not satisfy the requirements of an exception. Moreover, such efforts are also relevant in analyzing the intent of the arrangement for purposes of the anti-kickback statute. We note that the indirect compensation arrangements exception includes a condition that the arrangement not violate the anti-kickback statute. In addition, arrangements that interpose a leasing or other entity between the DHS entity and the referring physician may involve illegal kickbacks, even if they do not come within the definition of an indirect compensation arrangement.

Comment: A hospital association asserted that some hospitals collect information regarding physicians' financial relationships for purposes of monitoring conflicts of interest and suggested that we not use such information in determining whether a DHS entity satisfies the knowledge criteria in § 411.354(c)(2)(iii) for purposes of the indirect compensation arrangements definition.

Response: Any information in the possession of a hospital may be relevant in assessing whether the hospital knew or had reason to know of an indirect financial relationship involving a referring physician.

Comment: A commenter requested clarification of the example in Phase II regarding an indirect financial relationship involving a physician who has an ownership interest in a hospital that contracts for services with a clinical laboratory to which the physician refers (69 FR 16060). The commenter questioned our analysis, asserting that the hospital would not be receiving compensation that would vary with the volume or value of referrals, because the hospital would be paying for services furnished. The commenter requested further clarification.

Response: As we stated in Phase II, the arrangement referenced by the commenter normally would not create an indirect compensation arrangement. Absent unusual circumstances, the hospital would not receive aggregate compensation that reflects the volume or value of referrals because the hospital would not be receiving any compensation from the clinical laboratory (assuming the contracted charges for the laboratory services are at fair market value) (69 FR 16060). However, if the laboratory charged the hospital less than fair market value for its services (resulting in remuneration to the hospital), the arrangement could meet the definition of an indirect compensation arrangement between the referring physician and the laboratory (depending on the facts and circumstances). The arrangement would not satisfy the requirements of the indirect compensation arrangements exception because payments for the laboratory services were not at fair market value.

C. Special Rules on Compensation

Section 411.354(d) sets forth rules regarding several key terms, including ''set in advance,'' ''the volume and value of referrals,'' and ''other business generated between the parties.'' These terms are used in many of the compensation arrangements exceptions. In addition, § 411.354(d)(4) provides that, in certain circumstances, it is permissible for a physician's compensation from an employer, or under a managed care or other contract, to be conditioned on referrals to particular entities, notwithstanding the general ban in many exceptions on compensation that takes into account the volume or value of referrals.

In Phase I, we provided that compensation would be considered ''set in advance'' if the aggregate compensation or a time-based or per-unit of service-based amount is set in advance in the initial agreement in sufficient detail so that it can be effectively verified (66 FR 959). In Phase II, we modified the special rule to provide that compensation would also be considered ''set in advance'' if the specific formula for calculating the compensation is set out in an agreement between the parties before the furnishing of the items or services, and the formula is set forth in sufficient detail so that it can be effectively verified and is not changed during the course of the agreement in any manner that reflects (or takes into account) the volume or value of referrals or other business generated. The principal impetus for deeming formula-based compensation to be ''set in advance'' came from comments from associations representing physicians that urged us to accommodate common percentage compensation arrangements. This Phase III final rule retains flexibility for utilizing unit-based and percentage-based compensation formulae for arrangements.

In Phase I, we stated that unit-based compensation would be deemed *not* to take into account ''the volume or value of referrals'' if the compensation is fair market value and does not vary during the course of the arrangement in any manner that takes into account DHS referrals (66 FR 876). Similarly, in Phase I, we stated that unit-based compensation would be deemed *not* to take into account ''other business generated between the parties'' if the compensation is fair market value and does not vary during the course of the arrangement in any manner that takes into account other business generated by the referring physician, including private pay health care services (66 FR 877). We made no changes in Phase II with respect to either the ''volume or value'' or ''other business generated'' deeming provisions.

The Phase I special rules on compensation permitted entities furnishing DHS to condition physician compensation in certain circumstances on the physician's compliance with referral restrictions, if certain conditions were satisfied. Phase II clarified that the required referral provision applies to employment, managed care, and personal service arrangements only, and set forth new requirements specifying that: (1) the required referrals must relate solely to the physician services covered by the arrangement; and (2) the referral requirement must be reasonably necessary to effectuate the legitimate purpose of the compensation arrangement (69 FR 16069). In this Phase III final rule, we are amending the regulatory text in § 411.354(d)(4) to include expressly contracts for personal services.

Comment: Two commenters sought clarification that percentage-based compensation arrangements, the methodologies of which were fixed at the outset of the contract and did not vary during the term of the agreement, would satisfy the ''set in advance'' standard in § 411.354(d)(1) and be deemed not to take into account the ''volume or value'' of referrals or ''other business generated between the parties'' pursuant to § 411.354(d)(2) and (d)(3), respectively. One commenter requested that the text of § 411.354(d)(2) and (d)(3) be revised to reference percentage-based compensation specifically. Another commenter asked if compensation based on a percentage of collections satisfied

the requirements of the regulation, and another commenter asked about compensation that includes a percentage of the net revenues of a business unit for which the physician is responsible.

Response: To satisfy the requirements of many compensation arrangements exceptions, compensation must be ''set in advance,'' consistent with fair market value, *and* not take into account the volume or value of referrals or other business generated by the referring physician.

The first two commenters are correct that, under the Phase II special rule in § 411.354(d), percentage-based compensation arrangements can be considered ''set in advance'' if the methodology is fixed at the outset of the contract with sufficient specificity and not changed during the course of the agreement in a manner that reflects referral volumes or other business generated.

With respect to the comments about percentage of collections and percentage of revenues compensation methodologies, such methodologies may be able to meet the ''set in advance'' test, depending on the facts. However, such compensation arrangements must also meet the other terms of a relevant exception, such as the terms excluding compensation that takes into account the volume or value of referrals or other business generated between the parties. This would involve, among other things, testing the arrangements against the deeming provisions in § 411.354(d)(2) and § 411.354(d)(3) related to ''volume or value of referrals'' and ''other business generated between the parties''; these deeming provisions apply only to unit-based compensation and require that unit-based compensation be fair market value and unrelated to referrals. We cannot determine based on the facts provided whether the arrangements would comply with an exception. We are not persuaded that § 411.354(d)(2)and (d)(3) should be revised to reference specifically percentage-based compensation arrangements.

Comment: Three commenters objected to § 411.354(d)(4), which provides that a physician's compensation from an employer or under a managed care or other contract may be conditioned on referrals to particular entities in certain circumstances. Two of the commenters also objected to our response to a comment in Phase II that stated that a hospital may require its employees to refer patients to its home health agency if the requirements in § 411.354(d)(4) are satisfied (69 FR 16089). According to all three commenters, § 411.354(d)(4) conflicts with section 4321 of the Balanced Budget Act of 1997 (BBA 1997), which amended section 1861(ee)(2) of the Act, and which relates to hospitals' obligations under the discharge planning process to patients in need of home health services. Section 1861(ee)(2) of the Act requires the Secretary to develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of setting for post-discharge care. Section 4321 of BBA 1997 amended section 1861(ee)(2) of the Act to require, among other things, that the discharge plan advise the patient of participating home health agencies that serve the area in which the patient resides and that it identify any home health agency to which the patient is referred in which the hospital has a disclosable financial interest.

One commenter stated that allowing an entity to condition employment on an agreement to refer patients to a particular provider may implicate the Federal anti-kickback statute, and may encourage a violation of Federal and State antitrust laws or State unfair trade practices laws. The commenter suggested that we delete § 411.354(d)(4).

Response: Section 411.354(d)(4) does not conflict with the requirements of section 1861(ee)(2) of the Act, as amended by section 4321 of BBA 1997. Under section 4321 of BBA 1997, as part of the discharge plan, a hospital is required to provide a patient needing home health services or skilled nursing facility services a list of local home health agencies or skilled nursing facilities, as appropriate. If, after being provided the list, the patient expresses a choice as to the particular provider from which he or she wishes to receive treatment, the hospital and the patient's treating physician are required to honor that choice. Nothing in § 411.354(d)(4)(iv) permits a physician and the employing or contracting entity to override a patient's choice of provider. To the contrary, § 411.354(d)(4)(iv) affirmatively requires that the arrangement between the physician and the entity honor a patient's choice. Section 411.354(d)(4)(iv) requires that the arrangement must provide that the physician is not obligated to refer to a particular provider, practitioner, or supplier if: the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. Section 411.354(d)(4)(v) further provides that the requirement to make referrals to a particular provider, practitioner, or supplier must relate solely to the physician's services covered by the scope of his or her employment or contract.

Whether an arrangement implicates the anti-kickback statute is a matter for the Department of Justice (DOJ) and the OIG. Arrangements that include referral requirements may implicate the anti-kickback statute and should be closely scrutinized to ensure that no purpose of the compensation is to induce or reward referrals. An arrangement that fully complies with the requirements of § 411.354(d)(4), however, does not necessarily raise concerns under Federal and State antitrust or unfair trade practices statutes. Accordingly, we are not persuaded that the potential for implication of the anti-kickback statute or the Federal and State antitrust laws noted by the commenters warrants withdrawal of § 411.354(d)(4).

Comment: Commenters asked whether an agreement between an entity furnishing DHS and a referring physician could be amended during the first year of the agreement and still satisfy the ''set in advance'' requirement. According to one commenter, the definition of ''set in advance'' implies that an amendment is permissible, provided that the amendment is not related to the volume or value of referrals or other business generated between the parties. According to the commenter, the implication is that any number of amendments for other, *bona fide* reasons is permissible.

Response: The commenter is correct that amendments are permissible under the ''set in advance'' definition if they are made for *bona fide* reasons unrelated to the volume or value of referrals or other business generated between the parties. However, parties must still satisfy all requirements of an exception, including any requirements bearing on amendments of agreements. (See discussion in section IX.A below.)

VII. General Exceptions to the Referral Prohibition Related to Both Ownership and Compensation—§ 411.355

A. Physician Services

Section 1877(b)(1) of the Act specifies that the general prohibition does not apply to physician services (as defined in section 1861(q) of the Act) that are furnished: (1) Personally by another physician in the same group practice as the referring physician; or (2) under the supervision of another physician in the same group practice as the referring physician. In Phase I, we interpreted the

exception to apply to referrals to, or physician services supervised by, a ''member of the group practice'' or an independent contractor who qualifies as a ''physician in the group practice'' as defined at § 411.351 (69 FR 879). We made no changes to this exception in Phase II. In this Phase III final rule, we are making no substantive modifications to this exception; however, we are deleting § 411.355(a)(3), which incorrectly suggests that diagnostic tests are ''incident to'' services. As we clarified in the CY 2003 Physician Fee Schedule final rule published December 31, 2002, any diagnostic service that has its own benefit category cannot be billed as an ''incident to'' service (67 FR 79994). In addition, § 411.355(a)(3) is repetitive of § 411.355(a)(2) and, therefore, is unnecessary.

Comment: One commenter suggested that we amend the physician services exception by deleting from § 411.355(a) ''physician in the same group practice'' (as defined at § 411.351) from among the types of physicians who can be the ''referring physician.'' According to the commenter, this change would clarify that referrals within a group practice to independent contractor pathologists who perform services for the group in off-site ''pod labs'' are impermissible under the physician services exception. According to the commenter, the development of the concept of ''physician in the group practice'' was not intended to allow group practices simply to refer to independent contractors for whose services the group could then bill on reassignment.

Response: The physician services exception in section 1877(b)(1) of the Act and § 411.355(a) enables group practice physicians to make referrals within their group practices for physician services that are DHS and that are performed or supervised by either a member of the group practice or by a ''physician in the group practice.'' A ''physician in the group practice'' is considered to be in the group practice only when he or she is performing services in the group practice's facilities. Accordingly, although professional services performed by a member of the group practice may be provided on or off the group practice's site for purposes of this exception, professional services performed by an independent contractor physician must be performed in the group practice's facilities. Thus, the exception is not applicable to services provided by independent contractors in off-site locations that are not group facilities.

However, we do not believe that it is appropriate to ban group practices from referring to any independent contractor physician. We appreciate the commenter's concerns regarding independent contractor pathologists who perform services for the group practice in off-site ''pod labs'' and continue to study the issue. At this time, we decline to make the change to the physician services exception requested by the commenter. We note that, in addition to physician self-referral considerations, the provision of off-site services by group practices raises significant concerns under the anti-kickback statute.

B. In-office Ancillary Services

The in-office ancillary services exception is one of the most important exceptions to the physician self-referral prohibition. Generally, it permits a physician or group practice to order and provide DHS, other than most durable medical equipment (DME), in the office of the physician or group practice, provided that the DHS is truly ancillary to the medical services furnished by the group practice. The statutory exception has four main components—

- The *nature* of the DHS;
- The *personnel* who perform or supervise the DHS;
- The *location* where the DHS are provided; and
- The *manner* in which the DHS are billed.

The Phase I rule interpreted the statutory provision by permitting great flexibility in the provision of ancillary services in the ''same building'' (as defined at § 411.351) where a physician or a group practice routinely provides the full range of their medical services, while limiting the availability of the ''centralized building'' (as defined at § 411.351) option to premises that are used on an exclusive and full-time basis. With respect to the other requirements, the Phase I rule clarified the types of DHS that could be provided under the exception and relaxed the supervision requirements by incorporating the Medicare coverage and payment supervision rules and permitting independent contractor physicians to provide supervision on a group practice's premises.

In response to public comments urging a more ''bright-line'' test, Phase II revised the criteria for determining when services are furnished in the ''same building'' where the physician or group furnishes the full range of their medical services. Under the revised location requirement, DHS qualify for the exception if they are furnished in the ''same building'' in which—

- The referring physician or his or her group practice has an office that is normally open to patients at least 35 hours per week, and the referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients in that office at least 30 hours per week; or
- The referring physician or his or her group practice has an office that is normally open to patients at least 8 hour per week, the referring physician regularly practices medicine and furnishes physician services to patients in that office at least 6 hours per week, and the patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice at this location; or
- The referring physician or his or her group practice has an office that is normally open to patients at least 8 hours per week, the referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week, and the referring physician is present and orders the DHS during a patient visit on the premises or a member of the referring physician's group practice is present while the DHS are furnished.

In each of the three alternative tests, the minimum hourly requirement for furnishing physician services must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS.

We received numerous comments on aspects of the in-office ancillary services exception. We are making no substantive changes to the in-office ancillary services exception. We respond to issues of concern to the commenters below.

We also received a large number of comments from physical and occupational therapists and groups representing physical and occupational therapists objecting to the in-office ancillary services exception, asserting that the exception has a detrimental effect on their practice. The in-office ancillary exception is a statutory exception and we have no discretion to eliminate the exception as requested by these commenters. However, we may propose additional changes to the exception in a future rulemaking.

Comment: Several commenters requested further guidance regarding the amount of physician services that would be considered unrelated to the furnishing of DHS for purposes of satisfying the requirement that at least

''some'' physician services furnished in the same ''building'' are unrelated to the furnishing of DHS.

Response: For the reasons previously set forth in Phase II, we decline to provide a quantitative measure of ''some'' non-DHS (69 FR 16073). The critical factor is that the premises are used for the regular provision of the group practice's physician services, even if on a part-time basis, with respect to the requirements in § 411.355(b)(2)(i). In evaluating whether ''some'' physician services unrelated to DHS are performed in the building, we will take into account the nature of the group's overall practice (for example, the specialties of the group's physicians) and the referring physician's full range of practice. Creating a satellite office that appears to satisfy the ''same building'' requirements, but in fact is merely a sham arrangement, will result in claims denial. For example, renting office space part-time in a freestanding imaging facility purportedly to provide physician services unrelated to DHS at the facility location would be considered a sham if few or no such services were actually contemplated or provided. In addition, a part-time arrangement cannot meet the centralized building test. As we have noted in other contexts, the operation of an arrangement, not its form on paper, is determinative. Thus, for purposes of the in-office ancillary services exception, all of the conditions related to supervision, location, and billing must be strictly satisfied with respect to each claim for DHS submitted to the Medicare program.

Comment: A physician professional association requested clarification regarding whether the requirements relating to the quantity and type of physician services necessary to satisfy the ''same building'' requirement can be met by including services provided to patients physically present in remote locations via telemedicine. Specifically, the commenter requested ''additional guidance * * * for practitioners with offices in rural locations in which they may not be physically present but nonetheless provide the requisite amount and types of care.''

Response: We assume that the comment pertains to the situation in which a patient is present in one location and a physician, who is present in another location during an appointment with the patient, orders an item or service that he or she wishes to be furnished in the office in which the patient is located. We do not consider the ordering physician to be located in the rural office with the patient for purposes of satisfying any of the ''same building'' tests in § 411.355(b)(2)(i). Rather, the physician's time spent performing telemedicine services is counted for purposes of the ''same building'' requirement as time spent in the location where the physician is physically present. However, there are three alternate methods for meeting the ''same building'' test that provide considerable flexibility, even in situations where physicians provide some services via telemedicine. For example, in the case of a referring physician who is a member of a group practice, time spent by other physician members of the group at the patient's location would count toward the ''same building'' requirement.

Comment: A commenter stated that it appreciated Phase II's added flexibility of the three alternative tests for determining whether services furnished in the ''same building'' meet the requirements of the in-office ancillary services exception. The commenter stated, however, that it was concerned that requiring physician presence, either by the referring physician when ordering, or by a member of the group practice when furnished, may be too onerous for some group practices. According to the commenter, it may be difficult for a group practice to distinguish its operations as clearly meeting one test or another, as well as to track and document its compliance with the alternative tests.

Response: We believe that it should not be difficult for a group to distinguish and document the nature of the services furnished by the physicians at its various locations. To the extent that some additional complexity was added by Phase II, it is a necessary consequence of allowing additional flexibility through the three alternative tests.

Comment: One commenter asked for further guidance on physicians who provide DHS to their patients in a shared space in the same building. Specifically, the commenter asked whether the physicians could use simultaneously the facilities (for example, an imaging suite, clinical laboratory, or physical therapy office) and simply share the costs and administration of the DHS without having to separately lease the facilities for specific blocks of time determined in advance.

Response: A physician sharing a DHS facility in the same building must control the facility and the staffing (for example, the supervision of the services) at the time the designated health service is furnished to the patient. To satisfy the in-office ancillary services exception, an arrangement must meet all of the requirements of § 411.355(b), not merely on paper, but in operation. As a practical matter, this likely necessitates a block lease arrangement for the space and equipment used to provide the designated health service. Shared facility arrangements must be carefully structured and operated (for example, with respect to billing and supervision of the staff members who provide DHS in the facility). We note that common per-use fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception and may implicate the anti-kickback statute.

Comment: Several commenters strongly criticized the centralized building prong of the in-office ancillary services exception. They requested that the rule be changed to require, in addition to full-time use of the facility, that the arrangement meet a ''commercially reasonable'' test. According to the commenters, the Phase II rule permits numerous abusive arrangements that are designed solely to permit group practices and physicians to refer and bill for DHS that section 1877 of the Act would otherwise prohibit. Commenters objected to group practices developing satellite DHS facilities, sometimes in different states, specifically to capture ancillary income. Several commenters identified ''condominium'' pathology laboratories that rent space to urology groups as the types of abusive arrangements that are proliferating. On the other hand, one commenter complained that the requirement that the centralized building be occupied exclusively by the group practice is too restrictive.

Response: Section 1877 of the Act permits group practices to furnish DHS in a centralized building. However, we recognize that part-time, shared, off-site facilities are readily subject to abuse. To address this obvious potential for abuse, the Phase I final rule included the requirement that a centralized building be used on an exclusive basis (66 FR 881). In the CY 2007 update to the physician fee schedule, we proposed additional requirements for the centralized building test (71 FR 49056–49057). We will address those proposals in a separate rulemaking. In the meantime, we caution parties to arrangements such as those described by the commenters that, as with shared facilities in the same building, off-site arrangements must fully comply with the in-office ancillary services exception in operation, not only on paper. In other words, compliance is required with respect to every DHS claim filed. ''Condominium'' arrangements are

particularly vulnerable to non-compliance, and staff and operations at the off-site facility should be closely monitored. For example, a supervising physician who is an independent contractor of a group practice must be in the group practice's specific premises at the specific time a designated health service is furnished (and supervised) for a group practice patient. Moreover, these arrangements raise substantial concerns under the anti-kickback statute.

Comment: Several commenters commended us for the flexibility provided by the in-office ancillary services exception. A number of other commenters complained that the exception effectively vitiated the prohibition on physician self-referral.

Response: The in-office ancillary services exception allows a physician to provide DHS to his or her own patients, which may appear to undercut the purpose of the physician self-referral prohibition. Nevertheless, the statutory exception evidences intent by the Congress to permit a physician to furnish DHS to his or her own patients if certain conditions are met. We are considering whether certain types of arrangements, such as those involving in-office pathology labs and sophisticated imaging equipment, should continue to be eligible for protection under the in-office ancillary services exception.

Comment: One commenter requested that we confirm that compliance with the in-office ancillary services exception is not necessary if an arrangement complies with the rural provider exception in § 411.356(c)(1).

Response: Compliance with the in-office ancillary services exception is not necessary with respect to referrals from owners or investors if an ownership or investment interest complies with the rural provider exception in § 411.356(c)(1). As a reminder, the rural provider exception protects ownership and investment interests only; it does not protect compensation arrangements. Thus, if the group practice submits claims for DHS referred by employed or contracted physicians, an exception, such as the in-office ancillary services exception, must apply.

Comment: A commenter suggested that, where group practices or physicians in the same building share DHS facilities, the in-office ancillary services exception should be restricted to clinical laboratory and imaging services that are necessary on an urgent basis.

Response: Without further review, we do not believe that it is appropriate or feasible to restrict the in-office ancillary services exception as suggested by the commenter. We will continue to monitor the situation to determine whether to propose additional restrictions to safeguard against program or patient abuse.

Comment: One commenter requested that we confirm that a hospital-employed physician would be treated the same as any other sole practitioner for purposes of satisfying the in-office ancillary services exception (that is, whether any non-group practice physician meeting the same requirements of personal supervision or personal performance and location may fit within the exception). The commenter asserted that when the facts are the same (that is, supervision, location, and other requirements are satisfied), it should not matter whether the employer is a group practice or a hospital. The commenter believed that hospitals in States that prohibit the corporate practice of medicine are disadvantaged because they cannot set up a group practice to employ the physician (who, presumably, could utilize the in-office ancillary services exception).

Response: As set forth in section 1877(b)(2) of the Act, the in-office ancillary services exception applies only to certain DHS furnished by a physician or group practice; it does not apply to inpatient or outpatient hospital services billed by a hospital employer. In order to utilize the in-office ancillary services exception, a hospital-employed physician, such as the one described by the commenter, must meet all of the requirements set forth in § 411.355(b). If a hospital-employed physician's referred DHS are billed by the hospital employer, the in-office ancillary services exception would not apply. The hospital would be the entity furnishing the DHS (not the physician or a group practice), and the hospital-employed physician would not meet the billing requirement in § 411.355(b)(3). We are not persuaded to create a similar exception for hospital-employed physicians. We see no disadvantage as described by the commenter. Hospitals may use other exceptions, including the exception for *bona fide* employment relationships, to protect legitimate arrangements with referring physicians.

Comment: One commenter requested clarification that the in-office ancillary services exception did not override our policies on reassignment and purchased diagnostic tests. Another commenter requested clarification that the rules on purchased diagnostic tests and purchased test interpretations were not altered by our implementation of section 952 of the MMA.

Response: The physician self-referral rules do not supersede Medicare payment and billing rules and policies, including rules on reassignment, supervision, or purchased diagnostic tests; however, the physician self-referral rules do affect their application. For example, following enactment of section 952 of the MMA, we amended § 424.80 of our regulations to provide that an independent contractor physician may reassign to an entity his or her right to bill Medicare, regardless of whether the services were performed on the premises of the entity (as required prior to section 952 of the MMA) or off the premises of the entity. However, where the independent contractor physician who wishes to reassign to a DHS entity with which he or she has a financial relationship, it is not enough that the rules on reassignment are met. Rather, the rules on physician self-referral must also be satisfied. For example, where an independent contractor physician wishes to reassign his or her right to receive Medicare payment for DHS to a group practice to which he or she will refer DHS, an exception such as the physician services exception or the in-office ancillary services exception must be met. The services performed by the independent contractor in this example must be performed in the group practice's facilities (see the definition of ''physician in the group'' at § 411.351).

Conversely, the fact that an arrangement complies with the physician self-referral rules does not negate the relevancy of other rules, such as the rules on reassignment and purchased diagnostic tests. For example, where an independent contractor physician furnishes DHS in a centralized building of a group practice and the other requirements of the in-office ancillary services exception are satisfied, the anti-markup rules would nonetheless apply if the service at issue is a diagnostic test of the type that is covered under the provision at § 414.50 and the physician and the group have effected a valid reassignment (including completing the 855–R).

We are amending § 411.350 to state clearly that nothing in the physician self-referral rules alters a party's obligation to comply with—

- The rules regarding reassignment of claims (§ 424.80);
- The rules regarding purchased diagnostic tests (§ 414.50);
- The rules regarding payment for services and supplies ''incident to'' a physician's professional services (§ 410.26); or
- Any other applicable Medicare laws, rules, or regulations.

We note that § 424.80 states that nothing in that section alters a party's obligation to comply with the physician self-referral statute and other authorities.

Comment: Commenters asked whether, in order to satisfy the requirements of the in-office ancillary services exception, a physician who is an independent contractor with a group practice must perform DHS supervision services *on the premises* of the group practice, regardless of coverage policies.

Response: For purposes of compliance with the physician self-referral rules, independent contractor physicians are ''physicians in the group practice'' only when performing services on the group practice's premises, regardless of whether reassignment or coverage rules would allow an independent contractor physician to perform services off the premises of the billing entity. Therefore, in order to satisfy the requirements of the exception, an independent contractor must supervise services *on the premises* of the group practice.

Comment: Section 1877(b)(2)(B) of the Act and § 411.355(b)(3) require that, in order for the in-office ancillary services exception to apply, the services must be billed by one of the following: The physician performing or supervising the service; the group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice; the group practice if the supervising physician is a ''physician in the group practice'' under a billing number assigned to the group practice; or by an entity that is wholly-owned by the physician or the group practice under the entity's own billing number or under a billing number assigned to the physician or group practice. Two commenters asked for clarification that the billing requirement in the in-office ancillary services exception in § 411.355(b)(3) can be satisfied by an entity (that is, a billing entity) that is wholly-owned by the group members in their individual capacities (as opposed to being owned by the group practice), but structured to mirror the group practice (for example, ownership of the billing entity is contingent on membership in the group practice). According to the commenters, the separate structure is common to avoid tax liability.

Response: We disagree with the commenters. Section 1877(b)(2)(B) of the Act and the corresponding regulations in § 411.355(b)(3)(iv) require that the supervising physician, the referring physician, or the group practice must wholly own the billing entity. The arrangement described by the commenters would not satisfy this requirement. The regulations make clear that claims submitted by a wholly-owned entity must be submitted under a billing number assigned to the entity or under a billing number assigned to the physician or group practice. Moreover, the arrangement may not comply with our rules on reassignment. Under our longstanding policy, only *individuals* may reassign benefits. If the commenter is, in effect, asking whether a physician member or a ''physician in the group practice'' is allowed to reassign benefits to the group, which would then reassign benefits to the billing entity, we do not believe that the arrangement would comply with our rules on reassignment. Nothing in the regulations prohibits the use of an independent billing company in an administrative capacity to process and submit claims on behalf of billing physicians or group practices under billing numbers assigned to them.

C. Services Furnished by an Organization (or Its Contractors or Subcontractors) to Enrollees

Section 1877(b)(3) of the Act creates an exception for services provided pursuant to certain Medicare managed care arrangements. In Phase I, we interpreted the provision broadly and updated the references to covered managed care plans in light of changes to the Medicare program. In Phase II, we again expanded the exception, which appears at § 411.355(c), to include Medicaid managed care plans. This Phase III final rule makes no changes to Phase II.

Comment: Comments submitted on behalf of Alaskan tribal health organizations requested that we create an exception for referrals made by physicians under compensation arrangements with tribal health care providers. According to the commenter, the native tribal organizations have assumed much of the responsibility for carrying out the programs of the Indian Health Service. In discharging that responsibility, the tribes have developed a comprehensive, integrated health care system that utilizes primary, secondary, and tertiary caregivers and clinics staffed by employees, independent contracting practitioners, Federal employees, and commissioned officers. The commenter asserted that, because of limited funds, utilization of services is carefully monitored and strictly controlled, giving them many characteristics of managed care organizations. According to the commenter, services are prioritized so that only certain services are covered, and firm policies exist requiring prior authorization for non-emergent care and notice for emergency care at non-tribal or Indian Health Service facilities. The commenter stated that the tribal health care providers have three principal types of compensation arrangements. First, and most frequently, the providers have physician employees. Second, the providers have personal service arrangements with physicians. Third, the providers enter into agreements with the Indian Health Service under which Federal employees are assigned to work for a specific tribal health program, and under which the providers are responsible for the costs of such employees. The commenter asserts that monitoring and reviewing the myriad compensation arrangements with physicians in the Alaska tribal health network consumes scarce time and financial resources. In light of the system's integration and strong elements of managed care, the commenter urged that referrals in the network be protected.

Response: We agree that many of the arrangements between the Indian Health Service and various Indian nations have many of the characteristics of managed care. However, when Medicare services are furnished, the exception in § 411.355(c) for services furnished to enrollees of a prepaid health plan would not apply. We decline to create an exception at this time to address the commenter's concerns for two reasons. First, we question whether we have the legal authority to expand the exception in § 411.355(c) or to create a new exception without first proposing such an expansion or new exception through a notice of proposed rulemaking. Second, the commenter has not supplied us with an adequate explanation thus far as to why existing exceptions such as those for *bona fide* employment relationships (§ 411.357(c)) or personal service arrangements (§ 411.357(d)) would be insufficient to protect the arrangements at issue. The commenter appears to recognize that these exceptions are available, but states that monitoring and reviewing the compensation arrangements consumes scarce time and financial resources. We believe, however, that the parties should be able to design model structures for the compensation arrangements, which would be applicable for existing and newly hired physicians. Monitoring and reviewing for compliance is necessary and prudent to ensure compliance with the physician self-referral law, other fraud and abuse laws, and other Medicare rules and regulations.

D. Reserved

There is no regulation at § 411.355(d). Section 411.355(d) continues to be ''reserved'' in this Phase III final rule.

E. Academic Medical Centers

In Phase I, we created a new exception for payments to faculty of academic medical centers that meet certain conditions that ensure that the arrangements pose no risk of fraud or abuse (66 FR 916). The exception required that the referring physician: (1) Is a *bona fide* employee of a component of an academic medical center on a full-time or substantial part-time basis; (2) is licensed to practice medicine in the State(s) in which he or she practices medicine; (3) has a *bona fide* faculty appointment at the affiliated medical school; and (4) provides either substantial academic or substantial clinical teaching services for which the referring physician receives compensation as part of his or her employment relationship with the academic medical center. In addition, the exception required the total compensation paid to the referring physician for the previous 12-month period from all academic medical center components to be set in advance, in the aggregate not exceed fair market value for the services provided, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated within the academic medical center.

Phase II made several changes to broaden the applicability of the academic medical centers exception. We expanded the definition of an academic medical center to allow hospitals or health systems that sponsor four or more medical education programs to qualify as a component of an academic medical center. We revised the exception to include not-for-profit supporting organizations (whose primary purpose is supporting the teaching mission of the academic medical center) as a potential component of an academic medical center. We revised the regulatory text to make clear that the majority of physicians on the medical staff must be on the faculty of an affiliated medical school and that the aggregation of faculty from any affiliated medical school is permitted. We expanded the exception modestly to cover DHS referrals within an academic medical center if the money the academic medical center pays to the referring physician for research is used for teaching services in addition to *bona fide* research (if consistent with the terms and conditions of the grant). To guard against fraud and abuse, we declined to extend the protection of the exception to DHS referrals to an academic medical center if the academic medical center pays the referring physician for research and the research funds are used for indigent care or community service. Finally, we modified the requirement that the relationship among the components of the academic medical center be set out in a written agreement; the revised provision allows the relationship to be memorialized in multiple writings.

In Phase II, we also added a ''safe harbor'' provision that deems any referring physician who spends at least 20 percent of his or her professional time or, in the alternative, 8 hours per week providing academic services or clinical teaching services to be compliant with the requirement in § 411.355(e)(1)(i)(D) that the physician provide ''substantial academic services or clinical teaching services.'' We also deleted the requirement, formerly in § 411.355(e)(2)(ii), that the faculty practice plan (or plans) be organized as a tax-exempt organization under either section 501(c)(3) or (c)(4) of the Internal Revenue Code.

In Phase II, we made clarifications to the academic medical centers exception, including: (1) that the referring physician may be on the faculty of the affiliated medical school *or* the accredited academic hospital; (2) that an academic medical center may have more than one affiliated faculty practice plan (and that the faculty practice plans may be affiliated with other components such as the teaching hospital, the medical school, or the accredited academic hospital); (3) that a hospital or health system under § 411.355(e)(2)(i) may be the same hospital that meets the ''affiliated hospital'' requirement in § 411.355(e)(2)(iii); and (4) that the substantial services test may be met through either academic services or clinical teaching services, or a combination of both. We declined to extend the protection of the exception to services referred by a physician who is not an employee of a component of an academic medical center, where the referring physician does not provide substantial academic services or clinical teaching services (as may be the case with volunteer and primary care physicians), or where the referring physician does not meet the other requirements in § 411.355(e)(1)(i).

This Phase III final rule adopts the Phase II rule with minor clarifications. For example, for purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all physicians holding the same class of privileges at the affiliated hospital.

Comment: One commenter asked us to clarify that the academic medical centers exception protects payments to physicians for the provision of indigent care or community service. The commenter sought an explanation of our statement in Phase II that payments to referring physicians for indigent care or community service may be structured to fit other exceptions. (69 FR 16110–16111.)

Response: Nothing in § 411.355(e) prohibits academic medical centers from compensating faculty members for the provision of indigent care or community service, provided that the funds do not derive from research funding (see § 411.355(e)(1)(iii)(C)); the total compensation paid to the referring physician is fair market value and satisfies the other requirements of § 411.355(e)(1)(ii); and the physician also performs the requisite clinical teaching or academic services under § 411.355(e)(1)(i)(D). The Phase II language referenced by the commenter was in response to a suggestion that we revise the definition of ''academic medical center'' at § 411.355(e)(1)(iii). Section 411.355(e)(1)(iii) provided that, to qualify as an academic medical center for purposes of the exception, all research grant money paid to a referring physician must be used solely to support *bona fide* research. The Phase II comment suggested that we revise the provision to include the use of *research* money for teaching, indigent care, and community service (as opposed to for *bona fide* research only). (69 FR 16110–16111.) We agreed in part with the commenter and revised the provision in § 411.355(e)(1)(iii) to require that any money paid to a referring physician for research must be used solely to support *bona fide* research or teaching, which are core academic medical center functions. However, we declined to extend the provision to cover the use of research money for indigent care and community service, explaining that research grants can be subject to potential abuse. (66 FR 917.) We note that the academic medical center exception is available for DHS furnished by academic medical centers that pay physicians to provide indigent care and community service, provided that all other provisions of the exception are met and the money used for the payments does not come from research grant funds. If an academic medical center pays a physician using research funds and the payments are used for purposes other than *bona fide* research or teaching, the academic medical

center would not satisfy the conditions of § 411.355(e)(1)(iii), and the exception would be unavailable for any DHS furnished by the academic medical center.

Comment: A commenter stated that the requirement in § 411.355(e)(1)(ii) that the total compensation paid by all components of an academic medical center to the referring physician be ''set in advance'' was unnecessary. According to the commenter, the flows of money within an academic medical center support the missions of patient care, education, and research, which are the core of any academic medical center. The commenter asserted that the other criteria for meeting the exception provide adequate assurances that abuses will not occur. Because the exception is available only to *bona fide* employees of an academic medical center component, the criteria for compensation should mirror those for the exception for *bona fide* employment arrangements, which does not require that compensation be set in advance.

Response: The commenter misunderstands the purpose of the academic medical centers exception. It is designed to protect compensation received by the physician from *all* components of the center, not only the component with which he or she has an employment relationship. Therefore, although the employment exception may protect the compensation the physician receives from the component that employs the physician, it does not protect the physician's aggregate compensation. We disagree with the commenter that the ''set in advance'' requirement for *aggregate* compensation from *all* components of the academic medical center is unnecessary. We believe that it is appropriate to treat physician compensation under the academic medical center exception the same as compensation for independent contractor physicians under the exception for personal service arrangements. (69 FR 16066.)

Comment: One commenter asked that we clarify that the condition in § 411.355(e)(1)(ii), which requires that the total compensation to referring physicians be set in advance, does not require that the actual amount of the compensation be set in advance. The commenter also asked that we confirm its understanding that our use of ''total'' compensation was intended to reflect that faculty physicians in an academic medical center setting may be paid by more than one component of the academic medical center and that each such payment arrangement must meet each of the requirements of the exception, namely that the compensation be set in advance, not exceed fair market value for the services provided, and that it not take into account the volume or value of referrals or other business generated by the referring physician within the academic medical center.

Response: The commenter is correct that the actual dollar amount of the referring faculty physician's compensation need not be set in advance. It is sufficient if the contribution of *each* component of the academic medical center to the aggregate compensation uses a methodology that qualifies under § 411.354(d). The commenter is also correct that, where a physician is paid by more than one component of the academic medical center, *each* such payment arrangement must not take into account the volume or value of referrals or other business generated by the referring physician within the academic medical center. The commenter is incorrect, however, that the exception requires that compensation paid by each component must satisfy a fair market value test. Rather, § 411.355(e)(1)(ii) states that the aggregate (that is, the total from all components) compensation cannot exceed fair market value for the services provided. We have clarified the language of § 411.355(e)(1)(ii).

Comment: An association of medical schools asserted that, due to the numerous and complex criteria of the academic medical center exception, we should provide advisory opinions to entities that submit a request for a definitive opinion as to whether they meet those criteria.

Response: We believe that the criteria set forth in the academic medical centers exception are clear and that most entities should be able to determine whether they qualify as an academic medical center. We believe that an advisory opinion, although appropriate in some circumstances, would normally not be needed. In addition, institutions that do not satisfy the definition of an academic medical center may be able to comply with one or more of the other physician compensation arrangements exceptions.

Comment: A commenter asked for clarification regarding § 411.355(e)(2)(iii), which defines an academic medical center to include an affiliated hospital in which, among other things, ''a majority of the physicians on the medical staff consists of physicians who are faculty members.'' The regulation provides that any faculty member ''may'' be counted for purposes of this requirement, including courtesy and volunteer faculty. The commenter sought confirmation that an affiliated hospital may exclude courtesy staff when determining whether the majority of the physicians on its medical staff are faculty members of the affiliated medical school.

Response: An affiliated hospital may exclude courtesy staff when determining whether the majority of the physicians on its medical staff are faculty members of the affiliated medical school or on the faculty of the educational programs at the accredited affiliated hospital. We are modifying § 411.355(e)(2)(iii) to clarify that, if a hospital elects to include or exclude a physician holding a particular class of privileges (for example physicians holding courtesy privileges), the hospital must include or exclude, respectively, all individual physicians with the same class of privileges at the affiliated hospital when determining whether the majority of the physicians on its medical staff are faculty members of the affiliated medical school or are on the faculty of the educational programs at the accredited academic hospital.

Comment: One commenter stated that the requirement in § 411.355(e)(2)(iii) that faculty members order the majority of hospital admissions is difficult for many accredited hospitals to control and, effectively, renders most community hospitals ineligible for the academic medical center exception. According to the commenter, community hospitals that sponsor four or more approved education programs (and which potentially could constitute an academic medical center) frequently provide substantial services unrelated to those training programs, particularly if there are few other hospitals serving that area.

Response: We believe that the requirement that faculty members order the majority of admissions is a good measurement of a hospital being sufficiently integrated into an academic medical center. As we noted in Phase II, it is important to ensure that the relationship between the components is sufficiently focused on the academic medical center's core mission (69 FR 16109). The tests for affiliated hospital faculty and admissions set forth in § 411.355(e)(2)(iii) are strong indicators of that core relationship. The academic medical centers exception is designed to supplement—not supplant—other exceptions, such as the exception for *bona fide* employment relationships in § 411.357(c) and the exception for personal service arrangements in § 411.357(d). To the extent that a hospital or other entity cannot take advantage of the academic medical centers exception, it should be able to

structure its legitimate compensation arrangements with physicians to meet another exception.

Comment: One commenter stated that a newly-affiliated hospital might not qualify as an academic medical center because it fails to meet ''the two majority tests'' in § 411.355(e)(2)(iii) (that is, the majority of physicians on the medical staff are faculty members and the majority of admissions are made by faculty members). According to the commenter, the hospital may execute an academic affiliation agreement under which it increases the number of physicians on its medical staff who are faculty members so that it meets the requirement that a majority of its medical staff are faculty members, but the hospital would not immediately meet the requirement that a majority of admissions are made by the faculty (as the new faculty will begin admitting only upon execution of the agreement). The commenter requested guidance that would clarify when a hospital could rely on the academic medical centers exception in such circumstances.

Response: We disagree that the regulation is unclear as to when a compensation arrangement between a physician and a newly-affiliated hospital will satisfy the academic medical centers exception. We believe that the regulation is clear that all conditions must be met at the time the referral is made. To the extent that the commenter is suggesting that we allow a transition period during which the two majority tests would not apply or would be relaxed, we decline to do so. If an arrangement does not meet the academic medical centers exception, another exception may be available.

Comment: Two commenters asked for clarification regarding the applicability of § 411.357(p), the indirect compensation arrangements exception, in the academic medical center setting. One of the commenters asserted that many academic medical centers have organizational structures that enable them to satisfy the requirements of the exception for indirect compensation arrangements, citing the situation where a referring physician does not have a direct financial relationship with an affiliated hospital. For example, a hospital component of an academic medical center could be an organization separate and distinct from the university that operates the faculty practice plan as a wholly-owned division of the university in connection with the university's school of medicine. According to the commenter, any financial arrangements between the hospital and the university with respect to the physicians in the faculty practice plan would be indirect. Moreover, if the physicians were salaried employees of the university, with no compensation paid from the hospital to the physicians, there would be no direct *or* indirect compensation arrangement within the meaning of the definition at § 411.354(c)(2) if the physician's compensation did not vary with or otherwise reflect the physician's referrals to the hospital. According to the commenter, even if this arrangement were construed as being an ''indirect compensation arrangement'' (which the commenter did not believe was the case), it would qualify for the exception for indirect compensation arrangements in § 411.357(p) if the physician's compensation were fair market value and not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician for the hospital. The second commenter simply asked that we confirm that the exception for indirect compensation arrangements applies in the academic medical center setting.

Response: The definition of ''indirect compensation arrangement'' at § 411.354(c)(2) and the exception for indirect compensation arrangements in § 411.357(p) are potentially applicable to arrangements involving academic medical centers and physicians. As we have stated previously and in this Phase III final rule, parties generally may utilize any exception that the arrangement between them satisfies. If the academic medical centers exception applies to the DHS referrals at issue, it would not be necessary for another exception to apply. With respect to the situation described by the commenter, as discussed above, we have revised § 411.354 to clarify the application of the indirect compensation definition at § 411.354(c)(2) and the indirect compensation arrangements exception in § 411.357(p).

F. Implants Furnished by an Ambulatory Surgical Center

In Phase I, we established a new exception in § 411.355(f) for implants furnished by an ambulatory surgical center (ASC) when acting as an entity furnishing DHS. The new exception was intended to allow a physician-owner of an ASC that is not in a rural area (and thus not covered by the rural provider exception) to order and perform surgeries that implant DME, prosthetics, or prosthetic devices that are not reimbursed as part of the composite ASC payment rate. The new exception was necessary because many implantable items are DHS but are not bundled in the ASC composite rate. Without the exception, an ASC (which is often owned by one or more physicians) would become a DHS entity when it furnishes the implant. We did not make any changes to § 411.355(f) in Phase II, nor are we making any in this Phase III final rule.

Comment: One commenter referenced the discussion in Phase II where we noted that the exception in § 411.355(f) applies only when the implant is billed by the ASC and that, when the physician submits the claim for the implant, the physician is the entity furnishing DHS (69 FR16111). The commenter asked whether the exception in § 411.355(f) applies if the ASC furnishes and submits the claim for the implant procedure, but the physician furnishes and submits the claim for the device.

Response: The exception does not apply in the situation described by the commenter. Under Medicare payment policy (section 10.3–10.4 of the CMS Internet-only Manual, publication 100–04, Claims Processing Manual, Chapter 14 (ambulatory surgical centers)), whenever an implant is performed during an ASC procedure, the provider/supplier (that is, the ASC) must bill for the implanted item. We did not mean to imply that any individual or entity other than the ASC may bill for an item implanted during an ASC procedure.

G. EPO and Other Dialysis-Related Drugs Furnished in or by an End-Stage Renal Disease Facility

Phase I created a new exception in § 411.355(g) for epoetin (EPO) and certain other dialysis-related outpatient prescription drugs furnished in or by an end-stage renal dialysis (ESRD) facility. The drugs that may qualify for this exception were initially identified by CPT and HCPCS codes in Phase I (66 FR963–964), and updates to that list appear on our Web site and in annual updates published in the **Federal Register**. There were no changes to § 411.355(g) in Phase II, nor are we making any in this Phase III final rule.

Comment: A commenter wrote that the list of ESRD drugs in § 411.355(g) was incomplete. The commenter asked that the exception be expanded to include all drugs furnished as part of a dialysis treatment, whether in a home or at a facility. Alternatively, the commenter asked that the exception include by reference our Single Drug Pricer file. [The Single Drug Pricer file is a drug-pricing file used prior to January 1, 2004 that contains the allowable price for each drug covered ''incident to'' a physician's service. This includes the allowable price for drugs furnished by independent dialysis facilities that are separately billable

from the composite rate and for clotting factors to inpatients.] The commenter voiced concern that a dialysis center with physician-owners or other financial relationships with physicians would not be able to deliver the same convenient, quality care that could be provided by a center without these relationships.

Response: We believe that the list of ESRD drugs, as updated annually, is complete and that we are acting within the constraints of the statute. Section 1877(h)(6) of the Act specifically includes outpatient prescription drugs as DHS. However, we established a broad exception in § 411.355(g) using our authority under section 1877(b)(4) of the Act, which allows the Secretary to establish an exception if there is no risk of program or patient abuse. We intend for the exception to include drugs that have to be administered at the time of dialysis ''that are required for the efficacy of dialysis.'' (69 FR 16117.) For the reasons stated in Phase II, we believe that we cannot further expand the list as suggested by the commenter without creating a risk of program or patient abuse (69 FR 16117–16118). Although we do not want to burden Medicare beneficiaries unnecessarily by making them go elsewhere for intravenous drugs, the Congress prohibited physician self-referrals for outpatient prescription drugs, and we are concerned that expanding the list of drugs subject to this exception may lead physicians to order intravenous administration of a drug when oral administration is as effective, or to not choose the most cost-effective appropriate drug.

To the extent that individuals or organizations believe that specific drugs should qualify for the exception because they are required for the efficacy of dialysis and must be administered at the time of dialysis, they may contact us. We also note that the list of drugs that qualify for this exception is updated annually in the Physician Fee Schedule, and comments on the list are accepted upon publication of the proposed rule for the Physician Fee Schedule. We note that the Single Drug Pricer file is no longer in use.

H. Preventive Screening Tests, Immunizations, and Vaccines

In Phase I, we created a new regulatory exception for certain preventive screening tests, immunizations and vaccines furnished under circumstances that do not pose a risk of abuse (66 FR 923). The exception requires that: (1) The preventive screening tests, immunizations, and vaccines are subject to CMS-mandated frequency limits; (2) the arrangement does not violate the anti-kickback statute; (3) the arrangement does not violate any Federal or State law or regulation governing billing or claims submission; and (4) the preventive screening tests, immunizations, and vaccines are covered by Medicare and listed as eligible for this exception on the list of CPT/HCPCS codes. Phase I included a listing of the CPT and HCPCS codes for screening tests that qualify for the exception if all of the other requirements of the exception are satisfied.

In Phase II, we made no major changes to the exception (69 FR 16116). We did, however, decline to expand the exception to protect referrals for diagnostic Pap smears or mammography tests, as we were unpersuaded that these types of referrals would not pose a risk of program or patient abuse. We clarified in Phase II that we recognized that some of the vaccines covered under the exception may be paid by Medicare using a different reimbursement system than the fee schedule required under the exception. To avoid confusion we deleted the requirement that the preventive screening tests, immunizations, or vaccines be reimbursed by Medicare under a fee schedule.

We received no comments to Phase II regarding § 411.355(h) and are making no changes in this Phase III final rule.

I. Eyeglasses and Contact Lenses Following Cataract Surgery

In Phase I, we created a new regulatory exception for eyeglasses and contact lenses following cataract surgery (66 FR 923). The exception requires that: (1) The eyeglasses or contact lenses are provided in accordance with Medicare coverage and payment policies (§ 410.36(a)(2)(ii) and § 414.228, respectively); (2) the arrangement does not violate the anti-kickback statute; and (3) the arrangement does not violate any Federal or State law or regulation governing billing or claims submission.

Phase II made no changes to § 411.355(i) (nor were any comments received on Phase I). We received no comments to Phase II regarding this exception. We are not making any changes to § 411.355(i) in this Phase III final rule.

J. Intra-Family Rural Referrals

Phase II created a new exception in § 411.355(j) for certain referrals from a referring physician to his or her immediate family member or to a DHS entity with which the physician's immediate family member has a financial relationship. The exception requires that the patient being referred reside in a rural area and that there is no other person or entity available to furnish the referred DHS in a timely manner, in light of the patient's condition, either: (1) At the patient's residence (in the case of home health services or other DHS required to be furnished in the patient's home); or (2) within 25 miles of the patient's residence (in the case of services furnished outside the patient's home). In addition, the exception requires that the referring physician make reasonable inquiries as to the availability of other persons or entities and that the financial relationship does not violate the anti-kickback statute or any other Federal or State law or regulation governing billing and claims submission. We are making one modification to § 411.355(j) in this Phase III final rule. Specifically, we are modifying the exception to include an alternative distance test based on transportation time from the beneficiary's residence.

Comment: One commenter stated that, notwithstanding the exception in § 411.355(j), the prohibition on intra-family referrals leads to unfair results, especially where one of the family members is a general practitioner or surgeon and the other is a pathologist or a radiologist, and the pathologist or radiologist is part of a group of physicians that provides services for local hospital inpatients and outpatients. The commenter asserted that, in these circumstances, the general practitioner or surgeon is unable to refer hospital patients for pathology or radiology services to the family member's group practice. In addition, the commenter stated that a physician should not be prohibited from referring patients to a member of his or her immediate family (for example, a brother or sister) if the referring physician receives no economic benefit from the referral. The commenter suggested that we accept an attestation from the referring physician that he or she receives no economic benefit from referrals to the family member.

Another commenter asserted that CMS should revise the intra-family rural referral exception (or modify the definition of ''referral'') to allow a physician to make referrals to an immediate family member (or his or her employer) provided that the immediate family member has an excepted financial arrangement under which the family member does not receive remuneration that takes into account the volume or value or referrals or other business generated by the family member.

Response: Section 1877(a) of the Act prohibits referrals for DHS to entities in cases in which a physician ''or an immediate family member of such physician'' has a financial relationship with the entity, unless an exception applies. The law does not authorize a case-by-case inquiry into whether the referring physician actually benefits from referrals to entities with which an immediate family member has a financial relationship.

We recognize the commenters' concerns, but section 1877(b)(4) of the Act allows us to create an exception only if there is no risk of program or patient abuse. We are not expanding the exception in § 411.355(j) in the manner recommended by the commenters because we do not believe that it would be consistent with congressional intent, nor do we believe that we could do so without creating a risk of program or patient abuse.

Comment: One commenter asked that we modify § 411.355(j) to include patients in any medically underserved area or Healthcare Professional Shortage Area (HPSA). The commenter also requested that we modify the exception to permit a referring physician to refer to an immediate family member (or to an entity furnishing DHS with which the immediate family member has a financial relationship) after the referring physician determined, following reasonable inquiry, that there was no other available person or entity to furnish the referred DHS.

Response: The definition of rural is sufficiently broad to encompass many HPSAs and medically underserved areas, and we do not believe that the change suggested by the commenter regarding HPSAs and medically underserved areas is necessary. With respect to the commenter's second inquiry, we have reconsidered § 411.355(j) as it pertains to the availability of services in a rural area. We believe that a test that takes into account distance, posted speed limits, and weather conditions would be an appropriate alternative to a test that considers only whether a provider is a specific distance from a patient's home. Therefore, we are modifying § 411.355(j) to permit parties to utilize an alternative test that allows a physician to refer a patient to an immediate family member (or to a DHS entity with which the immediate family member has a financial relationship) for DHS if the DHS cannot be provided otherwise within 45 minutes transportation time from the patient's home at the time the referral for the DHS is made. We are making no changes to the 25-mile rule in § 411.355(j). Referring physicians are free to choose either of the tests (that is, 25 miles from the beneficiary's residence or 45 minutes transportation time from the beneficiary's residence) when determining whether a DHS referral may be made to an immediate family member under § 411.355(j). However, whichever test the physician chooses must be applied both for purposes of § 411.355 (j)(1)(ii) (determining distance or transportation time from available services) and § 411.355(j)(2) (the physician's reasonable inquiry as to the availability of persons or entities to provide the needed DHS).

The new alternative test requires a case-by-case analysis of the conditions that exist at the time of the referral for the DHS. Although a bright-line test may be preferred by many physicians, we do not believe that such a test always provides sufficient flexibility to ensure that our beneficiaries receive needed DHS in a timely manner and in a location that is convenient to the beneficiary. The modification to § 411.355(j) would permit some intra-family referrals when the distance to the closest non-family member physician (or entity) is less than 25 miles from the beneficiary's residence.

We note that, when the new alternative test is utilized, because compliance will be determined on a case-by-case basis, an intra-family referral that is permitted at one time (for example, in the winter months when snow covers mountain roads and limits access) may not be permitted at a different time (for example, in the summer months when roads are clear and a non-family member physician (or entity) is available to provide the needed DHS within 45 minutes transportation time from the beneficiary's residence). Physicians utilizing the 45 minutes transportation time test should maintain documentation of the information used in determining the transportation time. Resources including websites that provide detailed mileage and drive time (such as Mapquest or MapBlast) and published weather reports (either online or in print, for example, in the newspaper) should be consulted when determining a beneficiary's transportation time from his or her residence to the location of the available DHS.

Comment: One commenter noted that we stated in Phase II that the exception ''does not take into account the quality of other available DHS entities'' and that other laws exist to address quality issues. The commenter asserted that this statement suggests that the physician would not be able to refer to an immediate family member if there is another entity furnishing DHS within 25 miles of the patient's residence, even if that entity does not participate in the patient's health plan or has lesser qualifications (for example, no board certification). The commenter requested that we clarify what we meant by this statement.

Response: For the reasons noted in Phase II, we do not believe that it is feasible to craft an objective, qualitative measure in the exception for intra-family rural referrals as suggested by the commenter. As we stated in Phase II, this exception ''looks to timely availability of DHS, [but] it does not take into account the quality of other available DHS entities'' (69 FR 16084). However, in a situation such as that described by the commenter in which the only entity that can furnish the DHS needed by a beneficiary within 25 miles of or 45 minutes transportation time from the beneficiary's home does not participate in Medicare, the entity should be treated as if it does not exist. In other words, the beneficiary constructively cannot obtain needed DHS within 25 miles of or 45 minutes transportation time from his or her home.

Comment: We received two comments concerning *urban* hospitals that have exclusive arrangements with a radiology group practice for performing the professional component of radiology services. The commenters were concerned that a physician in the community would not be able to refer patients *to the hospital* for radiology services when the physician's immediate family member is a member of the group practice with the exclusive arrangement.

The first commenter asserted that the prohibition on referring Medicare patients to immediate family members is a severe hardship for the patients of physicians with immediate family members who are radiologists, radiation therapists, or pathologists, and that many such family situations exist. The commenter noted that a physician could refer a patient to an immediate family member for other types of physician services without implicating the physician self-referral rules and, therefore, it is difficult to understand why radiologists, radiation therapists, and pathologists are treated differently. This commenter recommended that we either not consider the professional component of a service to be a designated health service, or allow referrals if the physician's immediate family member personally performs the DHS.

The second commenter suggested that we modify the definition of ''radiology and certain other imaging services'' to permit referrals in the situation described above, or that we modify the definition of ''referral'' so that the referral in this situation would be deemed a referral to the hospital rather than to the group practice in which the immediate family member practices. The commenter offered what it considered to be program safeguards that could be included in a new exception or a modification of an existing exception or definition.

Response: We note that the comments pertained to situations in which the patient would not be located in a rural area and, thus, the exception in § 411.355(j) for intra-family referrals would not be applicable. We decline to adopt either of the suggestions offered by the first commenter.

We do not believe that it would be consistent with congressional intent to include as DHS only the technical component, and not the professional component, of radiology, radiation therapy, or pathology services. The physician self-referral rules treat radiology, radiation therapy, and pathology services differently than other physician services because section 1877(h)(6) of the Act specifically includes these services, which have a significant professional component, as DHS, whereas other physician services specifically are not subject to the physician self-referral prohibition.

We are not modifying the exception for intra-family rural referrals because we are authorized under section 1877(b)(4) of the Act to create regulatory exceptions only where doing so would pose no risk of program or patient abuse, and we do not believe that the fact that the family member would personally perform the services, by itself, would remove all risk of abuse. For the same reasons, we do not believe that it is appropriate to modify the definition of ''referral'' as requested by the commenter. Where the requirements of the exception for intra-family rural referrals cannot be satisfied, the parties to the arrangement can take certain actions to avoid any potential problems arising from intra-family referrals. For example, where the referral to the group practice comes from a physician whose immediate family member is a physician in the group practice, the group practice could forward the referral to a physician outside the group to perform the service and bill for it. Alternatively, the group practice could have one of the physicians in the group practice (other than the family member) perform the service and bill for it directly (instead of reassigning his or her right to bill to the group practice).

VIII. Exceptions to the Referral Prohibition Related to Ownership or Investment Interests—§ 411.356

A. Publicly-Traded Securities and Mutual Funds

Section 1877(c) of the Act creates an exception for ownership in certain publicly-traded securities and mutual funds that may own DHS entities to which the physician may refer patients. As we explained in the 1998 proposed rule, ''we believe that the purpose of this exception is to allow physicians or family members to acquire stock in large companies if the transaction does not particularly favor the physicians over other purchasers'' (63 FR 1698). To qualify for the exception in section 1877(c)(1) of the Act:

(1) The securities must be securities that may be purchased on terms generally available to the public;

(2) The securities must (i) be listed on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or (ii) be foreign securities listed on a recognized foreign, national, or regional exchange, or (iii) be traded under the automated inter-dealer quotation system operated by the National Association of Securities Dealers; and

(3) The securities must be in a corporation that had shareholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous three fiscal years.

In addition, section 1877(c)(2) of the Act permits ownership of investments in mutual funds with total assets exceeding $75 million at the end of the most recent fiscal year or the average of the last three fiscal years. Investment securities include shares or bonds, debentures, notes, or other debt instruments.

In Phase II, we interpreted the statutory provision in section 1877(c)(1) of the Act, which requires that the investment securities be those that ''may be purchased on terms generally available to the public,'' to mean that the ownership interest must be in securities that are generally available to the public at the time of the DHS referral (69 FR 16081). We are making no changes in this Phase III final rule to § 411.356(a) (regarding publicly-traded securities) or § 411.356(b) (regarding mutual funds).

Comment: One commenter supported our clarification that the investment interest must be available to the public at the time the referral is made and not at the time the interest is acquired. However, the commenter was concerned that it will be difficult for either the physician or the entity furnishing DHS to determine if the entity is in compliance.

Response: We disagree. The inquiry turns on objective facts that are readily ascertainable to the physician or the entity furnishing DHS.

B. Hospitals Located in Puerto Rico

Section 1877(d)(1) of the Act provides that an ownership or investment interest in a hospital located in Puerto Rico is not considered a financial relationship within the meaning of section 1877 of the Act. In the January 1998 proposed rule, we proposed to incorporate this exception into our regulations at § 411.356(c)(2) (63 FR 1667). We received no comments to § 411.356(c)(2) and made no changes in Phase I to the exception. Phase II similarly made no changes to the exception (69 FR 16082). We received no comments on Phase II regarding § 411.356(c)(2) and are making no changes to the exception in this Phase III final rule.

C. Rural Providers

Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in entities that furnish DHS in a rural area if substantially all of the DHS are furnished to individuals residing in a rural area. Section 507 of the MMA amended section 1877(d)(2) of the Act to specify that, for the 18-month period beginning on December 8,2003, the rural provider exception was not available for specialty hospitals. Section 507 of the MMA defined the term ''specialty hospital'' in new section 1877(h)(7) of the Act. The moratorium expired on June 7, 2005.

In the January 1998 proposed rule, we defined a ''rural provider'' as an entity that furnishes at least 75 percent of its total DHS to residents of a rural area. Consistent with the statute, the proposed rule provided that, although the DHS entity (that is, the ''rural provider'') need not be located in a rural area, the exception applied only in the case of DHS furnished in a rural area. The proposed rule would have defined rural area as an area that is not considered to be an urban area pursuant to § 412.62(f)(1)(ii) (that is, an area outside of a Metropolitan Statistical Area (MSA)).

Phase II adopted the January 1998 proposed rule without change. This Phase III final rule makes no substantive changes to § 411.356(c)(1).

Comment: One commenter asked for confirmation that, if an entity furnishing DHS qualified for the rural ownership exception in § 411.356(c), the arrangement did not also have to meet the in-office ancillary services exception in § 411.355(b).

Response: The commenter is correct with respect to the referring physician's ownership or investment interest. Any compensation arrangement would have to meet a compensation arrangements exception, such as the in-office ancillary services exception in § 411.355(b). We address this issue more fully in section VI.B of this preamble.

Comment: A commenter complained that it was difficult to determine if a specific location qualified as ''rural'' for purposes of the exception. The commenter suggested that we provide a list of rural zip codes on our Web site. Another commenter asked that we clarify the definition of ''rural.'' The commenter recommended that we provide our own definition of ''rural'' rather than cross-referencing to other statutes. The commenter also requested confirmation that the definition of rural does not include Micropolitan Statistical Areas.

Response: We decline to create a list of all zip codes in counties that are considered rural for physician self-referral purposes because the amount of resources that would be required to create and update a list of zip codes is significantly greater than the effort required for health care entities with physician ownership to determine whether they are furnishing DHS in a rural area to patients who reside in a rural area. However, we explain below how a health care entity would determine whether a particular location is in a rural area.

For physician self-referral purposes, a location is in a rural area if it is not located in a MSA. This test differs from the rural/urban test that a hospital uses for wage index purposes. To determine whether an entity is furnishing DHS in a rural area for physician self-referral purposes, see the current list of MSAs on the Web site of the Office of Management and Budget (OMB). This list, which includes the constituent cities and counties of each MSA, currently may be accessed at (*www.whitehouse.gov/omb*) by typing in ''update of statistical area definitions,'' and by then locating the list entitled ''Metropolitan Statistical Areas.'' We also will provide a link to the OMB Web site on our physician self-referral Web site.

A Micropolitan Statistical Area is an area containing a single urbanized core population of at least 10,000 but less than 50,000. (65 FR 82230, 82233.) Micropolitan Statistical Areas are not within MSAs; thus, for purposes of the physician self-referral rules, Micropolitan Statistical Areas are not considered urban and are, therefore, rural areas.

The rural provider exception in section 1877(d)(2) of the Act applies to rural areas as defined in section 1886(d)(2)(D) of the Act (regarding the computation of urban and rural standardized amounts under the inpatient hospital prospective payment system). The non-codified material following section 1886(d)(2)(D) of the Act states that ''the term 'urban area' means an area within a [MSA] (as defined by [OMB]) or within such similar area as the Secretary has recognized under subsection (a) by regulation * * *.'' In Phase II, we defined a ''rural area'' as ''an area that is not an urban area pursuant to § 412.62(f)(1)(ii) of this chapter,'' that is, an area outside a MSA (69 FR 16082–16083). Although we no longer use MSAs to determine urban areas for purposes of the inpatient hospital prospective payment system, we decline to adopt a categorization other than MSAs for physician self-referral purposes.

Comment: A commenter stated that DHS entities serving patients located in rural areas that subsequently are classified as urban should continue to receive some protection. The commenter related a situation in which an existing hospital/physician joint venture owned a MRI machine. The county in which the joint venture served patients previously was not a constituent county in a MSA and thus was considered to be located in a rural area for physician self-referral purposes. However, the county was later reclassified as a constituent county of a MSA and physician-investor referrals to the joint venture would now violate the physician self-referral provisions. The commenter stated that it was no longer able to satisfy the rural provider ownership exception, despite the fact that the area was designated as medically underserved and the only other MRI machine was located 30 miles away. The commenter requested that we adopt alternative criteria for the exception in § 411.356(c)(1) that would address the situation, such as location in a medically underserved area in which the nearest DHS entity (except for the one owned by the physician) is at least 30 miles away.

Response: The rural provider ownership exception is statutory. A physician who invests in an entity furnishing DHS in a rural area takes a risk that the area will subsequently be classified as an urban area.

Section 1877(b)(4) of the Act allows us to create an exception only if there is no risk of program or patient abuse. We do not believe that an across-the-board exception for a medically underserved area in which the nearest DHS entity (except for the one owned by the physician) is at least 30 miles away is appropriate because we cannot determine that, even with this restriction, there would be no risk of program or patient abuse. Physician ownership of DHS entities is at the heart of the physician self-referral law and is precisely the conduct at which the statute is aimed. The Congress provided limited exceptions for ownership of DHS entities, expressly carving out a rural provider exception with a very specific definition of ''rural.''

D. Ownership Interest in a Whole Hospital

Section 1877(d)(3) of the Act provides that, with respect to DHS provided by a hospital, an ownership or investment interest in a hospital (and not merely in a subdivision of the hospital) is not a financial relationship within the meaning of section 1877 of the Act if the referring physician is authorized to perform services at the hospital. Section 507 of the MMA amended section 1877(d)(3) of the Act to provide that, effective for the 18-month period beginning on December 8, 2003, the ownership or investment interest must not be in a specialty hospital. Section 507 defined the term ''specialty hospital'' in a new subsection 1877(h)(7) of the Act. The moratorium expired on June 7, 2005.

The January 1998 proposed rule interpreted the requirement that the DHS be ''provided by the hospital'' to mean that the services had to be furnished by the hospital and not by another hospital-owned entity, such as a skilled nursing facility or a home health agency (63 FR 1698). We stated that the exception protects only services provided by an entity that is a ''hospital'' under the Medicare conditions of participation and that the referring physician must be authorized to perform services at the hospital to which he or she wishes to refer. In addition, the interest must be in the whole hospital, not in a part or department of the hospital. We further explained that a physician can have an ownership or investment interest in a hospital by virtue of holding an interest in an organization (such as a health system) that owns a chain of hospitals that includes the particular hospital, because the statute does not require the

physician to have a direct ownership or investment interest in the hospital. (63 FR 1713.)

The Phase I final rule adopted the proposed rule with incidental conforming changes. Phase II made no changes other than conforming amendments to incorporate the provisions of section 507 of the MMA. This Phase III final rule makes no changes to § 411.356(c)(3). We discuss issues related to the moratorium in section XI, below.

Comment: Two commenters objected to our decision to limit the protection of § 411.356(c)(3) to referrals to the hospital, rather than extending the protection to separately-licensed subsidiary providers or suppliers, such as a hospital's wholly-owned home health agency, skilled nursing facility, or durable medical equipment supplier. According to one commenter, the requirement that services be provided directly by the hospital is not found in the language of the statute and does not serve a public policy purpose. The second commenter stated that, if a physician owns an interest in the whole hospital, the exception should apply to referrals for all services provided by the hospital and its affiliates or subsidiaries because the nexus between a physician's referrals and his or her return on investment is extremely limited or non-existent, thereby causing little or no risk of program or patient abuse.

Response: For the reasons stated in Phase II, we believe that our interpretation of the statute is faithful to its language and purpose (69 FR 16084–81605). As we explained in Phase II, we believe that the better reading of the statute is that the Congress intended to protect ownership and investment interests in a hospital with respect to services furnished by the hospital. Therefore, we decline to modify the exception. Further, we do not believe that the Congress intended to create a blanket exemption for physician ownership in for-profit hospital conglomerates, which would, in our view, intensify rather than diminish the incentive to refer due to increased profit opportunities.

Comment: One commenter stated that, whereas CMS has some legitimate concerns that expanding the exception in § 411.356(c)(3) to cover all services provided by a hospital and its affiliates or subsidiaries could result in an overbroad exception, we should consider that the definition of an ownership interest is very broad and includes a security interest. Thus, a physician's security interest ''in a hospital,'' even if extremely attenuated, could result in a prohibition on referrals to other entities owned by the hospital. Therefore, if we decline to expand the exception to cover ownership in providers owned by a hospital, we should consider allowing the exception to cover ownership in providers owned by a hospital where such ownership derives only from a security interest in the hospital.

Response: It is unclear whether the commenter is referring to a security interest in equipment sold to a hospital or a security interest in the hospital itself. As noted in section VI.A of this Phase III final rule, we are clarifying that a security interest in equipment sold to a hospital by a physician and financed through a loan to the hospital by the physician is not an ownership interest in the hospital, but rather a compensation arrangement. A security interest in the hospital itself is an ownership interest in the hospital (and an indirect ownership interest in any subsidiary owned by the hospital). We decline to expand the exception to protect the referrals of a physician who has, by virtue of a security interest in the hospital, an ownership interest in DHS entities owned by a hospital.

IX. Exceptions to the Referral Prohibition Related to Compensation Arrangements—§ 411.357

A. Rental of Office Space and Equipment

Sections 1877(e)(1)(A) and (e)(1)(B) of the Act set forth exceptions for certain lease arrangements for space and equipment that meet six specific criteria:

(i) The lease is in writing, signed by the parties, and specifies the space or equipment covered by the lease;

(ii) The space or equipment rented or leased does not exceed what is reasonable and necessary for the legitimate business purposes of the lease or rental (except that space leases may include appropriately prorated payments for common areas), and, when used by the lessee, is done so exclusively;

(iii) The rental or lease term is at least 1 year;

(iv) The rental charges over the term of the lease are set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;

(v) The lease would be commercially reasonable even if there were no referrals between the parties; and

(vi) The lease meets other requirements set forth by the Secretary to protect against program or patient abuse.

''Fair market value'' is defined at section 1877(h)(3) of the Act as the value of rental property for general commercial purposes (not taking into account the property's intended use). For rentals or leases where the *lessor* is a potential source of patient referrals to the *lessee*, fair market value means general commercial value not taking into account intended use or the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor. The August 1995 final rule established § 411.357(a) and (b) (exceptions for the rental of office space and rental of equipment, respectively), which tracked the statutory language, including the definition of ''fair market value.''

In the January 1998 proposed rule, we proposed several clarifications to the statutory provisions. Leases could be terminated for cause within the initial 1-year period, provided that the parties did not enter into another lease until after the expiration of the original term (63 FR 1713). Any renewal of a lease would have to be for at least 1 year, thereby precluding holdover month-to-month leases (63 FR 1713). Subleases would be prohibited unless the sublease itself satisfied the conditions of the exception (63 FR 1714). Capital leases would not qualify for the exceptions (63 FR 1714). ''Per click'' (for example, per-use or per-service) equipment rental payments would qualify for the equipment rental exception, unless the payments were for the use of the equipment on patients referred by the lessor-physician (63 FR 1714).

Phase II adopted the provisions of the January 1998 proposed rule, with several changes (69 FR 16085). Specifically—

- Leases or rental agreements may be terminated with or without cause during the term of the agreement as long as no further agreement is entered into between the parties within the first year of the original lease term. (Any new lease would need to satisfy the requirements of an exception on its own terms (§ 411.357(a)(2) for space leases or § 411.357(b)(3) for equipment leases.)
- Month-to-month holdover leases for up to 6 months, immediately following the expiration of an agreement of at least 1 year that met the conditions of a rental exception, will continue to satisfy the requirements of the exception if the holdover is on the same terms and conditions as the immediately preceding lease (§ 411.357(a)(7) for space leases or § 411.357(b)(6) for equipment leases).

• All leases or rental agreements, whether operating or capital, are eligible for the lease exceptions if they meet the applicable criteria.

• A lease (or sublease) is considered to satisfy the ''exclusive use test'' provided that the lessee (or sublessee) does not share the rented space or equipment with the lessor during the time it is rented or used by the lessee (or sublessee) (§ 411.357(a)(3) for space leases or § 411.357(b)(2) for equipment leases). (We note that a subleasing arrangement could create a separate indirect compensation arrangement between the lessor and a sublessee that would need to be evaluated under the indirect compensation rules.)

• ''Per-click'' rental payments are permitted for DHS referred by the referring physician provided that the payments are fair market value and do not take into account the volume or value of referrals or other business generated by the referring physician, as those concepts are defined at § 411.351 and § 411.354.

We are making no substantive changes to § 411.357(a) or (b).

Comment: Two commenters sought clarification as to whether lease agreements between physicians and entities furnishing DHS may be amended prior to the stated termination of the agreement. The commenters asked about several different scenarios involving amendments to lease agreements prior to their expiration, specifically:

(1) Whether the parties to an agreement may amend an agreement during or after the first year of a multi-year agreement if the amendment is not related to the volume or value of referrals or other business generated between the parties;

(2) Whether an amended agreement must continue for an additional term of at least 1 year following the amendment even if the termination date of the original agreement would occur in less than 1 year;

(3) Whether a ''without cause'' termination clause in a multi-year agreement is permissible and whether the parties could simply amend an agreement they wish to change, rather than go through the formality of terminating the original agreement and entering into a new agreement; and

(4) Whether there is a limit on the number of amendments that may be made in the first year of an agreement.

Response: In order to satisfy the requirements of § 411.357(a) and (b), rental charges for the rental of office space and equipment must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. In addition to these and other requirements, the written agreement must provide for at least a 1-year term. An amended lease agreement must comply with these four criteria, as well as the remaining conditions of the exception. Changes to the rental charges (including changes to the methodology for calculating the rental charges) and changes to certain other terms that are material to the rental charges (for example, a change to the amount of space rented) may jeopardize compliance with one or more of these four criteria, and thus, § 411.357(a) or (b).

Because rental charges, including the methodology used to calculate rental charges, must be ''set in advance,'' as defined at § 411.354(d)(1), parties may not change the rental charges at any time during the term of the agreement. Parties wishing to change the rental charges must terminate the agreement and enter into a new agreement with different rental charges and/or other terms; however, the new agreement may be entered into only after the first year of the original lease term (regardless of the length of the original term). In addition, the new lease must be for a term of at least 1 year and must comply with all other criteria in the relevant rental exception. As we stated in Phase II (69 FR 16085), leases or rental agreements may provide for termination with or without cause.

Parties may amend a lease agreement multiple times during or after the first year of its term, provided that the rental charges are not changed and all other requirements of the exception are satisfied. However, changes to terms that are material to the rental charges, such as the amount of space leased, may cause the rental charges to fall out of compliance with the fair market value and ''volume and value of referrals'' requirements. For example, if the original rental charges were $5,000 per month for 200 square feet of space and the amended lease added 100 square feet of space but did not require additional payment beyond the original monthly payment of $5,000, the rental charges under the new agreement likely would not be consistent with fair market value and may take into account the volume or value of referrals or other business generated between the parties.

An amended agreement need not continue for an additional 1 year following its amendment if the original termination date of the agreement would occur sooner. Rather, because the exceptions in § 411.357(a) and (b) require a term of 1 year from the inception of the lease or rental agreement, the amended agreement may terminate upon the original expiration date, provided that the original term of the agreement is at least 1 year. As we noted above, rental charges may not be amended.

If the parties merely wish to end an arrangement prior to the original termination of the written agreement, as we stated in Phase II, they may terminate without cause at any time (subject to the terms of the agreement, of course), provided that the parties do not enter into a new lease agreement within the first year of the original term and any new agreement complies with an exception (69 FR 16085–16086). As we also stated (69 FR 16085), leases and rental agreements may provide for termination with or without cause.

Comment: One commenter asked for clarification regarding the termination of a lease. The commenter wanted confirmation that the prohibition on entering into a new lease agreement in § 411.357(a)(2) applied only to a new lease for the same office space. According to the commenter, the parties should not be prohibited from entering into a personal service arrangement or even a lease agreement for different office space.

Response: The commenter is correct that the prohibition on entering into a new lease applies to only a new lease for all or part of the same office space. The parties are not prohibited from entering into a personal service arrangement or a lease agreement for completely different office space.

Comment: One commenter described a ''time-share'' leasing arrangement under which a physician or group practice pays the lessor for the right to use office space exclusively on a turn-key basis, including support personnel, waiting area, furnishings, and equipment, during a schedule of time intervals for a fair market value rate per interval of time or in the aggregate. The commenter suggested that, although this arrangement may qualify under the exceptions for the rental of space and equipment, it would be addressed more appropriately in the fair market value exception (§ 411.357(l)) or payments by a physician exception (§ 411.357(i)). The commenter urged us to clarify that such ''time-share'' arrangements may qualify under § 411.357(l) or (i).

Response: We disagree with the commenter. As we stated in Phase II, we decline to permit space leases to be eligible for the fair market value exception in § 411.357(l) (69 FR 16086). Similarly, we are not persuaded that

§ 411.357(i) should protect space leases (69 FR 16099).

Comment: A number of commenters sought clarification regarding the application of § 411.357(a)(3) and (b)(2) to office-sharing arrangements in which several physicians and/or groups share facilities and some limited equipment without exclusivity. According to these commenters, sharing of facilities is extremely common for physicians and may not readily fit into the leasing exceptions.

Response: Irrespective of whether the office-sharing arrangements described by the commenters are common, both the statute and our regulations require that the lessee have *exclusive* use of the leased space or equipment when the lessee uses the space or equipment. In effect, § 411.357(a)(3) and (b)(4) require that space and equipment leases be for established blocks of time.

Comment: One commenter asked that we clarify that a sublessor and sublessee may share common areas. Another commenter requested guidance with respect to what is meant by ''common areas'' for the purposes of the exception. One commenter questioned whether the ability to share ''common space'' permitted parties to share actual *office space* (for example, exam rooms) if the arrangement is at fair market value.

Response: As we stated in Phase II, common areas may be shared if the rent is appropriately prorated (69 FR 16086). By common areas, we mean foyers, central waiting rooms, break rooms, vending areas, etc., to the extent that the areas are, in fact, used by the sublessee. (That is, the sublessee cannot pay rent for a break room that it will never use). Common areas do not include exam rooms. Common areas that contain certain limited equipment may be shared, such as hallways used by non-physician staff to weigh patients or draw fluid samples. Permissible equipment in shared common areas is limited to the type that is not usually separately leased (for example, scales). Non-exclusive arrangements, other than for common space (as described above), do not satisfy the requirements of § 411.357(a)(3) and (b)(2).

Comment: Several commenters expressed concern about the language in § 411.357(a)(3) and (b)(2) prohibiting a lessee from sharing space or equipment with a lessor or any person or entity related to the lessor. The commenters requested guidance on specific shared leasing arrangements, including whether the physician self-referral law prohibits the subleasing of space or equipment by a physician from a physician employed by or a group owned by a hospital.

Response: To prevent parties from circumventing the exclusive use requirement, we modified the space and equipment rental exceptions in Phase II (69 FR 16086) to preclude the sharing of rented office space or equipment with the lessor or any person or entity related to the lessor, including group practices, group practice physicians, or other entities owned or operated by the lessor. Determining whether a lessee is sharing space or equipment with a person or entity related to the lessor will require a case-by-case review of the facts. Nothing in § 411.357(a)(3) or (b)(2) prohibits physicians from subleasing space or equipment from a hospital, a hospital-owned group, or physicians employed by a hospital, provided that the sublessee has exclusive use of the space or equipment that is the subject of the sublease and all other requirements of the exception(s) are satisfied.

Comment: One commenter asked how tenant improvements should be addressed for purposes of compliance with the exception for the rental of office space. Specifically, the commenter asked whether the costs of any capital improvements should be allocated over the useful life of the improvements or be passed on in their entirety to the physician lessee who requested the improvements during the term of his or her lease.

Response: For accounting purposes, tenant improvements should be accounted for in accordance with generally accepted accounting practices. For purposes of determining the fair market value for rental charges, whether the costs of capital improvements should be allocated over the useful life of the improvements or be passed on in their entirety to the physician lessee who requested them will depend upon the facts and circumstances of the particular case. Specifically, if a lessor provides improvements for the benefit of a physician lessee that are unlikely to be chargeable to a subsequent tenant, the lessor should allocate the entire cost of these improvements to the lessee for whose unique benefit they are made. Improvements that the lessor reasonably expects would be chargeable to subsequent lessees may be allocated over their expected useful life.

Comment: A number of commenters welcomed the flexibility provided by § 411.357(a)(7) and (b)(6) with regard to lessees who hold over upon the expiration of space and equipment leases. The commenters requested confirmation that lessors could enforce leases that imposed higher fees during holdover tenancies, provided that the provisions were contained in the written lease at the time of initial or renewal execution of the lease. One commenter asked that the holdover grace period be extended indefinitely, provided that, during the holdover period, the lessor continually was taking steps to evict the lessee.

Response: We agree that lessors can charge a holdover rental premium, provided that the amount of the premium was set in advance in the lease agreement (or in any subsequent renewal) at the time of its execution and the rental rate (including the premium) remains consistent with fair market value and does not take into account the volume or value of referrals or other business generated between the parties. We decline to permit the holdover grace period to last for the length of time that the landlord is taking steps to evict the tenant as suggested by the commenter. We believe that the 6-month holdover period permitted in the regulations is sufficient.

B. Rental of Equipment

The exception in § 411.357(b) and the comments we received in response to Phase II are discussed above in section IX.A in conjunction with the exception in § 411.357(a) for the rental of office space.

C. Bona Fide Employment Relationships

Section 1877(e)(2) of the Act sets forth an exception for payments made by an employer to a physician (or immediate family member of the physician) with whom the employer has a *bona fide* employment relationship, if certain conditions are met. The August 1995 final rule incorporated the provisions of section 1877(e)(2) of the Act into our regulations in § 411.357(c) without change (60 FR 41975, 41981). The January 1998 proposed rule proposed to prohibit productivity bonuses paid to employed physicians based on DHS personally performed by the referring physician.

Phase II adopted the January 1998 proposed rule without the limitation on productivity bonuses given the Phase I determination that personally performed DHS are not referrals for purposes of section 1877 of the Act (69 FR 16087). We also declined to expand the definition of employee at § 411.351 in Phase II to include leased employees as defined by State law (69 FR 16087).

We received no comments concerning the exception in § 411.357(c) for *bona fide* employment relationships and we are making no changes.

D. Personal Service Arrangements

Section 1877(e)(3) of the Act establishes an exception for personal service arrangements that satisfy certain

requirements. The August 1995 final rule incorporated the personal service arrangements exception into the regulations in § 411.357(d). The January 1998 proposed rule would have retained the exception and proposed technical corrections and some additional interpretations (63 FR 1701).

Phase II adopted the January 1998 proposed rule with several modifications. In Phase II, we qualified the requirement in § 411.357(d)(1)(iv) that the term of an arrangement must be for at least 1 year to permit an arrangement to be terminated during the initial term with or without cause, provided that the parties do not enter into the same or substantially the same arrangement during the first year of the original term of the agreement (69 FR 16090). In Phase II, we modified the regulation to allow cross-referencing to a master list of contracts, in addition to the existing option of incorporation of multiple agreements by reference. We also added a requirement that a master list (or lists) be made available for inspection by the Secretary upon request (69 FR 16091). In Phase II, we declined to extend the exception beyond contracts between DHS entities and physicians or group practices. In addition, we declined to modify the exception to allow physicians to hire independent contractors or use wholly-owned companies to perform services they have contracted to provide, due to the potential for abuse (69 FR 16090).

Phase II also made minor changes to the physician incentive plan exception but did not expand significantly the exception. We clarified that the exception applies to downstream subcontractor arrangements related to health plan enrollees (69 FR 16090).

This Phase III final rule makes minor modifications to the personal service arrangements exception, including the addition of a provision in § 411.357(d)(1)(vii) to permit a holdover personal service arrangement similar to the holdover provisions in the exceptions for the rental of office space and equipment. We modified § 411.352(d)(2) to refer consistently to ''downstream contractor,'' a term for which we added a definition at § 411.351, as noted above.

Comment: One commenter asked how long the master list kept by an entity must include a record of a personal service agreement between the DHS entity and a referring physician. At some point, an expired agreement becomes irrelevant, according to the commenter. The commenter suggested 5 years after termination or expiration as the appropriate retention period. Another commenter asked for clarification as to whether the master list needs to include personal service agreements between the DHS entity and the physician that involved ''similar or related'' transactions, as opposed to *all* compensation and ownership arrangements between the parties. The commenter also asserted that the master list should have to include arrangements between the identical parties only, and not, for instance, contracts with the physician's family members.

Response: We note that the exception permits, but does not require, the use of a master list. Parties seeking protection under this exception must have a written agreement that covers all of the services to be furnished to the entity by the physician (or an immediate family member of the physician) or group practice. A master list may be used to meet this requirement. The master list must include all personal service arrangements with any physician, family member, or group practice. The condition in the exception requiring that the arrangement cover all services is not limited to ''similar or related'' services between the entity and the physician, but covers *all* services. This requirement is a bright-line rule that promotes transparency and is not dependent on subjective determinations of similarity or relatedness. Moreover, personal service arrangements with a physician's immediate family members must be included on the master list because section 1877(d) of the Act treats a financial relationship with an immediate family member of a physician the same as a financial relationship with the physician.

Comment: Two comments involved physician incentive payments referenced in § 411.357(d)(2). One commenter asked that we define a ''downstream contractor'' as used in § 411.357(d). A second commenter asked that the physician incentive plan exception be expanded to permit hospitals to pay physicians on a capitated or risk-sharing basis for services to hospital patients who are not enrolled in a managed care plan.

Response: We are revising the definition of ''physician incentive plan'' at § 411.351 to reference newly defined ''downstream contractor.'' As defined at § 411.351, and for purposes of § 411.357(d)(2), a ''downstream contractor'' means both a ''first tier contractor'' as defined at § 1001.952(t)(2)(iii) and a ''downstream contractor'' as defined at § 1001.952(t)(2)(i). Therefore, for physician self-referral purposes, a downstream contractor includes both an individual or entity that has a contract directly with an eligible managed care organization to provide or arrange for items and services (that is, a first tier contractor) and an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision of or arrangement for items or services that are covered by an agreement between an eligible managed care organization and the first tier contractor. We also note that, in § 411.357(d)(2), we used the terms ''downstream contractor'' and ''downstream subcontractor'' interchangeably. We have revised § 411.357(d)(2) to use only the term ''downstream contractor''.

The commenter wants DHS entities to be allowed to provide incentives to physicians for their services in connection with fee-for-service patients provided that the incentives ''fit the general structure of the [personal service arrangements] exception (for example, no payment to reduce medically necessary services).'' We are not persuaded to make such a change. In the exception for personal service arrangements, the Congress included a statutory provision permitting certain physician incentive plan payments (structured to protect patient care) that would otherwise run afoul of the general restriction on compensation determined in a manner that takes into account the volume or value of referrals or other business generated between parties. This provision facilitates certain managed care arrangements that conceptually compensate physicians based on limiting the volume of care provided or ordered by a ''gatekeeper'' physician. The exception proposed by the commenter, for similar payments related to fee-for-service patients, would pose a risk of program or patient abuse. (For example, see section 1128A(b)(1) of the Act, which authorizes civil monetary penalties for payments made by hospitals to physicians to reduce or limit services to hospital patients.) However, as we discussed in Phase II, compensation related to patient satisfaction goals or other quality measures unrelated to the volume or value of business generated by the referring physician and unrelated to reducing or limiting services would be permitted under the personal service arrangements exception, provided that all requirements of the exception are satisfied (for example, compensation to reward physicians for providing appropriate preventive care services where the arrangement is structured to satisfy the requirements of the exception) (69 FR 16091).

CMS is working on two demonstration projects that concern

hospital incentives paid to physicians in connection with the provision of high quality care, as authorized under section 646 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and section 5007 of the Deficit Reduction Act of 2005 (DRA). In addition, section 5001(b) of the DRA requires CMS to propose a demonstration for FY 2009 that would provide incentives to hospitals for the provision of high quality care. This will be a ''rewards sharing'' demonstration under which hospitals will share money with physicians based on quality of care rather than on reducing or limiting medically necessary services.

Comment: Several commenters raised issues regarding the exceptions for personal service arrangements and indirect compensation arrangements as they are applied to relationships involving a DHS entity, a group practice, and the physicians employed by the group practice who refer patients to the DHS entity. One commenter requested confirmation that, if a hospital contracts with a group practice for the provision of services, the relevant analysis is whether the arrangement meets the indirect compensation arrangements exception in order to ensure that referrals from individual physician-employees in the group practice are protected. One commenter asked for clarification that the personal service arrangements exception does not apply to most medical foundations because they typically contract with a group practice which, in turn, employs or contracts with physicians. Another commenter asserted that, if the personal service arrangements exception would protect an arrangement directly between a DHS entity and a physician, it should also be applicable to and protect an arrangement pursuant to which the physician has an indirect relationship with the DHS entity. Finally, one commenter asked for clarification that compliance with either the personal service arrangements or indirect compensation arrangements exception is sufficient to protect a compensation arrangement.

Response: As discussed in section VI.B, we now consider a physician to ''stand in the shoes'' of his or her group practice or physician organization. In the hypothetical situations posed by the first two commenters, the referring physician would stand in the shoes of the group practice that employs the physician and be considered to have a direct relationship with the hospital or the medical foundation, respectively, on the same terms as the hospital's or medical foundation's arrangement with the group practice. Thus, in the first hypothetical situation, the financial relationship between the hospital and the physician (who is standing in the shoes of the group practice) must meet an exception in order for the physician to be able to refer patients to the hospital. However, if the hospital contracts with a medical foundation which, in turn, contracts with the group practice which employs the physician (who stands in the shoes of the group practice), compliance with the indirect compensation arrangements exception would still be necessary for the physician to refer patients to the hospital (assuming that the arrangement meets the definition of an indirect compensation arrangement at § 411.354(c)(2)). The chain of financial relationships would be hospital—foundation—group practice—physician. However, if the physician makes a referral to the medical foundation's clinic (as opposed to a hospital with which the medical foundation contracts) for DHS furnished by the clinic, then the relationship between the physician (standing in the shoes of his or her group practice) and the medical foundation's clinic would be deemed to be a direct relationship (that is, medical foundation clinic—physician standing in the shoes of his or her group).

As we noted in Phase II, the exception for personal service arrangements would apply to payments made by a nonprofit medical foundation under a contract with an individual physician to provide health care services (69 FR 16077, citing H. R. Conf. Report No. 103–213 at 814 (1993)). Upon the effective date of this final rule, when the group practice physician stands in the shoes of the group practice with which the medical foundation has contracted, the medical foundation may apply the personal service arrangements exception to the arrangement between it and the group practice in order to protect referrals from the physician.

Finally, as we discussed in Phase I, where more than one exception can apply to a financial relationship, the relationship needs to satisfy the requirements of only one of the applicable exceptions (66 FR 916).

Comment: One commenter asked that we revise the exception in § 411.357(d)(1) to permit a holdover personal service arrangement on terms similar to those specified in the equipment and space lease context.

Response: We agree and have modified the regulation accordingly by adding a new provision in § 411.357(d)(1)(vii).

Comment: One commenter asked for clarification regarding when and on what terms a contract for personal services can be amended.

Response: A personal service contract can be amended in the same manner as an office space or equipment lease as noted above in section IX.A.

E. Physician Recruitment

Section 1877(e)(5) of the Act excepts remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the hospital's medical staff. To qualify for the protection of the exception, the following requirements must be satisfied—

- The physician is not required to refer patients to the hospital;
- The amount of remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician; and
- The arrangement meets any other requirements imposed by the Secretary to protect against program or patient abuse.

The August 1995 final rule incorporated the provisions of section 1877(e)(5) of the Act into our regulations in § 411.357(e), with the additional requirements that the arrangement and its terms be in writing and signed by both parties, and that the physician not be precluded from establishing staff privileges at another hospital or referring to another entity. The January 1998 proposed rule would have made minor editorial changes.

Based on public comments, Phase II substantially modified the rule (69 FR 16094–16095) in the following respects—

- A physician must relocate his or her practice, rather than his or her residence. To be eligible for the exception, a physician must be new to the hospital's medical staff and relocate to the geographic area served by the hospital (defined as the lowest number of contiguous postal zip codes from which the hospital draws at least 75 percent of its inpatients).
- Relocation of a physician's practice to the geographic area served by the hospital must involve either: (1) Relocating the physician's office a minimum of 25 miles; or (2) establishing that at least 75 percent of the physician's revenues from services provided by the physician to patients (including services to hospital inpatients) are derived from services provided to new patients.
- Residents and physicians who have been in medical practice less than 1 year will not be considered to have an established practice and will, therefore,

be eligible for compensation under the physician recruitment exception regardless of whether the physician actually moves his or her practice location.

• Federally qualified health centers may make recruitment payments to physicians on the same basis as hospitals.

• Recruitment payments made through existing group practices (rather than directly to the recruited physician) are permitted under certain conditions. (These conditions are designed to ensure that any remuneration in connection with recruiting a new physician that flows from the hospital through an existing group is remuneration for the benefit of the recruited physician and does not inure to the benefit of the group.)

We received a substantial number of comments regarding the physician recruitment exception. We are making several changes to the exception in response to the comments, and are clarifying our interpretation of certain provisions as requested by commenters. Because the exception in § 411.357(e) applies to federally qualified health centers and (now) rural health clinics in the same manner as it applies to hospitals, references to ''hospital'' below also implicitly include federally qualified health centers and rural health clinics.

Amendments to the text of § 411.357(e) include—

• Permitting rural health clinics to utilize the exception;

• Deeming the geographic area served by a hospital to be the area comprised of *all* of the contiguous zip codes from which the hospital's inpatients are drawn when the hospital draws fewer than 75 percent of its inpatients from contiguous zip codes;

• Permitting a hospital located in a rural area to determine the ''geographic area served by the hospital'' using an alternative test that encompasses the lowest number of contiguous (or in some cases, noncontiguous) zip codes from which the hospital draws at least 90 percent of its inpatients;

• Permitting a more generous income guarantee under certain circumstances in the case of a physician who is recruited to replace a deceased, retiring or relocating physician;

• Permitting group practices to impose certain practice restrictions;

• Permitting rural hospitals to recruit physicians into an area outside of the hospital's geographic service area if it is determined through a CMS advisory opinion that the area has a demonstrated need for the recruited physician;

• Exempting from the relocation requirement a physician who, for the 2 years immediately prior to the recruitment arrangement, was employed on a full-time basis by a Federal or State bureau of prisons (or similar entity operating correctional facilities), the Department of Defense or Department of Veterans Affairs, or facilities of the Indian Health Service, provided that the physician did not maintain a separate private practice in addition to such full-time employment;

• Exempting from the relocation requirement those physicians whom the Secretary has deemed in an advisory opinion not to have an established medical practice comprised of a significant number of patients who are or could become patients of the recruiting hospital;

• Clarifying that a physician must relocate his or her practice from outside the geographic service area to a location inside the service area and either: (1) Move his or her medical practice at least 25 miles; or (2) have a new medical practice that derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years, measured on an annual basis (fiscal or calendar year); and

• Clarifying that § 411.357(e)(4)(iii) pertains to any type of income guarantee.

Comment: Many commenters requested clarification as to the effect of Phase II on pre-existing recruitment arrangements that did not meet the Phase II requirements. Commenters urged us to grandfather any pre-existing recruitment arrangements.

Response: We posted guidance regarding pre-existing physician recruitment agreements on July 14, 2004 on the physician self-referral website in the form of a question and answer (*www.cms.hhs.gov/physicianselfreferral*). We are still not persuaded that we should grandfather pre-existing arrangements. Thus, any arrangement that was in effect as of July 26, 2004, should have been amended to comply with Phase II, whether the arrangement was in a payout period or in a forgiveness period.

Comment: Two commenters questioned the need for the requirement in § 411.357(e)(1) that the recruited physician not already be on the medical staff. One commenter said it was unnecessary in light of the relocation requirement. The other commenter stated that the requirement should not apply to physicians who are not active or who are on the hospital's courtesy staff only.

Response: We disagree with the first commenter. Section 1877(e)(5) of the Act states that the recruited physician must ''relocate * * * in order to be a member of the medical staff of the hospital.'' This language makes clear that the recruited physician cannot already be a member of the hospital's medical staff. We believe that the relocation requirement is insufficient to establish that a physician who is already a member of the hospital's active staff needs an incentive to move his or her practice. We are not persuaded that permitting recruitment of physicians who are not on a hospital's ''active'' medical staff, but who hold some type of medical staff privileges (for example, courtesy privileges), poses no risk of program or patient abuse. Moreover, defining ''active'' privileges is difficult, as many hospitals use different terminology to refer to different types of medical staff privileges.

Comment: One commenter objected to the conditions in § 411.357(e)(1)(iii) and (e)(4)(v) that the remuneration not directly or indirectly take into account the volume or value of actual or anticipated referrals or other business generated by the recruit or the physician practice, if it received any payments. According to the commenter, hospital recruitment arrangements always anticipate referrals to the hospital.

Response: We recognize that parties to a physician recruitment arrangement may anticipate some referrals by the recruited physician. In this context, the ''volume and value'' condition prohibits the *amount* of assistance payable to the physician or the group practice from taking into account, in any manner, the volume or value of past or anticipated referrals to the hospital. The unconditional payment of actual moving expenses, for example, would not take into account the volume or value of referrals.

Comment: One commenter asserted that a Mississippi statute prohibits physician employees of county- or city-owned hospitals from having any contractual relationship with the hospital other than an employment contract. Because of this restriction, these hospitals that recruit physicians as employees are unable to enter into a recruitment agreement that is separate and distinct from the employment agreement between the hospital and the recruit. The commenter requested that, in order to avoid placing community hospitals in a position where they have to choose between obeying State law or our physician self-referral regulations, we delete the word ''separate'' from the

phrase ''except as referrals may be restricted under a separate employment or services contract'' in § 411.357(e)(1)(iv).

Response: The commenter misunderstands the purpose of the quoted language in § 411.357(e)(1)(iv). This language appears in, and pertains to, the physician recruitment exception, not the employment exception (which would apply if the hospital was to employ the recruited physician directly and all requirements of the exception were satisfied). The purpose of the physician recruitment exception is to allow hospitals, subject to certain conditions, to provide remuneration directly or indirectly to physicians in order to induce them to relocate their medical practices to the hospital's geographic service area. The exception contemplates that recruited physicians will either practice on their own or as part of a physician practice. The exception does not contemplate that the recruited physicians will be employees of the recruiting hospitals, although nothing in the exception specifically precludes this result if all requirements of the exception are satisfied. Section 411.357(e)(1)(iv) provides that, as a condition of compliance with the recruitment exception, the recruited physician must be allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities, except to the extent that referrals may be restricted under a separate employment, managed care, or services contract that complies with § 411.354(d)(4). The ''separate employment contract'' contemplated in the regulation would be between the recruited physician and, for example, a group practice that employs the physician recruited by a hospital. Where a hospital wishes to recruit a physician as an employee, it need comply only with the requirements of the exception in § 411.357(c) for *bona fide* employment relationships, and, if it wishes to restrict the ability of the physician-employee to refer patients to other entities, with the requirements in § 411.354(d)(4) (special rule on compensation). Neither the employment exception nor the special rule on compensation requires the employing hospital to set forth referral restrictions in an agreement separate and distinct from the underlying employment contract.

Comment: Several commenters objected to the explanatory language in the Phase II preamble that appeared to condone credentialing restrictions aimed at restricting a recruited physician from competing with the recruiting hospital (69 FR 16095). Two commenters were concerned that such language lends itself to ''economic credentialing'' and objected to what they characterized as an inconsistent interpretation of what would be considered an inappropriate practice restriction on physicians. One commenter asked for examples of what we mean by ''reasonable credentialing restrictions.''

Response: The preamble discussion referenced by the commenters was primarily concerned with clarifying that recruited physicians cannot be prohibited from establishing staff privileges at other hospitals and from referring to other hospitals, even if such hospitals are competitors of the hospital that recruits the physician. We also intended to convey that the exception does not prevent hospitals from imposing reasonable credentialing restrictions on physicians when they compete with the recruiting hospital. Such restrictions must not take into account the volume or value of referrals. We take no position as to the application of any other State or Federal law or regulation pertaining to such credentialing restrictions. We merely intended to clarify that the physician self-referral law and our regulations do not prohibit reasonable credentialing restrictions that do not take into account in any way the volume or value of referrals or other business generated by the physician.

Comment: Some commenters asked that § 411.357(e) be expanded to protect recruitment of mid-level non-physician practitioners into a hospital's service area, including into an existing group practice. Other commenters asked that § 411.357(e)(5) be expanded to protect rural health clinics.

Response: Section 1877(e)(5) of the Act limits the recruitment exception to physicians, and, under section 1877(b)(4) of the Act, we cannot create a new exception unless there is no risk of program or patient abuse.

The physician recruitment exception in § 411.357(e) applies only to payments made directly (or, in some circumstances, passed through) to a recruited physician. Recruitment payments made by a hospital directly to a non-physician practitioner would not implicate the physician self-referral law, unless the non-physician practitioner serves as a conduit for physician referrals or is an immediate family member of a referring physician. Payments made by a hospital to subsidize a physician practice's costs of recruiting and employing non-physician practitioners would create a compensation arrangement between the hospital and the physician practice for which no exception would apply. These kinds of subsidy arrangements pose a substantial risk of fraud and abuse.

We are, however, persuaded to modify the exception to include rural health clinics, subject to the same conditions that apply to recruiting hospitals. We do not believe that such an expansion poses a risk of program or patient abuse. We have amended the regulation text accordingly.

Comment: A number of commenters objected to the condition in § 411.357(e)(1) that a hospital may recruit physicians only into the ''geographic area served by the hospital,'' which is defined at § 411.357(e)(2) as the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. Commenters noted that this condition prevents hospitals from recruiting physicians into outlying parts of their service areas where there is likely to be greater need. Some commenters asserted that this condition hurts rural hospitals, and that it is very difficult for federally qualified health centers to satisfy the condition. Still other commenters stated that the restriction was unnecessary in light of the requirement that the physician relocate at least 25 miles or establish a practice with 75 percent of revenues derived from professional services provided to patients not seen or treated by the physician within the preceding 3 years. Although most of these commenters requested that we eliminate this condition, some commenters suggested that, in the event the geographic restriction is retained, we should revise the regulation. Suggested revisions included: expanding the geographic area served by the hospital to 90 percent of zip codes from which the recruiting hospital draws its inpatients; making the 75 percent of inpatients/least number of zip codes requirement a *minimum* service area; permitting case-by-case determinations for good cause; and allowing a hospital to use any methodology permitted by the State in which it is located to determine the hospital's service area.

Response: We are not persuaded to eliminate the requirement that a recruited physician establish his or her medical practice within the geographic area served by the hospital; however, we are persuaded by some of the commenters that suggested an expansion of the definition of ''geographic area served by the hospital.'' With respect to a hospital located in a rural area, the ''geographic area served by the hospital'' may be the area composed of the lowest number of contiguous zip codes from which the

hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the ''geographic area served by the hospital'' may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital's inpatients resides, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients. A rural hospital will continue to have the option of determining the ''geographic area served by the hospital'' using the methodologies applicable to all hospitals. We believe that this expansion will address much of the concern that Phase II did not permit recruiting into outlying portions of a rural hospital's service area. We are also modifying the regulation by adding a new provision in § 411.357(e)(5) to permit rural health clinics, rural hospitals, and federally qualified health centers located in rural areas to recruit a physician into an area outside the entity's geographic service area if it is determined by the Secretary in an advisory opinion issued under section 1877(g)(6) of the Act that the area has a demonstrated need for the recruited physician.

Comment: Some commenters asked for clarification regarding what they perceive as an inconsistency between the regulation text and the preamble language in Phase II regarding whether a recruited physician must relocate his or her practice from *outside* the geographic area served by the hospital (as defined in the regulation) *into* the area, or whether the physician may simply relocate his or her practice within the geographic service area as long as the physician either: (1) Moves the site of his or her practice a minimum of 25 miles; or (2) derives at least 75 percent of the relocated practice's revenues from services provided by the physician to new patients.

Response: With respect to the commenters' concern regarding what they perceive as an inconsistency between the regulation text and the preamble language in Phase II, we confirm that the final regulation requires that the recruited physician relocate his or her medical practice from outside the ''geographic area served by the hospital'' (as defined in the regulation) into the area, and that the recruited physician must also either: (1) move the site of his or her practice a minimum of 25 miles; or (2) derive at least 75 percent of his or her practice's revenues from services provided by the physician to new patients. To the extent that the Phase II preamble discussion inadvertently suggested a different interpretation, we are clarifying our intent here. Our interpretation here is consistent with the regulatory text in Phase II. We are making additional conforming changes in the regulatory text in § 411.357(e)(2)(iv) for greater clarity.

Comment: Commenters raised a number of specific questions concerning the use of zip codes for purposes of determining the geographic area served by a hospital, including:

(1) What is the appropriate geographic service area if the zip codes contiguous to the hospital account for only 69 percent of the hospital's inpatients? Specifically, the commenter asked what a hospital should consider to be its geographic service area if the contiguous zip codes proximate to the hospital account for only 69 percent of the hospital's inpatients and, due to the national reputation of the hospital and its medical staff, the remainder of the hospital's inpatients are drawn from distant, noncontiguous zip codes.

(2) What if there is a zip code ''hole'' in the contiguous area (with the geographic service area resembling a donut)? May a hospital recruit a physician to establish his or her medical practice location in the zip code that forms the hole?

(3) What if multiple configurations of zip codes will satisfy the 75 percent requirement?

(4) How often can a hospital determine its service area and what, if anything, must a hospital do if the service area changes after a physician is recruited by the hospital?

(5) If a health system has two hospitals, is the geographic service area determined at the hospital or system level?

Response: Phase II defined ''geographic area served by the hospital'' at § 411.357(e)(2) as the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. As noted above, in this Phase III final rule, we are amending § 411.357(e) to permit a hospital located in a rural area to determine its geographic service area using noncontiguous zip codes if the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients. Other than as determined using our new rule for hospitals located in rural areas, the geographic area served by the hospital must be comprised of contiguous zip codes. We are clarifying that ''contiguous zip codes'' does not mean only zip codes that are contiguous to the zip code in which the hospital is located. It is our intention that ''contiguous zip codes'' means zip codes that are next to (or contiguous to) each other. A hospital should look at its inpatient data to determine where patients live and then calculate the lowest number of zip codes that touch at least one other zip code in which the inpatients reside. Our specific responses are as follows.

(1) We do not expect that many hospitals would be in the situation described by the commenter. However, to the extent that this situation exists, the hospital would be prohibited from relying on the recruitment exception because, under the Phase II definition of ''geographic area served by the hospital,'' the contiguous zip codes from which the hospital draws inpatients would not meet either the ''at least 75 percent of inpatients'' test (applicable to all hospitals) or, under this Phase III final rule, the ''at least 90 percent of inpatients'' test (the optional test for hospitals located in rural areas). In order to avoid this result, we are modifying § 411.357(e) to deem a hospital's geographic service area as comprising *all* of the contiguous zip codes from which the hospital's inpatients are drawn when the hospital draws fewer than 75 percent of its inpatients from those contiguous zip codes (or 90 percent in the case of the new optional test for hospitals located in rural areas). Using the commenter's example, the hospital would be permitted to recruit into the zip codes from which it draws the 69 percent of its inpatients.

(2) Provided that the ''hole'' zip code is surrounded by contiguous zip codes as described by the commenter, if no people reside in the ''hole'' zip code, the hospital may recruit a physician to establish a practice into the ''hole'' zip code. For example, a ''hole'' zip code might be one assigned to a large office building or commercial district. We have modified the regulation accordingly.

(3) If multiple configurations containing the same number of zip codes permit the hospital to meet the applicable percent of inpatients threshold (that is, 75 percent for all hospitals or 90 percent for hospitals located in rural areas), the hospital is free to use any of the configurations.

(4) A hospital may use any configuration that satisfies the lowest number of zip codes/applicable percent of inpatients test on the date it enters into the recruitment arrangement (that is, the date on which all parties have signed the written recruitment agreement). In some cases, this may result in the use of a different

geographic service area for different recruitment arrangements.

(5) The determination of the geographic area served by a hospital is applied at the *hospital* level rather than at the hospital *system* level. Therefore, the service area is hospital-specific, not system-specific.

Comment: One commenter asked whether, for purposes of § 411.357(e)(3), a ''residency'' includes all training, including post-residency fellowships.

Response: For purposes of § 411.357(e)(3), a residency includes all training, including post-residency fellowships.

Comment: Section 411.357(e)(3) specifies that the relocation requirement does not apply to residents and physicians who have been in practice 1 year or less, provided that the resident or physician establishes his practice in the geographic area served by the hospital. One commenter requested that we expand this provision to include other physicians who do not have a private medical practice, such as physicians on active military duty who are ending their military careers; physicians who live in, but have never practiced medicine in, the geographic area served by the hospital; and physicians who are employed by the Department of Veterans Affairs, Native American Hospital System, or a staff model HMO. According to the commenter, such physicians do not have an established medical practice that is capable of being relocated because virtually none of their patients could be treated by the recruited physician (or another physician) in the recruited physician's new medical practice and virtually none of the patients could become patients of the recruiting hospital.

Response: The recruitment exception in § 411.357(e) excepts certain remuneration that is intended to induce a physician ''to relocate his or her medical practice'' to the geographic area served by the hospital. In Phase II, we stated that residents and physicians who have been in practice 1 year or less would not be considered to have an established medical practice to relocate and that recruitment arrangements involving such physicians could qualify for the recruitment exception regardless of whether or not the physician actually moves his or her practice location, provided that all other conditions of the exception are satisfied (69 FR 16094–16095). We agree that some of the physicians identified by the commenter have practices that are incapable of being relocated due to unique restrictions that effectively prevent the recruited physician's patients from receiving medical care furnished by either the recruiting hospital or the recruited physician's new medical practice. Thus, we are expanding § 411.357(e)(3) to provide that, as long as the recruited physician establishes his or her medical practice in the geographic area served by the hospital, the relocation requirement will not apply if, for at least 2 years immediately prior to the recruitment arrangement, the recruited physician was employed on a full-time basis by one of the following—

- A Federal or State bureau of prisons or similar entity (operating correctional facilities) to serve exclusively a prison population;
- The Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or
- Facilities of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service.

Also, the physician must not have maintained an independent private practice in addition to his or her full-time employment with one of the above entities. We believe that the 2-year employment restriction is necessary to prevent program abuse. Because physicians often see patients less than once a year, we believe that an experienced physician may have an established medical practice that is capable of being relocated even when the physician has not practiced in that location for a period of time. Thus, for example, we believe that the exception's relocation requirement should apply in the case of a physician who left private practice in the hospital's geographic service area to become a full-time employee of the Indian Health Service for 1 year only.

In addition, to accommodate those rare instances in which a hospital should be permitted to provide recruitment assistance to a physician whose practice cannot be relocated for reasons other than those stated above, we are modifying the exception to provide that the relocation requirement will not apply if the Secretary has deemed in an advisory opinion issued under section 1877(g)(6) of the Act that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.

Comment: One commenter asked for clarification with respect to the signatories to the recruitment contract. The commenter was concerned that § 411.357(e)(4)(i), which requires that the recruitment agreement be signed also by the party to whom the payments are directly made, could be interpreted to require that the hospital, the physician practice, and the recruited physician all had to sign one document. The commenter asserted that this would be unnecessary and would add unnecessarily to the transaction costs. The commenter suggested that we require a written agreement between the hospital and either: (1) The recruit; or (2) the physician practice to which the payments will be made. The commenter suggested, alternatively, that it should be acceptable to limit the contracting parties to the hospital and the physician practice receiving the recruitment assistance and require the recruited physician to sign a one-page acknowledgement agreeing to be bound by the terms and conditions set forth in the recruitment agreement signed by the hospital and the physician practice.

Response: The exception requires a written agreement signed by all parties, including the recruiting hospital, the recruited physician, and the physician practice that the physician will be joining, if any. Nothing in the regulations precludes execution of the agreement in counterparts. This requirement is necessary to safeguard against program and patient abuse, and we are not persuaded that it creates any undue burden.

Comment: Two commenters asked whether a hospital could require a group practice that was receiving recruitment assistance to guarantee repayment of any monies advanced to the group on behalf of the recruited physician if the physician did not fulfill his or her community service requirement.

Response: Nothing in this rule precludes a hospital from requiring a physician practice to repay any monies advanced to the group on behalf of the recruited physician if the physician does not fulfill his or her community service requirement. However, if requiring the physician practice to guarantee repayment on behalf of the recruited physician is used to shield the recruited physician from any real liability for failure to fulfill his or her community service obligation under a recruitment agreement, the parties would be at significant risk of noncompliance with the fraud and abuse laws, particularly if the recruiting hospital failed to collect amounts owed by the physician practice making the guarantee. Any such arrangement should be carefully scrutinized under the fraud and abuse laws (including the physician self-referral law and the anti-kickback statute) for other implications, such as problematic relationships

between the group practice and the recruited physician or additional, unexcepted remuneration from the hospital to the group practice or the recruited physician.

Section 411.357(e)(4) excepts remuneration provided by a hospital to a physician: (1) Indirectly through payments to a physician practice; or (2) directly to a physician who joins a physician practice. To the extent that a physician practice guarantees the obligations of the recruited physician, and indemnifies the recruited physician against repayment of those obligations, the indemnification would create a remunerative relationship between the physician practice and the recruited physician (and potentially between the physician practice and the hospital) that could implicate the fraud and abuse laws, including the physician self-referral law and the anti-kickback statute.

Comment: A number of commenters requested clarification regarding the applicability of § 411.357(e)(4)(ii) to situations in which a group practice, through which a hospital makes indirect recruitment payments to a recruited physician, employs the recruited physician. The commenters requested clarification that the group practice could deduct from the amount passed through to the physician in salary, the group practice's actual costs attributable to recruiting the physician. Examples of such costs include headhunter fees, travel expenses and moving expenses associated with the recruitment, and employee benefits, taxes and professional fees attributable to hiring the recruited physician. The commenters pointed out that § 411.357(e)(4)(iii) specifically permitted such adjustments in the case of an income guarantee.

Response: Under § 411.357(e)(4)(iii), the costs allocated by a group practice that employs the recruited physician under an income guarantee may include the group's actual additional incremental costs attributable to the recruited physician. Depending on the circumstances, these costs may include those noted by the commenters. This provision was included in § 411.357(e)(4)(iii) in Phase II (69 FR 16096–16097).

Comment: A commenter requested clarification regarding the types of expenses that qualify as recruiting expenses. The commenter suggested that the following should qualify as covered expenses: Headhunter fees; air fare, hotel, meals, and other costs associated with visits by the recruited physician and his or her family to the relevant geographic area; moving expenses; telephone calls; and the cost of tail malpractice insurance covering the physician's prior practice. Another commenter asked whether a hospital could pay a physician or a group practice for time spent recruiting a physician into the hospital's service area, and whether our answer depends on if the recruited physician joined the recruiting physician's or group's practice or an unrelated medical practice.

Response: We understand the first commenter to be asking about the language in § 411.357(e)(4)(ii) that refers to ''actual costs incurred by the * * * physician practice in recruiting the new physician * * *.'' This language describes only costs incurred in the recruiting of the physician and does not include costs incurred after the physician is recruited and has joined the group. Depending on the circumstances, these costs incurred in recruiting could include the actual costs of headhunter fees; air fare, hotel, meals, and other costs associated with visits by the recruited physician and his or her family to the relevant geographic area; moving expenses; telephone calls; and tail malpractice insurance covering the physician's prior practice.

With respect to the second commenter's questions, if a hospital pays a physician or group for time spent recruiting a physician, as opposed to the expenses discussed above, such compensation would have to meet all of the requirements of a compensation exception (other than the recruitment exception). It would not matter whether the recruited physician actually joined the compensated physician's practice.

Comment: Several commenters requested clarification regarding what types of income guarantees trigger the application of § 411.357(e)(4)(iii). Several commenters claimed that *revenue* guarantees are not considered income guarantees.

Response: Any income guarantee, whether gross income, net income, revenues, or some variation, involves a potential cost to the guarantor hospital and a benefit to the recipient physician. Any such guarantee triggers the application of § 411.357(e)(4)(iii). We have modified the provision to clarify that § 411.357(e)(4)(iii) applies to any type of income guarantee.

Comment: Many commenters objected to the condition in § 411.357(e)(4)(iii) that a group practice cannot allocate more than its actual, additional incremental costs attributable to the recruited physician under an income guarantee. According to the commenters, the limitation will prevent groups from recruiting new physicians using hospital funding, and is unreasonable. The commenters requested that we revise the regulation to permit other reasonable methods of allocating overhead costs, such as *pro rata* or *per capita*. The commenters noted that § 411.352 permits group practices to use such allocation methods for distributing certain group practice revenues. A number of commenters stated that the rule was particularly unfair when the new physician was merely replacing a deceased, retiring, or relocating group physician, because there was no real benefit to the remaining physicians from a replacement physician who merely ''takes over'' the overhead costs of the deceased, retired, or relocated physician.

Response: We agree that, in the limited situation in which the recruited physician is replacing a deceased, retiring, or relocating physician in an underserved area, a physician practice may, for purposes of an income guarantee, allocate to the recruited physician a *per capita* allocation of the practice's aggregate overhead and other expenses, not to exceed 20 percent of the practice's aggregate costs. In the alternative, the practice may allocate the actual additional incremental costs attributable to the recruited physician as provided for in Phase II (69 FR 16096–16097). This additional flexibility should assist hospitals that seek to replace needed physicians in their communities. In all other cases, the group may allocate to the recruited physician only the actual additional incremental expenses attributable to the recruited physician.

Contrary to the commenter, we perceive no unfairness. Physician practices that use their own funds to recruit physicians to join them are free to use any cost allocation method when compensating the recruited physicians (subject to any conditions necessary to satisfy the requirements of an applicable physician self-referral exception, such as the exception for *bona fide* employment relationships or the in-office ancillary services exception). In the case of a hospital-subsidized income guarantee, a restriction on the allocation of costs becomes necessary to prevent physician practices from inappropriately shifting overhead costs to the hospital to which the physician practice refers. If a hospital were to subsidize costs that are not genuinely attributable to the recruited physician, the hospital would confer remuneration on the physician practice for which no exception would apply and which could reflect referrals. This would pose a substantial risk of program abuse under

the physician self-referral law, as well as under the anti-kickback statute. We believe that permitting broader overhead allocation in the limited way described above will provide appropriate assistance in underserved areas, where a deceased, retired, or relocated physician might create a deficit in available care for patients, without the risk of increased program or patient abuse. We are modifying the regulation in § 411.357(e)(4)(iii) accordingly.

Comment: One commenter asked whether the income guarantee requirements in § 411.357(e)(4)(iii) with respect to ''actual additional incremental costs'' apply to a recruited physician who leases space and equipment from and is co-located with (rather than a member of or a physician in) a group practice.

Response: The requirements of § 411.357(e)(4)(iii) apply only in the case of income guarantees provided by a hospital when a physician *joins* a physician practice. For purposes of the recruitment exception, a physician has not ''joined'' a physician practice unless he or she has become a ''physician in the group practice'' or a ''member of the group'' (or the equivalent, in the case of a physician who joins a practice that is not a ''group practice'' as defined at § 411.352). In the case of a physician who joins a physician practice, except as provided in new § 411.357(e)(4)(iii), the physician practice may not allocate costs under the income guarantee that exceed the actual additional incremental costs attributable to the recruited physician. In the case of a physician who merely co-locates with a physician practice (for example, by leasing office space from a group practice), none of the provisions of § 411.357(e)(4) would apply. Rather, the arrangement must satisfy the requirements of the recruitment exception without reference to § 411.357(e)(4), or satisfy the requirements of another exception. The recruitment exception would not protect any remuneration provided by the hospital to the physician practice indirectly through payments made to the recruited physician. For example, the exception would not protect an arrangement in which a recruited physician uses funds from a hospital (including amounts pursuant to an income guarantee) to pay inflated rental payments to a group practice. Nor, for example, would it protect any arrangement in which a hospital uses a recruitment arrangement with a recruited physician who co-locates with a physician practice to provide remuneration indirectly to the physician practice (for example, by arranging for the recruited physician to co-locate with, but not join, the existing physician practice and to pay that practice inflated amounts for rent or services). We are aware of no circumstances in which it would be appropriate for a physician practice to be a party to an income guarantee made by a hospital to a recruited physician who is not joining the practice.

We caution that the physician practice and the physician may not improperly shift costs to the hospital making the income guarantee. We note that any lease or contract between the recruited physician and the physician practice would create a financial relationship that would require an exception, such as the exception for the rental of office space in § 411.357(a), if the recruited physician refers DHS to the physician practice. Moreover, such lease would potentially create an indirect compensation arrangement between the hospital and the physician practice's physicians who refer DHS to the hospital (the chain links the hospital to the recruited physician (via the income guarantee) to the physician practice (via the lease) to the referring physicians (via ownership or employment)). Such arrangement would need to satisfy the requirements of the indirect compensation arrangements exception in § 411.357(p), and should also be closely scrutinized under the anti-kickback statute.

Comment: One commenter asked for confirmation that § 411.357(e)(4)(iv) requires that the physician practice keep records of its actual costs and the amount passed through to the recruited physician, and that a physician practice's failure to keep the records would not, by itself, subject the hospital to sanction.

Response: Section 411.357(e)(4)(iv) requires that records of costs be maintained for at least 5 years and made available to the Secretary upon request. Because the recruiting hospital is the DHS entity seeking payment from Medicare in the scenario presented, it is the hospital's responsibility to maintain the necessary records. The commenter is correct that the physician practice's failure to keep records would not subject the hospital to sanction under the physician self-referral provisions. However, the hospital's failure to keep full, complete and accurate records of the actual costs it has subsidized and the amounts passed through to the physician it has recruited would preclude protection under the physician recruitment exception. Hospitals should take appropriate steps to ensure that their funds, intended for the benefit of recruited physicians, are appropriately handled by the physician practices that receive them.

Comment: We received many comments concerning the requirement in § 411.357(e)(4)(vi) that a physician practice may not impose additional practice restrictions on the recruited physician other than conditions related to quality of care. Commenters (including hospital associations) that addressed the issue of the allowability of non-compete agreements were uniformly opposed to prohibitions on them. They also stated that the restriction limited the utility of the exception and was contrary to State laws permitting such restrictions. Several commenters suggested that § 411.357(e)(4)(vi) be revised to prohibit only restrictions that prohibit the physician from practicing in the hospital's geographic service area. The commenters asserted that non-compete agreements are a standard business practice between physician groups and physicians. They stated that, without the ability to enter into non-compete agreements, physician practices would be less likely to take on new physicians and, as a result, hospitals may be unable to attract new physicians, and certain health care needs of the surrounding communities could go unmet. Other commenters questioned whether the following were permitted—

- Restrictions on moonlighting;
- Prohibitions on soliciting patients and/or employees of the physician practice;
- Requiring that the recruited physician treat Medicaid and indigent patients;
- Requiring that a recruited physician not use confidential or proprietary information of the physician practice;
- Requiring the recruited physician to repay losses of his or her practice that are absorbed by the physician practice in excess of any hospital recruitment payments; and
- Requiring the recruited physician to pay a predetermined amount of reasonable damages (that is, liquidated damages) if the physician leaves the physician practice and remains in the community.

Response: We indicated in Phase II that we considered a non-compete clause to be a practice restriction and not a condition related to quality of care (69 FR 16096–16097). Although we did not list other examples of such practice restrictions, we intended to include only such restrictions placed on the recruited physician by a physician practice that would have a substantial effect on the recruited physician's ability to remain and practice medicine

in the hospital's geographic service area after leaving the physician practice or group practice. We do not consider the restrictions, prohibitions, and requirements that are specifically mentioned in the bulleted points above as falling into the category of having a substantial effect on the recruited physician's ability to remain in the hospital's geographic service area. (We note that we may consider a liquidated damages clause requiring a *significant or unreasonable* payment by the physician leaving the physician practice to have a substantial effect on the recruited physician's ability to remain in the recruiting hospital's geographic service area.) Our purpose in prohibiting practice restrictions such as non-compete clauses was to avoid frustrating the purpose of the exception. That is, we intended to discourage physician practices that recruit physicians using hospital funding from making it difficult for a recruited physician to remain in the community and fulfill his or her commitments under the recruitment agreement with the hospital. Allowing a physician to remain in the community not only furthers the health care needs of the community, but also obviates the need for the hospital to enter into a new recruitment agreement to replace the physician.

Upon review of the comments, however, we are persuaded that categorically prohibiting physician practices from imposing non-compete provisions may have the unintended effect of making it more difficult for hospitals to recruit physicians. We are concerned that physician practices and individual physicians may be unable or reluctant to hire additional physicians, regardless of the receipt of financial assistance from hospitals, unless they are able to impose a limited, reasonable non-compete clause. Therefore, we are amending § 411.357(e)(4)(vi) to state that physicians and physician practices, may not impose on the recruited physician any practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital. Although we are not *per se* conditioning payment for DHS on compliance with State and local laws regarding non-compete agreements, we believe that any practice restrictions or conditions that do not comply with applicable State and local law run a significant risk of being considered unreasonable. (Nothing in § 411.357(e)(4)(vi) should be construed, however, as prohibiting a hospital that provides financial assistance to the hiring physician practice from entering into an agreement with the practice that prohibits the hiring physician practice from imposing a non-compete agreement or other practice restriction.)

Comment: Several commenters asked whether money paid to a group practice under a physician recruitment arrangement constitutes indirect compensation within the meaning of § 411.354(c)(2). Other commenters asked why physician recruitment arrangements could not qualify for the fair market value exception in § 411.357(l).

Response: With respect to the first comment, as discussed in Phase II (69 FR 16097), the provisions of § 411.357(e)(4) related to pass-through hospital recruitment payments establish an exception applicable to the compensation arrangement created between the hospital and the recruited physician (and to the compensation arrangement between the hospital and the existing physician practice) (69 FR 16097). With respect to the second comment, physician recruitment arrangements cannot qualify for the fair market value compensation exception for the reasons explained in Phase II (69 FR 16096). Our position with respect to the application of the fair market value compensation exception to recruitment arrangements has not changed.

Comment: A commenter requested that we amend the physician recruitment exception to provide that the requirements in § 411.357(e)(4) do not apply in the case of remuneration involving the recruitment of a faculty physician to a nonprofit faculty practice plan affiliated with the hospital. The commenter stated that the Phase II preamble was clear that physician recruitment activities conducted in compliance with the academic medical centers exception do not need to comply with the physician recruitment exception. The commenter also stated, however, that an academic medical center may choose not to structure its compensation arrangements to fit within the academic medical centers exception, either because the indirect compensation rules apply or because another exception or exceptions are available for the compensation arrangements. The commenter theorized that our concerns with hospital payments for the recruitment of a physician who joins an existing physician practice arise from the potential incidental benefit that such arrangements may confer on the existing physician practice and its owner-physicians (who may have existing referral relationships with the hospital). However, the commenter asserted that, where a nonprofit hospital provides remuneration to recruit a needed faculty physician to an affiliated nonprofit faculty practice plan, it is unlikely that any improper incidental benefit would be conferred on any physician group.

Response: To the extent that a hospital, including one affiliated with an academic medical center, wishes to provide remuneration to a physician for recruitment purposes, the arrangement, depending on the facts and circumstances, may be structured to satisfy one or more exceptions, such as the exception for *bona fide* employment relationships in § 411.357(c), the academic medical centers exception in § 411.355(e), or the physician recruitment exception in § 411.357(e). Where the only exception potentially applicable is the physician recruitment exception (because some remuneration would be paid to another physician or to a physician practice), the arrangement must satisfy all of the requirements of § 411.357(e)(4). We are not persuaded that any additional protection under the physician self-referral statute for a nonprofit hospital's recruitment of faculty physicians is necessary or appropriate. We believe that the potential for program and patient abuse in the form of anti-competitive behavior or over-utilization exists whether the DHS entity is a for-profit or nonprofit entity.

F. Isolated Transactions

Section 1877(e)(6) of the Act provides that an isolated transaction, such as a one-time sale of property or a medical practice, is not considered to be a compensation arrangement for purposes of the prohibition on physician referrals if the following conditions are met—

- The amount of remuneration for the transaction is consistent with fair market value and is not determined, directly or indirectly, in a manner that takes into account the volume or value of referrals;
- The remuneration is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity; and
- The transaction meets any other requirements that the Secretary may impose by regulation as needed to protect against program or patient abuse.

Phase II incorporated the provisions of section 1877(e)(6) of the Act into our regulations in § 411.357(f), with a requirement that there be no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically permitted under another

exception (69 FR 16098). Phase II set forth definitions of ''transaction'' and ''isolated transaction'' at § 411.351. Phase II provided that installment payments could qualify as isolated transactions, as long as the total aggregate payment is: (1) set before the first payment is made; and (2) does not take into account, directly or indirectly, referrals or other business generated by the referring physician (69 FR 16098). Additionally, the payments must be immediately negotiable or guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party. Phase II also clarified that post-closing adjustments that are commercially reasonable and not dependent on referrals or other business generated by the referring physician will be permitted if made within 6-months of the date of a purchase or sale transaction (69 FR 16098). We are making no changes to the isolated transactions exception in this Phase III final rule.

Comment: Two commenters raised questions regarding the requirement in the definition of isolated transaction at § 411.351 that the payments be immediately negotiable or secured by a negotiable promissory note, among other options. According to one commenter, a promissory note is immediately negotiable if the note so states, although as a practical matter, there may not be a market for the note. The other commenter claimed that promissory notes are typically immediately negotiable only in the event of default, and that requiring immediate negotiability is inconsistent with installment payments. One of the commenters also pointed out that a promissory note does not necessarily secure the underlying debt; rather, it can serve as security for a different obligation. Both commenters sought clarification of the ''immediately negotiable'' note requirement.

Response: We have carefully considered the commenters' questions and assertions. The critical element with respect to installment payments is that a mechanism is in place to ensure payment (even in the event of default by the purchaser or obligated party). The regulation provides for several options to accomplish this: (1) Immediately negotiable payments or payments that are guaranteed by a third party; (2) payments that are secured by a negotiable promissory note; or (3) payments that are subject to a mechanism similar to (1) and (2) that ensures payment in the event of default. The regulation at § 411.351 does not require that a *promissory note* be *immediately* negotiable. Installment payments need only be secured by a *negotiable* promissory note if that is the mechanism chosen by the parties to ensure payment in the event of default. The parties are free to choose one of the other options to satisfy the requirements for installment loans in isolated transactions. Whether a promissory note is negotiable is governed by the State's version of the Uniform Commercial Code or other applicable State law.

Comment: One commenter asked for clarification concerning separate transactions involving related parties, such as a hospital's purchase of a group practice and the purchase of an office building that is owned by some of the group practice physicians through a separate limited liability company. The commenter believed that such transactions are not unusual but would not appear to qualify for the exception.

Response: The commenter's example appears to describe two isolated transactions between different parties that would each need to satisfy the requirements of the isolated transactions exception: a transaction between the hospital and the group practice, and a transaction between the hospital and the limited liability company. These arrangements could qualify for the exception, provided that they are structured with separate payments for each transaction and all other conditions of the exception are satisfied.

Comment: Two commenters asked for clarification regarding post-closing adjustments. One commenter stated that the 6-month limit on post-closing adjustments is too brief. The commenter asserted that, as a practical matter, it would encourage recalcitrant parties to ''hold out'' to increase their bargaining leverage. The commenter interpreted the exception as not precluding post-closing adjustments after 6 months, but precluding only other isolated transactions. The commenter suggested that the commercial reasonableness test provided sufficient protections. The commenter also requested clarification that an adjustment based on a breach of a warranty will not be considered a post-closing adjustment. The second commenter asked that post-closing adjustments be permitted for 24 months. According to the commenter, many purchase and sale agreements provide for warranties, representations, and indemnities to continue in effect for at least one complete audit cycle (that is, 1 fiscal year plus additional months, as needed, to complete the audit) to enable the buyer's auditors to fully examine financial statements.

Response: The exception for isolated transactions permits commercially reasonable post-closing adjustments within the first 6 months following an isolated transaction, provided that the adjustments do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician(s). After 6 months, any post-closing adjustment would be treated as a separate, additional transaction that would need to satisfy the requirements of an exception. Claims based on breach of warranty are not considered post-closing adjustments or new transactions; rather, they are considered part of the original transaction and, therefore, may occur at any time without jeopardizing compliance with the exception in § 411.357(f).

Comment: Several commenters were concerned with the interplay between the definition of ''ownership,'' which includes, for example, a security interest in property sold to an entity furnishing DHS, and the definition of the term ''isolated transaction'' at § 411.351, which permits installment payments only if the instruments are secured or guaranteed by a third party. According to the commenter, as a practical matter, the result is that a hospital has few options if it wants to purchase a physician's equipment or practice using installment payments. Another commenter asked whether a guarantee from an entity furnishing DHS made to a physician would create an ownership interest in the entity. The commenters sought clarification as to how the exception would apply to these transactions.

Response: Hospitals and physicians can use other arrangements and methods (that is, other than installment payments made from the hospital to the physician) to secure legal obligations arising from transactions between them. However, we note that, as discussed in section VI.A, we do not consider a security interest in equipment sold by a physician to a hospital and financed through a loan from the physician to the hospital to be an ownership interest in the hospital or a portion of the hospital. Where a physician extends a loan to an entity and is granted a security interest by the entity in the equipment sold by the physician to the entity, the arrangement creates a compensation arrangement (subject to a contrary provision in the security instrument or agreement of the parties). In response to the second comment, a guarantee does not create an ownership interest in the entity providing the guarantee.

G. Remuneration Unrelated to Designated Health Services

Under section 1877(e)(4) of the Act, remuneration provided by a hospital to a physician that does not relate to the furnishing of DHS does not constitute a prohibited compensation arrangement. The exception does not apply to remuneration from a hospital to a member of a physician's immediate family, nor does it apply to remuneration from entities other than hospitals.

Under Phase II, the exception is available only if the remuneration is *wholly* unrelated to the provision of DHS (69 FR 16093). Phase II provided that, for purposes of the exception, any item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under applicable cost reporting principles is considered to be related directly or indirectly to the provision of DHS. In addition, remuneration is considered related to DHS for purposes of this exception if it is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditional manner to medical staff or other physicians in a position to make or influence referrals. The exception does not apply to any other remuneration that is related in any manner to the provision of DHS. This Phase III final rule makes no changes to Phase II.

Comment: Numerous commenters, including several hospital trade associations, strongly objected to § 411.357(g) as set forth in Phase II. According to the commenters, the regulation is inconsistent with the statutory language and congressional intent. Some of the commenters argued that the Congress intended that hospitals could provide any amount of remuneration to physicians provided that it was not *directly* related to the provision of DHS services. The commenters uniformly urged us to reconsider the position we took in Phase II in this regard.

Response: As we discussed in Phase II, § 411.357(g) is consistent with the statutory scheme and congressional intent (69 FR 16093–16094). We do not believe that the Congress intended that a hospital could provide any remuneration it chooses to physicians provided that the amount of remuneration is not *directly* related to the provision of DHS services. *Bona fide* compensation relationships related in any way to the furnishing of DHS should be structured to fit in another exception.

Comment: Two commenters asked us to provide additional examples of arrangements that would qualify under the exception in § 411.357(g). Another commenter asked for clarification regarding what would constitute an improper targeted, preferential, or selective process for distributing a benefit. The commenter asked, for example, if a hospital could waive the entry fee for its charity golf tournament for the entire medical staff and still qualify for the exception.

Response: The determination of whether an arrangement is unrelated to the furnishing of DHS will require a detailed review of the facts and circumstances surrounding the arrangement. The examples provided in Phase II are suitably illustrative (69 FR 16093–16094). Parties seeking guidance on particular transactions may submit a request for an advisory opinion. Waiving an entry fee would be a targeted benefit if applied to the medical staff and not to all other participants. However, the arrangement between the hospital and a particular physician could fit into the exception in § 411.357(k) if the value of the total nonmonetary compensation to the physician during a calendar year is not greater than $300 (as adjusted by the CPI–U).

Comment: One commenter requested confirmation that, where there are no explicit cost reporting guidelines or requirements with respect to the allowability of an item, it is sufficient to apply a good faith reading of general Medicare cost principles.

Response: We understand the commenter's concern to be situations in which a hospital does not know and could not reasonably be expected to know whether a particular item, service, or cost could be allocated in whole or part to Medicare or Medicaid under cost reporting principles, as required by § 411.357(g)(1). In such a situation, we would not consider the item, service, or cost to relate to the furnishing of DHS under § 411.357(g)(1). However, it is not sufficient to satisfy § 411.357(g)(1) alone in order to qualify for protection under the exception. Sections 411.357(g)(2) and (g)(3) set forth additional grounds for determining that remuneration relates to the furnishing of DHS. Specifically, remuneration also relates to the furnishing of DHS if either: (1) It is furnished directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditional manner to medical staff or other persons in a position to make or influence referrals; or (2) otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

Comment: One commenter expressed concern that the exception in § 411.357(g) was narrowed so much under Phase II that it does not allow hospitals to provide assistance with malpractice insurance premiums.

Response: As discussed below in section IX.R, assistance with malpractice insurance premiums may be structured to satisfy the requirements of other exceptions, such as the fair market value compensation exception (§ 411.357(l)), the exception for *bona fide* employment relationships (§ 411.357(c)), the exception for personal service arrangements (§ 411.357(d)), or the exception for obstetrical malpractice insurance subsidies (§ 411.357(r)). We note that the January 1998 proposed rule clearly stated that this exception would not protect malpractice insurance premium subsidies (63 FR 1702).

H. Group Practice Arrangements With a Hospital

Section 1877(e)(7) of the Act provides that an arrangement between a hospital and a group practice under which DHS are furnished by the group practice but are billed by the hospital does not constitute a compensation arrangement for purposes of the prohibition on referrals if certain conditions are met. The August 1995 final rule incorporated the provisions of section 1877(e)(7) of the Act into our regulations in § 411.357(h) (60 FR 41920, 41975). In the January 1998 proposed rule, we proposed revising § 411.357(h) to make several minor changes and to apply the provision to all DHS, not just clinical laboratory services (63 FR 1669–1670, 1702–1703). The changes included clarifying that the exception protects only arrangements that have continued in effect, without interruption, since December 19, 1989; interpreting the regulatory language to allow changes to the arrangement over time with respect to the services covered by the arrangement or the physicians providing those services; and clarifying that at least 75 percent of the DHS covered under the arrangement must be furnished to patients of the hospital by the group practice under the arrangement (63 FR 1702–1703).

Phase II adopted § 411.357(h) as proposed (69 FR 16099). We received no comments on this exception and are making no changes in this Phase III final rule.

I. Payments by a Physician

Section 1877(e)(8) of the Act creates an exception for certain payments that a physician makes to a laboratory in exchange for clinical laboratory services

or to an entity as compensation for other items or services that are furnished at a price that is consistent with fair market value.

Phase II implemented section 1877(e)(8) of the Act in § 411.357(i) by making two clarifications (69 FR 16099). The first made the exception applicable to payments by a physician's immediate family members, as well as to payments by a physician. The second clarified that the exception does not apply to items or services for which there is another potentially applicable exception in § 411.355 through § 411.357. This Phase III final rule makes no change to this exception. However, we are amending the exception for fair market value compensation in § 411.357(l) to provide that that exception covers compensation *from* a physician, provided that all other conditions of the exception are satisfied. We note that the fair market value compensation exception does not protect office space lease arrangements; arrangements for the rental of office space must satisfy the requirements of the exception in § 411.357(a).

Comment: Two commenters objected to the provision in § 411.357(i)(2) that the exception applies only to items and services that are not specifically excepted by another exception in § 411.355 through § 411.357. According to the commenters, the restriction leaves many legitimate purchases of items or services by a physician from a DHS entity without an available exception. The first commenter gave the example of the lease of space on a non-exclusive basis to a physician. The commenters also noted that the statement in Phase II that the fair market value compensation exception was available is incorrect because that exception only protects payments to a physician from a DHS entity (69 FR 16099). The second commenter suggested that we either delete language in § 411.357(i) that indicates that the fair market value compensation exception is available, or that we allow the payments by a physician exception in § 411.357(i) to be generally available (rather than available only when another potential exception does not apply), except with respect to space rental arrangements.

Response: We continue to believe, as we stated in Phase II, that our policy of not allowing items and services addressed by another exception to be covered in this exception is consistent with the overall statutory scheme and purpose, and is necessary to prevent the exception from negating the statute (69 FR 16099). To that end, we are amending the text of the exception for fair market value compensation in § 411.357(l) to permit application of that exception to arrangements involving fair market value compensation to physicians from DHS entities, as well as to arrangements involving fair market value compensation to DHS entities from physicians. We believe that this approach is consistent with the statutory scheme and intent.

The expansion of the applicability of the fair market value compensation exception to compensation paid to DHS entities by physicians will require parties to use the exception in § 411.357(l), rather than the exception in § 411.357(i), when payments by a physician to a hospital are, for example, for equipment leases of less than 1 year. Upon further consideration, we believe that the required application of the fair market value compensation exception, which contains conditions not found in the less transparent exception for payments by a physician to a hospital, further reduces the risk of program abuse. As discussed below in section IX.L, we have amended the text of the exception for fair market value compensation in § 411.357(l) to exclude arrangements for the rental of office space. The only exception applicable to arrangements for the rental of office space is § 411.357(a).

J. Charitable Donations by a Physician

Using our authority under section 1877(b)(4) of the Act, in Phase II, we established an exception in § 411.357(j) for *bona fide* charitable donations made by a physician (or his or her immediate family member) to an entity furnishing DHS. To qualify for the exception, donations must be made to an organization exempt from taxation under the Internal Revenue Code (or to an exempt supporting organization, such as a hospital foundation). The exception provided that the donation may not be solicited or made in any manner that reflects the volume or value of referrals or other business generated between the parties. As with all regulatory exceptions promulgated under section 1877(b)(4) of the Act, a protected arrangement must not violate the anti-kickback statute or billing or claims submission rules. This Phase III final rule clarifies that the donation may not be solicited or *offered* in any manner that reflects the volume or value of referrals.

Comment: A hospital association objected to the requirement in § 411.357(j)(2) that the donation cannot be *made* in a manner that takes into account referrals or other business generated between the physician and the entity furnishing DHS. According to the commenter, a hospital cannot control how the donor makes the payment. The commenter asked that the exception be conditioned only upon the manner in which the charitable donations are solicited, rather than the manner in which they are both solicited and made.

Response: We disagree that only the manner of the solicitation should be relevant for this exception. We agree, however, that the phrase ''nor made, in any manner'' might be interpreted as implying that, irrespective of whether the entity had knowledge of an improper purpose of the donation, the donation is outside the protection of the exception simply if the physician intended that the donation was in exchange for future or past referrals or other business generated between the parties. Accordingly, we have amended § 411.357(j) to provide that the entity may not solicit the donation, nor may the physician *offer* the donation, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity.

Comment: Two commenters asked for further guidance regarding acceptable fundraising efforts directed at medical staff. One of the commenters emphasized that such efforts are very important to hospitals.

Response: We recognize the importance of fundraising to nonprofit health care entities and the crucial role often played by medical staff in fundraising. The regulation is sufficiently clear that it permits solicitations of the medical staff provided that neither the solicitation nor the offer of a contribution from the physician takes into account the volume or value of referrals or other business generated between the physician and the hospital.

Comment: Two commenters asserted that the purpose of the law is to regulate payments to physicians from entities furnishing DHS, not contributions from the physicians to the entities. One of the commenters suggested that we define remuneration to exclude charitable donations from physicians.

Response: We disagree with the commenters. All financial relationships between a DHS entity and a physician who refers Medicare patients to the entity for DHS must comply with the physician self-referral provisions. Contributions from a physician to a hospital are remuneration and must comply with an exception. Moreover, some ostensible charitable donations have been abusive. The current regulation adequately protects legitimate fundraising while imposing minimal restrictions.

K. Nonmonetary Compensation

In Phase I, using our authority under section 1877(b)(4) of the Act, we established a new regulatory exception to protect nonmonetary compensation provided to physicians up to $300 per year. Phase II provided that nonmonetary compensation that does not exceed $300 per year does not create a compensation arrangement if—

- The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician;
- The compensation is not solicited by the physician or the physician's practice; and
- The compensation arrangement does not violate the anti-kickback statute or other Federal or State law.

In addition, Phase II provided that the limit on the nonmonetary compensation would be adjusted for inflation to the nearest whole dollar effective January 1 of each calendar year using the increase in the Consumer Price Index-Urban All Items (CPI–U) for the 12-month period that ends the previous September 30. The nonmonetary compensation limit increased to $308 for CY–2005, $322 for CY–2006, and $329 for CY–2007. We display the increase in the CPI–U and these new limits on the physician self-referral Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp*.

This Phase III final rule makes two substantive changes to § 411.357(k): (1) The revised exception allows physicians to repay certain excess nonmonetary compensation within the same calendar year to preserve compliance with the exception; and (2) the revised exception allows entities, without regard to the dollar limitation in § 411.357(k)(1), to provide one medical staff appreciation function (such as a holiday party) for the entire medical staff per year. We are also clarifying that the aggregate limit in § 411.357(k)(1) is to be calculated on a calendar year basis.

Comment: Several commenters asked for clarification regarding the treatment under § 411.357(k) of specific activities. Two commenters believed that meals and reimbursement to physicians on a DHS entity's board should not count against the monetary limit, provided that the compensation is consistent with that provided to other non-physician board members. Other commenters asked that meals or other remuneration given to staff members for activities in connection with hospital business should not be subject to the limit. Examples provided by commenters included off-site meetings of the medical staff due to space constraints, assistance in recruiting, hospital leadership meetings, and other business meetings.

Response: We previously addressed the issues raised by these commenters in Phase II (69 FR 16113–16114). There, we said that, ''[w]hether a remunerative arrangement between specific parties would fit in an exception would depend on the particular facts and circumstances. For example, some dinners and meetings might fit in the exception for nonmonetary compensation [in] § 411.357(k) or the exception for fair market value compensation [in] § 411.357(l); others would not. Nothing in the statute precludes modest meals in connection with services provided by or to Boards of Trustees, Boards of Directors, or hospital administrators, and many of these activities can easily fit in an exception'' (69 FR 16114). We also noted that our regulations do not address every possible relationship between physicians and DHS entities of the type addressed by the commenter, nor could they. In some cases, relationships clearly will not involve a transfer of remuneration and thus will not trigger section 1877 of the Act. In others, an activity might involve the transfer of remuneration, and there may be no readily apparent exception. We expect that questions of the kind posed by the commenter will arise with some frequency. Parties may submit advisory opinion requests about specific arrangements according to § 411.370 (69 FR 16114).

Comment: One commenter sought clarification as to whether the dollar limit on nonmonetary compensation applied to the legal entity providing the compensation (such as a parent health system) or to the DHS entity. The commenter noted that some large systems could be hurt if the agency imposed aggregate limits, and suggested that the limit should be on each DHS provider.

Response: The limit applies to each DHS entity, and not to a parent health system. Remuneration provided by a parent health system to a referring physician could create an indirect compensation arrangement between the referring physician and the entity furnishing the DHS (for example, if the referring physician has a compensation relationship with the parent health system, which has an ownership interest in the DHS entity).

Comment: Two commenters asked that the cap be raised. One suggested $500 and the other $600.

Response: We believe that the limit ($329 in CY–2007) is appropriate. As explained above and in Phase II, we have indexed the amount so that it will increase to account for inflation (69 FR 16112).

Comment: One commenter stated that inadvertently exceeding the yearly dollar limit on nonmonetary compensation could lead to disastrous and uncertain results. The commenter asserted that the harsh result should be mitigated by permitting the excessive payment to be cured by the physician's repayment of the excess. The commenter stated that errors can occur through, among other things, erroneously valuing a benefit, not properly accounting for a benefit, or not being aware of a family relationship between a physician and another person (including another physician). Another commenter asserted that, by their nature, gifts of nonmonetary compensation are very difficult to account for in traditional accounting systems. Tracking of such benefits is usually a manual process, based on the submission of reports from department heads and other members of hospital management. In addition, once the hospital becomes aware of a benefit provided to physicians, it is sometimes faced with difficult questions of how to value the benefit and allocate it among the physicians.

Response: Hospitals and other DHS entities that wish to use the exception for nonmonetary compensation should take steps to ensure the implementation of effective compliance systems, including appropriate tracking and valuation mechanisms. DHS entities should not provide benefits to physicians about which the entities are unaware or for which they are unable to account. However, we are persuaded to mitigate the potentially serious consequences of exceeding the nonmonetary compensation limits where the violation is inadvertent and the value of the overage is limited. Therefore, we are adding new subparagraph (3) to § 411.357(k) to provide some protection against inadvertent violations. Under this new provision, nonmonetary compensation will be deemed to be within the limit set forth in § 411.357(k)(1) if the entity has inadvertently exceeded the limit by no more than 50 percent during a calendar year and the physician repays the excess compensation within the earlier of: (1) The end of the calendar year in which the excess nonmonetary compensation was received; or (2) 180 days from the date the excess nonmonetary compensation was received. For example, if an entity gave nonmonetary

compensation with a value of $250 to a physician on April 15 and then inadvertently made another gift, this time valued at $200, to the physician on August 15, the total nonmonetary compensation to the physician is $450, which is less than 150 percent of the amount allowed ($329 × 150 percent = $493.50). If the physician repays the excess of $121 ($450 − $329 = $121) by December 31, the entity continues to satisfy the requirements of the exception. An entity will not be allowed to use this new provision more than once every 3 calendar years with respect to the same physician. With respect to DHS referrals made by a physician after his or her receipt of excess nonmonetary compensation, any billing or claims submission by the entity for such referrals will not violate the prohibition in section 1877(a)(1)(B) of the Act, provided that the deeming provision set forth in § 411.357(k)(3) and the remaining conditions of the nonmonetary compensation exception are satisfied. Once a DHS entity becomes aware that it has provided to a physician excess nonmonetary compensation that could qualify for the deeming provision, it would be prudent for the DHS entity to delay any billing and claims submission for the physician's DHS referrals until after the physician has returned the nonmonetary compensation in accordance with § 411.357(k)(3).

Comment: One commenter stated that its physician relations department had routinely arranged occasional small services for physicians as tokens of appreciation. Events included free haircuts, manicures, massages, golf tournaments, and tickets to plays and sporting events. The commenter requested clarification concerning whether the cap on nonmonetary compensation applied to the hospital's cost of the item or the fair market value of the item to the physician. The commenter suggested that the exception exclude one-time annual events provided that the event is open to the entire medical staff or a specialty, the fair market value of the event is less than $200 per attendee, and that there are no more than three such events per year. In addition, the commenter believed that hospitals should be permitted to give any staff member a token of appreciation annually if the fair market value does not exceed $100 and the provision of the gift is not tied to referrals or other business generated between the parties.

Response: We believe that the limit on nonmonetary compensation per calendar year period is sufficient to provide for tokens of appreciation. We note that we do not agree that all of the items listed by the commenter are ''small.'' The cap under the nonmonetary compensation exception applies to the fair market value of the item, which is the amount the physician would have paid if he or she had purchased the item or service in a fair market value transaction. However, we believe that allowing one annual, local social event for the entire medical staff would not create a risk of program or patient abuse. (This is in addition to the nonmonetary compensation permitted under § 411.357(k).) Accordingly, we are modifying the exception in § 411.357(k) to permit hospitals and other entities with formal medical staffs to provide one local medical staff appreciation event per year open generally to all medical staff (that is, all physicians and other medical practitioners who order hospital services for patients). The entity's cost per medical staff member for such event will not be counted against the limit set forth in § 411.357(k)(1) (as adjusted under § 411.357(k)(2)). However, any gifts or gratuities provided in connection with the medical staff appreciation event (such as door prizes) would be subject to the limit in § 411.357(k)(1) (as adjusted under § 411.357(k)(2)).

L. Fair Market Value Compensation

In Phase I, we finalized an exception for fair market value compensation arrangements that was originally proposed in the January 1998 proposed rule (66 FR 917–919). The exception, which was promulgated using our authority under section 1877(b)(4) of the Act, protects compensation from a DHS entity to a physician, an immediate family member of a physician, or a group of physicians for the provision of items or services by the physician or group to the DHS entity, provided that, generally—

- The arrangement is set out in a writing that is signed by the parties and describes the items or services;
- The writing sets out the timeframe for the arrangement, subject to some restrictions;
- The writing specifies the compensation, which must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician;
- The arrangement is commercially reasonable and furthers the legitimate business purposes of the parties; and
- The arrangement does not violate the anti-kickback statute or involve the counseling or promotion of any business arrangement that violates Federal or State law. Phase II made no substantive changes to § 411.357(l). This Phase III final rule makes one substantive and one clarifying change to § 411.357(l). Specifically, and as discussed at section IX.I, we are amending the exception to provide that it may apply to compensation provided to a physician from an entity and to compensation provided to an entity from a physician. We are also clarifying that the exception is not applicable to leases for office space; rather, such lease arrangements must comply with § 411.357(a).

Comment: One commenter objected to our position that physician recruitment is not a service to the hospital and, therefore, cannot qualify under § 411.357(l), the fair market value compensation exception.

Response: We disagree with the commenter for the reasons stated in Phase II (69 FR 16096). There, we said that ''the physician's relocation is not properly viewed as a benefit to the hospital, except as a potential source of DHS referrals—a consideration that is antithetical to the premise of the statute.'' Money spent on recruitment of physicians who will not be employed by the hospital offering the recruitment incentives is essentially a contribution made for the benefit of the community and not a payment for services provided to the hospital. Therefore, recruitment incentives offered by hospitals must be structured to satisfy the requirements of the recruitment exception or another exception, such as the exception for *bona fide* employment relationships or obstetrical malpractice insurance subsidies.

Comment: One commenter objected to our position that a lease of office space cannot qualify for the fair market value compensation exception in § 411.357(l) because it is not an ''item.'' The commenter noted that elsewhere in Phase II, we stated that a space lease is an item or service when a physician is the lessee (69 FR 16111).

Response: In Phase II, we explained that we could not expand the exception to be as comprehensive as the commenters advocated without posing a risk of fraud or abuse (69 FR 16111–16112). We do not believe that the lease of office space is an ''item or service.'' Moreover, because space leases have been subject to abuse, we believe that the use of the fair market value compensation exception for space leases may pose a risk of program or patient abuse. Therefore, a space lease must qualify under the exception for the rental of office space in § 411.357(a), which contains more restrictive conditions. We have modified the

regulatory text in § 411.357(l) accordingly.

Comment: The same commenter asked us to provide bright-line guidance as to what is fair market value. The commenter recommended that there be a rebuttable presumption that a transaction is fair market value.

Response: The statute and regulations provide a definition of fair market value for purposes of section 1877 of the Act. The parties to a transaction or an arrangement are in the best position to ensure that the remuneration is at fair market value and to document it contemporaneously. If questioned by the government, the burden would be on the parties to explain how the transaction meets the fair market value compensation exception requirements. We are not adopting the suggestion that a transaction be presumed to be fair market value.

M. Medical Staff Incidental Benefits

In Phase I, we established a new exception in § 411.357(m) for medical staff incidental benefits (66 FR 920–922). This exception is limited to benefits, such as parking, cafeteria meals, and lab coats, that are customarily provided by a hospital to members of its medical staff and that are incidental to services being provided by the medical staff at the hospital.

In Phase II, we clarified that the exception is not intended to cover the provision of tangential, off-site benefits, such as restaurant dinners or theater tickets, which must comply with the exception for nonmonetary compensation in § 411.357(k) (69 FR 16112–16113). We also made other clarifications in § 411.357(m)(1) and (m)(2), and stated in § 411.357(m)(8) that certain institutional entities (such as long-term care facilities), federally qualified health centers, and other health care clinics, that have *bona fide* medical staffs are permitted to provide incidental benefits to those staffs on the same terms and conditions that apply to hospitals under the exception (69 FR 16112–16114). Phase II also provided that the $25 limit on the value of each medical staff incidental benefit would be adjusted in the same manner as the limit on nonmonetary compensation in § 411.357(k). The limit for each medical staff incidental benefit for purposes of § 411.357(m) increased to $26 for CY 2005, $27 for CY 2006, and $28 for CY 2007.

We are making no substantive changes to this exception in this Phase III final rule.

Comment: One commenter requested the elimination of the ''on campus'' requirement in § 411.357(m). According to the commenter, the limitation is not necessary because the exception already requires the physician to be on rounds or otherwise engaged in services or activities that benefit the hospital or its patients. Alternatively, the commenter suggested that we define campus as a hospital and all facilities owned or operated by the hospital.

Response: We disagree with the commenter. The ''on campus'' limitation is integral to the exception and an important safeguard against program and patient abuse. A hospital's campus includes all facilities operated by a hospital except for facilities that have been leased for non-hospital purposes and are not used exclusively by the hospital.

Comment: One commenter requested clarification as to whether a hospital may provide a physician with a device that is used to access patients who are at home or at work or personnel who are in locations other than the hospital campus.

Response: A hospital may not provide a device used to access patients who are at home or at work or personnel who are in locations other than the hospital campus under this exception. A hospital can provide a physician with a device that is used to access patients and personnel on the hospital's campus, even if the physician is not on the campus. In Phase II, we indicated that the exception (as revised in that rulemaking) covers dedicated pagers or two-way radios used to facilitate instant communication with physicians in emergency or other urgent patient care situations when they are away from the hospital campus (69 FR 16113). A physician may use the dedicated pager or two-way radio: (1) to contact the physician's patients (who are hospital patients) only when the patients are on the hospital's campus; or (2) to contact personnel only when the personnel are on the hospital campus. We note that some arrangements involving health information technology used for patients or personnel who are not on the hospital campus may qualify under the exception in § 411.357(u) for community-wide health information systems or the exceptions in § 411.357(v) and (w) for arrangements involving the provision of electronic prescribing technology and electronic health records technology, respectively.

Comment: One commenter noted that, whereas § 411.357(m) specifically provides that mere identification of medical staff on a hospital website or in hospital advertising is covered by the exception, the preamble to Phase II states that advertising or promoting a physician's private practice would not satisfy the requirements of the exception (69 FR 16113). The commenter asserted that it is unclear whether hospital physician referral services would be considered advertising or promotion of the physician. The commenter requested clarification that a hospital's physician referral service could qualify for the exception in § 411.357(m).

Response: A hospital's physician referral service may be considered a medical staff incidental benefit and qualify for the exception if all of the requirements of § 411.357(m) are satisfied. Whether a hospital's physician referral service would constitute advertising or promotion of a physician or his or her private practice would depend on the nature of the particular referral service; however, many typical referral services constitute advertising or promotional activity. We note that hospital referral services sometimes involve payments by physicians to the hospital that operates the referral service. These payments, which are often assessed based on the costs of operating the referral service, would need to satisfy the requirements of an exception. Moreover, these payments also potentially implicate the anti-kickback statute. The payments could be structured to satisfy the exception in § 411.357(q) for referral services, which protects remuneration that satisfies all of the conditions of the safe harbor for referral services in § 1001.952(f).

N. Risk-Sharing Arrangements

In Phase I, we created a new exception for remuneration made pursuant to a *bona fide* ''risk-sharing arrangement,'' out of concern about the impact of the January 1998 proposed rule on commercial and employer-provided managed care arrangements (66 FR 912). The risk-sharing arrangements exception in § 411.357(n) applies to compensation (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physician association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission. In Phase II, we responded to several comments on the new risk-sharing arrangements exception in § 411.357(n) but made no changes to the exception (69 FR 16114). We received no comments on this exception and are making no changes to § 411.357(n) in this Phase III final rule.

O. Compliance Training

In the Phase I rulemaking, we exercised our authority under section 1877(b)(4) of the Act to create an exception for compliance training provided by a hospital to physicians who practice in the hospital's local community or service area (66 FR 915, 921). In Phase II, we modified the exception to include compliance training provided to a physician or a physician's office staff by any DHS entity and explicitly included training addressing the requirements of any Federal, State or local law governing the activities of the party receiving the training (69 FR 16114–16115). The Phase II exception excludes any programs for which continuing medical education (CME) credit is available.

This Phase III final rule amends § 411.357(o) to permit compliance training programs that involve CME credit, provided that compliance training predominates.

Comment: Several commenters objected that, under Phase II, § 411.357(o) does not protect any compliance training that also qualifies for CME credit. According to the commenters, provided that the compliance training program qualifies under the exception, it should not matter whether a physician receives CME credit.

Response: We agree that, if a program offers CME credit for compliance training, such compliance training should nonetheless be able to satisfy the requirements of § 411.357(o). However, we are concerned that the exception not be used to protect CME programs that are only incidentally about or related to compliance training. For the reasons set forth in Phase I and Phase II, we are not prepared to except generally from the physician self-referral law CME programs funded by DHS entities. Programs offering CME credit, when provided to a referring physician, have substantial value to the physician, who is required to obtain such CME credit for State licensure purposes. We are also not prepared to except CME programs merely because they contain a compliance training component. Instead, we are revising the exception in § 411.357(o) to cover all training programs of which compliance training is the primary purpose, including any genuine compliance training program that happens to qualify for CME credit. The revised exception does not protect traditional CME content under the guise of ''compliance training.'' The exception may not be used for other programs that are not compliance training programs, regardless of whether such programs may also provide CME.

Comment: A commenter requested clarification that internet-based compliance training can qualify as local training. The commenter also noted that many small- and medium-sized communities lack the resources to provide specialized compliance training and should be permitted to provide reimbursement for a physician's reasonable out-of-pocket expenses to obtain training outside of the local community.

Response: Section 411.357(o) protects compliance training provided by an entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity's local community or service area, provided that the training is held in the local community or service area. With respect to on-line compliance training, if the physician (or the physician's immediate family member or office staff) accesses the on-line training while in a location that is in the entity's local community or service area, the compliance training would qualify for the exception in § 411.357(o), provided that all other requirements of the exception are satisfied. We disagree that an entity should be permitted to reimburse out-of-pocket expenses (such as travel expenses) for physicians to obtain training outside of the entity's local community or service area. We are not persuaded that permitting payment of such expenses does not create a risk of program or patient abuse.

P. Indirect Compensation Arrangements

In Phase I, we established a new exception for indirect compensation arrangements using our authority under section 1877(b)(4) of the Act (66 FR 865). Indirect compensation arrangements qualify for the exception if the following conditions are satisfied:

- The compensation received by the referring physician (or immediate family member) from the person or entity in the chain of financial relationships with which the referring physician (or immediate family member) has the direct financial relationship is fair market value for the items or services provided under the arrangement and does not take into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS;
- The compensation arrangement between the person or entity in the chain with which the referring physician (or immediate family member) has the direct financial relationship is set out in writing, signed by the parties, and specifies the items or services covered by the arrangement (in the case of a *bona fide* employment relationship, the arrangement need not be set out in a written contract, but it must be for identifiable services and be commercially reasonable even if no referrals are made to the employer); and
- The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission. (66 FR 867.)

Phase II made no substantive changes to the indirect compensation arrangements exception. This Phase III final rule similarly makes no changes to the exception.

We received a number of comments regarding § 411.357(p), the indirect compensation arrangements exception. Some commenters questioned how the indirect compensation arrangements exception applies in circumstances involving a compensation arrangement between a DHS entity and a group practice that employs or contracts with referring physicians. As discussed in section VI.B, we have revised § 411.354(c), which specifically addresses direct and indirect compensation arrangements between DHS entities and physicians. Under the revised rule, the relationship between the physician and his or her physician organization (as defined in this Phase III final rule at § 411.351) is disregarded and the physician ''stands in the shoes'' of his or her physician organization. The effect of this new provision is that many arrangements that would have constituted indirect compensation arrangements if analyzed under Phase I and Phase II are now deemed to be direct compensation arrangements, and the indirect compensation arrangements exception cannot be used. Moreover, under this Phase III final rule, many arrangements that may not have met the definition of an ''indirect compensation arrangement'' under the Phase I and Phase II analysis will constitute direct compensation arrangements that must satisfy the requirements of an exception in order for the physician to make DHS referrals to the entity furnishing DHS. As discussed above in section VI, the ''stand in the shoes'' provisions in § 411.354(c) are applicable as of the effective date of this Phase III final rule. However, arrangements that satisfied the Phase II definition of ''indirect compensation arrangement'' and the requirements of § 411.357(p) as of the *publication* date of this final rule need not be amended during the original or current renewal term of the arrangement to comply with the Phase III final regulations.

Comment: One commenter stated that the indirect compensation arrangements exception was difficult to apply because the DHS entity had no ready ability to monitor or assess the basis of payment being made by the intervening entity to the physician. The commenter suggested that we expand the exception by adding an alternative whereby the arrangement would be protected if: (1) The direct payment made by the DHS entity to the intervening entity complies with an exception; (2) the physician provides a written representation that his or her compensation from the intervening entity is not based on referrals; and (3) the DHS entity has no actual knowledge of the falsity of the representation. Another commenter stated that the exception was unfair to hospitals and other DHS entities because compliance turns on the physician's compensation arrangement with the intervening entity, and hospitals have no control over those compensation arrangements.

Response: We believe that the new ''stand in the shoes'' provision will substantially address the commenters' concerns. Under that provision, many arrangements will use direct compensation arrangements exceptions (for example, personal service arrangements, fair market value compensation, office space rental, or equipment rental) rather than the indirect compensation arrangements exception in § 411.357(p). We perceive no unfairness to DHS entities, because the definition of an ''indirect compensation arrangement'' includes a knowledge element.

Comment: Several commenters requested confirmation that, if there exists an indirect compensation arrangement involving a hospital and a physician in the group practice and the arrangement qualifies for the indirect compensation arrangements exception, the direct compensation arrangement between the hospital and the group practice would not also have to satisfy the requirements of a direct compensation arrangements exception, such as those for the rental of office space or personal service arrangements. The commenters noted that the indirect compensation arrangements exception was considerably more flexible because, for example, the arrangement could be amended at any time.

Other commenters wanted clarification that, in an identical situation (that is, a chain of financial relationships involving a hospital and a group practice and the group practice's physicians), referrals by the physicians to the hospital would be protected, provided that the financial relationship between the hospital and the group practice complied with one of the direct compensation arrangements exceptions. One commenter requested confirmation that, whenever a direct or indirect compensation arrangements exception is applicable, the parties would be protected from the referral prohibition provided that they complied with any one of the potentially applicable exceptions.

Response: As noted above, the new ''stand in the shoes'' provision should address many of these commenters' concerns. Under this final rule, physicians ''stand in the shoes'' of physician organizations, including group practices. This means that, in the case of a chain of financial relationships involving a hospital, a group practice, and the group practice's physicians, the physicians ''stand in the shoes'' of their group and the financial relationship at issue is the direct relationship between the hospital and the group practice. The direct relationship could satisfy the requirements of any applicable direct compensation arrangements exception. The indirect compensation arrangements exception would not apply.

Where, after applying the ''stand in the shoes'' provision, an arrangement still meets the definition of an indirect compensation arrangement in § 411.354(c)(2) (for example, a chain of financial relationships involving a hospital, a leasing company, and a physician), the only available exception is the indirect compensation arrangements exception. As we explained in Phase I and Phase II, indirect compensation arrangements cannot fit in any of the direct compensation arrangements exceptions; the only available exception for an arrangement that meets the definition of an ''indirect compensation arrangement'' is the indirect compensation arrangements exception (66 FR 866–867, 69 FR 16060–16061). To satisfy the requirements of the indirect compensation arrangements exception, it is not necessary for each link in the chain of financial relationships to also satisfy the requirements of a separate exception. Consistent with the statutory scheme, the only financial relationship that triggers liability under section 1877 of the Act is the financial relationship between the DHS entity and the referring physician. (66 FR 864.)

Comment: Two commenters asked for confirmation that a contract based on a percentage of collections can satisfy the requirement in the indirect compensation arrangements exception that the compensation be fair market value and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the DHS entity. The commenter gave the example of a hospital contracting for outpatient radiology with a joint venture owned by the hospital and physicians, and basing payment on a percentage of collections. This commenter stated that, because the hospital is billing and collecting payment for the services, it is the entity furnishing DHS for purposes of the physician self-referral law. This commenter noted that, in Phase II, we acknowledged that the position we took in Phase I on percentage compensation arrangements was overly restrictive and that we amended § 411.354(d)(1) to permit percentage compensation arrangements under certain conditions (69 FR 16068). The commenter stated that, if the percentage compensation arrangement is at fair market value and is not inflated to compensate for the generation of business, the parties should be entitled to rely on the indirect compensation arrangements exception for the transaction described.

Response: The discussion in Phase II regarding percentage compensation arrangements and the modification to § 411.354(d)(1) pertained to the ''set in advance'' requirement that is contained in certain exceptions, but not in the indirect compensation arrangements exception. The joint venture relationship between the hospital and the physicians creates an indirect compensation arrangement between the hospital and the physicians that must satisfy the requirements of an exception. A percentage contract as described by the commenter will cause the arrangement to fall outside the indirect compensation arrangements exception if the return to the physician from the radiology joint venture takes into account in any manner the physician's referrals to the hospital (whether or not these referrals involve services provided by the joint venture). Moreover, a second indirect compensation arrangement exists between the hospital and the physicians, created by virtue of the ownership interest that does not meet an ownership exception (which, thus, creates a compensation arrangement), in the chain of relationships that runs: hospital—radiology venture—physicians. This arrangement would also need to satisfy the requirements of the indirect compensation arrangements exception. With respect to the second indirect compensation arrangement, the inquiry would be whether the compensation

under the percentage contract between the hospital and the radiology venture (the compensation arrangement nearest the referring physician) is fair market value not taking into account in any manner the volume or value of referrals or other business generated by the referring physician. We note that the indirect compensation arrangements exception requires that the compensation ''*received*'' by the referring physician (or immediate family member) is fair market value for services and items provided. A compensation arrangement based on a percentage of collections may not, depending on how the actual collections progress, result in fair market value received by the referring physician (or immediate family member).

Comment: Two commenters requested clarification regarding the potential application of the indirect compensation arrangements exception to medical foundations. One of the commenters noted that, whereas the agency had suggested that the personal service arrangements exception was available, most medical foundations contract with a physician group, thereby creating an indirect financial relationship between the foundation and the physicians. The commenter asked whether a group: (1) That received a percentage of collections from the foundation; (2) in which the physicians were both employees and shareholders; and (3) that compensated physicians based on RVUs and quality measures, would qualify under the indirect compensation arrangements exception.

Response: The new stand in the shoes provision should address the commenters' concerns. Physicians will stand in the shoes of their group practices. Thus, in the example given by the commenter, the arrangement between the medical foundation (as DHS entity) and the referring physicians would be treated as a direct compensation arrangement (rather than an indirect compensation arrangement) and the personal service arrangements exception would apply, provided that all conditions of the exception are satisfied. In section VI.C, we addressed the treatment of percentage compensation in exceptions, such as the personal service arrangements exception, that include the ''set in advance'' requirement. (If, by way of example, the hospital were to contract with a medical foundation for services provided to the hospital by the physician group with which the foundation contracts, the arrangement created between the hospital and the group physicians would be an indirect compensation arrangement that would need to satisfy the requirements of the indirect compensation arrangements exception. The physicians would stand in the shoes of their group practice, but not in the shoes of the foundation.)

Comment: One commenter asked whether a DHS entity that intentionally restructures an unprotected direct compensation arrangement to form a protected indirect compensation arrangement is engaging in a prohibited circumvention scheme under section 1877(g)(4) of the Act. The commenter described a situation in which a hospital elects to contract with an intervening entity for the medical director services of a physician rather than contract with the physician directly.

Response: Under the physician self-referral law, all financial relationships between DHS entities and referring physicians must be structured to satisfy the requirements of an exception. Restructuring an arrangement that does not meet a direct compensation arrangements exception so that it complies with the indirect compensation arrangements exception is not *per se* prohibited. Whether the restructuring of an arrangement constitutes a prohibited circumvention scheme under section 1877(g)(4) of the Act would depend on the specific facts and circumstances. The commenter has not clearly identified a set of specific circumstances sufficient for us to judge whether a circumvention scheme exists.

Q. Referral Services

In the Phase I rulemaking, we solicited comments on creating exceptions to the physician self-referral prohibition for arrangements that fit squarely in an anti-kickback statute ''safe harbor'' in § 1001.952 (66 FR 863). In Phase II, we created two new compensation exceptions for arrangements that fit in the anti-kickback safe harbors for referral services (§ 411.357(q)) and obstetrical malpractice insurance subsidies (§ 411.357(r)) (69 FR 16115). We received no comments on § 411.357(q) and this Phase III final rule makes no changes to the exception in § 411.355(q) for referral services.

R. Obstetrical Malpractice Insurance Subsidies

As discussed above in section IX.Q, we created a new exception in Phase II for compensation arrangements that fit in the anti-kickback safe harbor for obstetrical malpractice insurance subsidies (§ 411.357(r)) (69 FR 16115). This Phase III final rule makes no changes to the exception in § 411.357(r).

Comment: One commenter suggested that we permit the fair market value compensation exception in § 411.357(l) to be used for additional malpractice insurance assistance for medical staff.

Response: We see no reason why the fair market value compensation exception in § 411.357(l) cannot be used to offer medical staff assistance with malpractice insurance, provided that the value of the assistance is fair market value for services actually provided by the staff and the other requirements of the exception are satisfied.

Comment: Several commenters complained that the exception for malpractice insurance subsidies is too narrow and the limitation to health professional shortage areas (HPSAs) should be expanded to include all specialties and hospitals. One commenter urged us to revise the exception to include non-HPSA areas where at least 50 percent of the deliveries come from patients who reside in a HPSA. The commenters urged us to consult with the OIG and to develop a broader exception. Another commenter suggested that hospitals should be permitted to provide assistance if there is a community need.

Response: The exception in § 411.357(r) is one of several exceptions that allow DHS entities to provide assistance with malpractice insurance. Other exceptions that permit DHS entities to provide such assistance are the fair market value compensation exception (as discussed above in response to the previous comment) in § 411.357(l), the exception for *bona fide* employment relationships in § 411.357(c), and the exception for personal service arrangements in § 411.357(d) (provided that the value of the assistance is commensurate with the value of actual services furnished to the hospital by the physician). These exceptions allow any DHS entity to provide assistance with malpractice insurance, without regard to the specialty of the physician or the area in which the physician practices. The exception in § 411.357(r), on the other hand, is intended to mirror the anti-kickback safe harbor for malpractice insurance in § 1001.952(o). The OIG has not issued any guidance of general application that is broader than this exception and safe harbor. Finally, apart from the availability of other exceptions, we do not believe that it is advisable to relax the criteria of § 411.357(r) where a ''community need'' is present, because ''community need'' is too ambiguous a standard and does not, by itself, eliminate the potential for program or patient abuse. We note that, in the CY 2008 Physician Fee Schedule notice of

proposed rulemaking, we proposed to amend the exception in § 411.357(r) to remove the incorporation of the safe harbor for malpractice insurance in § 1001.952(o) and to include more flexible criteria.

Comment: One commenter asserted that we did not have the authority to create exceptions that were limited to specific geographic areas, for example, limiting the malpractice insurance subsidies exception to physician practices in HPSAs.

Response: Section 1877(b)(4) of the Act allows us to create additional exceptions to the general prohibition on physician self-referral where doing so would not result in a risk of program or patient abuse. It does not require us, where we exercise such authority, to make the additional exceptions available to all types of entities and physicians, or make them applicable in all areas. The Congress and CMS have long recognized the special needs and character of rural, urban, and underserved areas. Malpractice insurance availability in HPSAs poses specific concerns not present in other areas and supports a targeted exception.

S. Professional Courtesy

In Phase II, we established a new compensation arrangements exception (§ 411.357(s)) for professional courtesy provided to a physician or his or her immediate family members (69 FR 16116). We defined ''professional courtesy'' at § 411.351 as the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff. To qualify for the new exception, the arrangement must meet the following conditions (69 FR 16116)—

- The professional courtesy is offered to all physicians on the entitys *bona fide* medical staff or in the entitys local community without regard to the volume or value of referrals or other business generated between the parties;
- The health care items and services provided are of a type routinely provided by the entity;
- The entity's professional courtesy policy is set out in writing and approved in advance by the governing body of the health care entity;
- The professional courtesy is not offered to any physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need;
- If the professional courtesy involves any complete or partial waiver of any coinsurance obligation, the insurer is informed in writing of the reduction so that the insurer is aware of the arrangement; and
- The professional courtesy arrangement does not violate the anti-kickback statute or any billing or claims submission laws or regulations.

This Phase III final rule makes one substantive change to § 411.357(s), deleting the requirement that an entity notify an insurer when the professional courtesy involves the whole or partial reduction of any coinsurance obligation. We have also modified the exception to make clear our intent that § 411.357(s) applies only to hospitals and other providers with formal medical staffs.

Comment: A commenter noted that one of the conditions of the exception is that the arrangement does not violate the anti-kickback statute. The commenter questioned whether, given the 1994 OIG Special Fraud Alert, clinical laboratories would be prohibited from offering professional courtesy, notwithstanding that the actual language of § 411.357(s) does not exclude any specific type of entity or services and, therefore, appears applicable to clinical laboratory services. The commenter stated that, unlike the situation in which one physician extends professional courtesy to another physician, when a laboratory offers professional courtesy to a physician, it does not expect the same in return, a fact that makes kickback issues more significant. The commenter suggested that we clarify that the 1994 OIG Special Fraud Alert continues to be applicable to the provision of professional courtesy by all laboratories, including hospital outreach laboratories. The commenter also stated that, to the extent that the exception permits a hospital to offer professional courtesy only to physicians on its medical staff, instead of to all physicians in its local community or service area, the exception creates an inducement for referrals to the hospital.

Response: Nothing in these regulations affects in any respect the application of the OIG's guidance regarding the anti-kickback statute. We conclude from the comment that some clarification may be helpful with respect to the scope of the exception. The exception was promulgated in response to comments requesting an exception for providers that offer certain professional courtesy to physicians and their family members. We are clarifying the regulatory language to state specifically that the professional courtesy exception applies only to DHS entities with formal medical staffs. The exception does not apply to suppliers, such as laboratories or DME companies. The traditional reasons for professional courtesy provided by entities with medical staffs do not pertain to suppliers and such ''courtesy'' offered by suppliers would pose a risk of program abuse.

We believe that the exception contains sufficient safeguards to protect against abuse. In particular, we note that:

- Professional courtesy must be extended to all members of the *bona fide* medical staff (or in such entity's local community or service area) without regard to the volume or value of referrals (thus prohibiting expensive courtesy for high-referring physicians and only less costly courtesy for low-referring physicians);
- The entity's professional courtesy policy must be set out in writing and approved in advance by the entity's governing body; and
- The arrangement must not violate the anti-kickback statute.

Based on a comment received in response to Phase II, we are concerned that the current § 411.357(s)(3) may be misinterpreted as meaning that the requirements of the exception apply only if an entity, *in fact*, has a written policy regarding professional courtesy (that is, if an entity's policy is not reduced to writing, the entity need not comply with the requirements of the exception at all). Therefore, we are amending § 411.357(s)(3) to clarify that, as a prerequisite to extending professional courtesy, the entity *must* have a written policy that is approved by the entity's governing body.

Comment: Two commenters objected to limits placed on physicians extending professional courtesy. One commenter requested that we revise the regulation so as not to prohibit the longstanding practice of professional courtesy, including physician-to-physician professional courtesy. Another commenter approved of the exception generally, but objected to the restriction requiring the courtesy to be extended either to the entire medical staff or to all physicians in the community. This commenter requested that a hospital be able to extend the courtesy on the same terms as medical staff incidental benefits; that is, for example, to members of the medical staff practicing in the same specialty rather than to the entire medical staff.

Response: With respect to the first comment, physician-to-physician professional courtesy is unlikely to need a separate exception, unless the recipient physician is a source of DHS referrals to the physician (or physician practice) extending the courtesy. We believe the more typical situation would involve a group practice offering professional courtesy to its physicians

and their families. The in-office ancillary services exception would be available in such situations. Moreover, for purposes of the professional courtesy exception, we consider a group or other physician practice to be an entity with a formal medical staff that could use the exception, if all of the requirements of the exception were satisfied.

Second, we do not agree that a hospital, or other entity with a formal medical staff, should be allowed under the exception to extend professional courtesy only to certain members of its medical staff. The selective provision of professional courtesy to a physician gives rise to an inference that the recipient of the courtesy may have been chosen in a manner that took into account the volume or value of referrals from the recipient (or his or her family member or employer-physician) to the physician providing the professional courtesy or other business generated between the parties.

Comment: One commenter sought clarification as to the applicability of the exception to DHS entities that did not have medical staffs.

Response: The exception would not apply to such entities, for the reasons noted above. We are clarifying the regulatory text in § 411.357(s).

Comment: One commenter asked for clarification as to which Federal health care programs are referred to in § 411.357(s)(4) and how to document financial need.

Response: For purposes of the exception, the Federal health care programs are all Federal health care programs as defined at section 1128B(e) of the Act (69 FR 16115–16116). The determination and documentation of financial need should be reasonable, consistent, and contemporaneous.

Comment: Two commenters objected to the requirement that a hospital notify the insurer if any coinsurance obligation is waived in whole or in part. According to the commenters, the requirement is unreasonable and serves no purpose. The commenters requested that the condition be deleted.

Response: We agree that, in order to eliminate the risk of program or patient abuse, our standard under section 1877(b)(4) of the Act, we do not have to require a hospital or other DHS entity to notify a private insurer if it intends to waive in whole, or in part, any coinsurance obligation of the insurer's beneficiary. We are deleting the notification provision. Nonetheless, we believe that it would be a prudent practice for DHS entities to provide such notification; in fact, insurers may require such notification.

T. Retention Payments in Underserved Areas

In Phase II, in accordance with our authority under section 1877(b)(4) of the Act, we created a new exception for retention payments made to a physician by a hospital or federally qualified health center located in a HPSA (regardless of whether the HPSA is specifically designated for the physician's particular specialty) (69 FR 16097). In order to qualify for the exception under Phase II, the following conditions must be met—

- The physician must have a *bona fide* firm, written recruitment offer from a hospital or federally qualified health center that is not related to the hospital or the federally qualified health center making the payment, and the offer specifies the remuneration being offered;
- The offer must require the physician to move the location of his or her practice at least 25 miles *and* outside of the geographic area served by the hospital or federally qualified health center making the retention payment;
- The retention payment must be limited to the lower of: (1) The amount obtained by subtracting the physician's current income from physician and related services from the income the physician would receive from comparable physician and related services in the *bona fide* recruitment offer (provided that the respective incomes are determined using a reasonable and consistent methodology and that they are calculated uniformly over no more than a 24-month period); or (2) the reasonable costs the hospital or federally qualified health center would otherwise have to expend to recruit a new physician to the geographic area served by the hospital or federally qualified health center in order to join the medical staff of the hospital or federally qualified health center to replace the retained physician;
- Any retention payment must be subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the *bona fide* recruitment offer;
- The amount and terms of the retention payment may not be altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician;
- The requirements of § 411.357(e)(1)(i)–(iv), relating to physician recruitment arrangements, must be satisfied; and
- The arrangement must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

The exception in § 411.357(t) requires that retention payments be made directly from the hospital or federally qualified health center to the retained physician. A hospital or federally qualified health center may not enter into a retention payment arrangement with a physician more frequently than once every 5 years. Also, Phase II provided for approval of retention payments to physicians practicing in other underserved areas (or to physicians serving underserved patient populations), as determined on a case by case basis through an advisory opinion.

As discussed below, we are modifying § 411.357(t) in several respects, including expanding the exception by permitting (under certain circumstances) retention payments in the absence of a written recruitment offer, by adding flexibility for retention payments to physicians who serve underserved areas and populations, and by allowing rural health clinics to make retention payments. In addition, retention payments may be made on the basis of a written offer of employment as well as a *bona fide* firm, written recruitment offer.

Comment: A commenter that is the only hospital providing labor and delivery services for its county and the 100,000 people who reside in its service area requested modifications to the exception. The commenter believed that the exception should not be limited to retention payments in HPSAs or other underserved areas. According to the commenter, in 2003, the five obstetricians who were delivering babies at the hospital received an offer from an academic medical center located 30 miles away. Under the terms of the offer, the academic medical center would have provided through its captive insurance company malpractice insurance that was much less expensive than the insurance the obstetricians then carried. The commenter stated that the academic medical center required that the obstetricians perform their deliveries in a community hospital in a neighboring county with which the academic medical center was affiliated. The commenter wrote that its attorneys advised the hospital that the physician self-referral regulations prohibited it from countering the academic medical center's offer because the commenter's hospital is not located in a HPSA. The commenter proposed two alternative modifications to the retention exception: (1) Permit tax-exempt organizations to make retention payments if the payments would not constitute an improper private benefit or an excess benefit transaction under

applicable IRS principles; or (2) replace the HPSA requirement in both the retention exception and the obstetrical malpractice insurance subsidies exception with a super-majority board approval requirement.

Response: We intend for the retention payments exception to be limited to those areas in which there is a demonstrated shortage of physicians, and where special efforts are often necessary to attract and maintain physicians. As noted below, we are expanding the exception to permit retention payments where the physician's *current medical practice* is in a rural area or HPSA, or where at least 75 percent of the physician's patients either reside in a medically underserved area or are members of a medically underserved population.

With respect to the suggested modifications to the exception, we believe that they are too broad and subject to abuse. Compliance with the IRS excess benefit and private benefit rules, or securing a super-majority vote of the governing board, does not ensure that the physician is needed or cannot easily be replaced. Neither proposed modification necessarily would prevent retention payments from being abused to reward high referring physicians.

Comment: A number of commenters requested that we eliminate the requirement in § 411.357(t)(1)(iii) of a written offer. According to the commenters, many offers are not in writing until agreement is imminent, at which point it is too late for the hospital to retain the physician. Other commenters believed that the requirement for a written offer encourages physicians both to solicit offers, and to engage in insincere negotiations with others. One commenter believed that an entity should be able to offer retention payments provided it has a good faith belief that a physician may be recruited by another entity.

Response: We are revising § 411.357(t) to permit a hospital, rural health clinic, or federally qualified health center to offer assistance to a physician who does not have a *bona fide* written offer of recruitment or employment if the physician certifies in writing to the hospital, rural health clinic, or federally qualified health center that, among other things, he or she has a *bona fide* opportunity for future employment by a hospital, academic medical center, or physician organization that would require relocation of his or her medical practice at least 25 miles to a location outside of the geographic area served by the hospital, rural health clinic, or federally qualified health center. Revised § 411.357(t) also requires the physician to certify in writing: details regarding the steps taken by the physician to effectuate the employment opportunity; details of the physician's employment opportunity, including the identity and location of the physician's future employer and/or employment location, and the physician's anticipated income and benefits (or a range for income and benefits); that the future employer is not related to the hospital, rural health clinic, or federally qualified health center making the payment; the date on which the physician anticipates relocating his or her medical practice; and information sufficient for the hospital, rural health clinic, or federally qualified health center to verify the information included in the written certification. The hospital, rural health clinic, or federally qualified health center must take reasonable steps to verify the information in the certification.

In circumstances in which the retained physician provides a written certification to the hospital (or rural health clinic or federally qualified health center) rather than a *bona fide* written offer of recruitment or employment, the retention payment may not exceed the lower of the following: (1) an amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months) using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital in order to join the medical staff of the hospital to replace the retained physician. Where the physician has a written offer, the hospital may match the written offer, as provided in § 411.357(t)(1). (We note that the exception for retention payments applies to federally qualified health centers and rural health clinics in the same manner as it applies to hospitals.)

Comment: Several commenters asked that we broaden the exception to allow facilities in any medically underserved area to offer retention payments. Two commenters asked for clarification regarding whether the entity paying the retention payment must be located in an area of demonstrated need or whether the physician's patients must live in the area of demonstrated need. The commenters stated that the latter should be the test. For example, a hospital should be permitted to offer retention payments to keep a physician in an outreach area that is underserved. Another commenter urged that the exception be made available to rural health clinics.

Response: We agree generally with the comments and are expanding the exception in § 411.357(t) to permit retention payments that otherwise satisfy all of the conditions of the exception when: (1) the physician's current medical practice is located in a rural area, a HPSA, or an area of demonstrated need as determined by the Secretary in an advisory opinion issued under section 1877(g)(6) of the Act; or (2) at least 75 percent of the physician's patients either reside in a medically underserved area or are members of a medically underserved population. The location of the hospital in a HPSA is no longer a requirement of the exception. A retention payment may be made to a physician whose current medical practice is located in a HPSA, regardless of whether the HPSA has been designated for physicians in the retained physician's specialty. Further, we are also permitting retention payments to be made by rural health clinics under the same terms and conditions that apply to hospitals and federally qualified health centers. The purpose of this exception is to retain the physician's practice in a rural or underserved area.

Comment: Two commenters questioned why the exception requires a retention payment to be contingent on an offer from a hospital. According to the commenters, any offer of employment, including an offer from a group practice, should be sufficient.

Response: We agree and have modified the regulatory text in § 411.357(t)(1) to allow retention payments if a physician has a written offer from a hospital, academic medical center, or physician organization (as defined in this Phase III final rule at § 411.351) that is not related to the hospital, rural health clinic, or federally qualified health center making the retention payment. We have included a similar provision in new § 411.357(t)(2) related to the certification of an employment opportunity for which no written offer has been received.

Comment: In light of the prohibition against entering into a retention payment arrangement with the same physician more frequently than once every 5 years, several commenters objected to the provision requiring that retention payments be limited to the difference between the compensation set forth in the recruitment offer and the physician's current annual income averaged over a 24-month period. According to the commenters, the net effect is to make the retention payment offer non-competitive. Another

commenter asked whether an offer that is for a smaller amount than the difference over a 24-month period would qualify for the exception.

Response: We are not persuaded to revise the regulation to permit the hospital, rural health clinic, or federally qualified health center to make a retention payment that would match the physician's compensation specified in the recruitment offer (or offer of employment), irrespective of the period of the recruitment offer. Under our present rule, we allow entities to make a retention payment that takes into account the difference between what the physician earns in his or her current position and what the physician would earn if he or she accepted the recruitment offer, for a period of up to 24 months. For example, if a physician's monthly total compensation package in his or her current position is $13,000, and he or she has a *bona fide* written recruitment offer that would, over the next 36 months, provide the physician with total monthly compensation of $15,000, we would allow an entity to make a retention payment of up to $48,000 (24 months (the maximum number of months permitted) × $2000). We believe that allowing a retention payment that takes into account the difference between what the physician earns in his or her current position and what the physician would earn if he or she accepted the recruitment offer (or offer of employment) may create a potential for abuse if that payment is calculated over a period greater than 24 months. An entity is always free to offer a lesser amount. For clarity, we have amended the language in § 411.357(t)(1)(iv) that stated the retention payment ''is limited to the lower of'' to ''does not exceed the lower of.''

Comment: A hospital trade association objected to the provisions limiting the total retention payment to an existing physician to the costs of recruiting a new physician. The commenter believed that the restriction would require hospitals to limit their retention offers to the costs of a newly practicing physician. The commenter contended that hospitals should be permitted to take into account the physician's experience, training, and length of service in the area. Other commenters asked for confirmation that, in determining the costs of a replacement, a hospital could include all costs, both direct and indirect.

Response: We did not intend to limit the amount of a retention payment to the amount that it would cost to recruit a newly practicing physician in the same specialty to the same geographic area. Hospitals, rural health clinics, and federally qualified health centers may take into account experience, training, and length of service in the area. Both direct and indirect costs of a replacement can be included, provided that they are actual costs.

Comment: Two commenters asked whether a hospital could make retention payments to a group practice, rather than to the physician directly. One of these commenters noted that the physician recruitment exception in § 411.357(e) permits remuneration to be paid to the group on behalf of the physician.

Response: We do not believe that it is appropriate for the payment to be made to the group practice because the hospital, rural health clinic, or federally qualified health center should not be subsidizing expenses of the group practice through the retention payment. The purpose of the retention payment exception is to allow hospitals, rural health clinics, and federally qualified health centers to retain the physician receiving the retention payment in the facility's service area. We note that a written or other offer of employment by a local group practice with whom the physician is affiliated would not qualify for this exception. We note further that the commenter misunderstands the recruitment exception, which does not protect remuneration provided to a group practice. It protects remuneration provided directly or indirectly to a recruited physician, some part of which may pass through a group practice subject to specific conditions.

Comment: Several commenters complained that the exception did not permit hospitals to provide malpractice insurance assistance to physicians on their medical staffs facing exorbitant increases in their premiums.

Response: As noted in section IX.R of this preamble (in response to a comment on the exception for obstetrical malpractice insurance subsidies), there are several exceptions available to entities that wish to provide assistance with malpractice insurance. Moreover, we do not believe it is accurate to say that the retention payment exception does not permit assistance for malpractice insurance premiums. Remuneration in the form of a retention payment paid by an entity to a physician may be applied by the physician to malpractice insurance premiums.

Comment: One commenter questioned whether an arrangement that fully complies with the retention payments exception in § 411.357(t) at the time that it is entered into will be considered out of compliance if the HPSA designation is lost before the arrangement expires. Specifically, the commenter wanted to know whether a retention payment arrangement would be out of compliance after all payments have been made, but the physician remains under a community service obligation at the time of the HPSA redesignation.

Response: We have amended § 411.357(t)(3) to permit the payment of a retention payment to a physician whose current medical practice is in a rural area or a HPSA, or to a physician when 75 percent of his or her patients reside in a medically underserved area or are members of a medically underserved population. It is likely that a retention payment made by a hospital to a physician whose practice location was within an area that formerly was designated as a HPSA would satisfy one of the new, more flexible requirements in § 411.357(t)(3). Retention payments may be made only if the arrangement meets the conditions of the amended exception; however, a retention agreement may remain in compliance despite a continuing community service obligation (provided no additional retention payments are made) even if the HPSA designation was changed. We note that, under Phase II, the *entire* geographic area served by the hospital need not be located in a HPSA.

Comment: One commenter asked for clarification of the term ''relocation requirement'' in the Phase II regulation text in § 411.357(t)(2). According to the commenter, it is unclear from this provision as to whether the Secretary has the authority to waive the requirement that the physician receive a *bona fide* written offer from a facility to which the physician intends to relocate, or whether the Secretary has the authority to waive the requirement that the *bona fide* written offer would require the physician to relocate his practice at least 25 miles from its present location and outside the geographic area served by the entity that would make the retention payment, or both.

Response: The term ''relocation requirement'' refers to the requirement that the bona fide written offer requires the physician to relocate his or her practice at least 25 miles from its present location to a location outside the geographic area served by the hospital that would make the retention payment.

Comment: One commenter stated that the advisory opinion alternative in the exception in § 411.357(t)(2) is unworkable because the process takes too long and has an uncertain result. The commenter asserted that a physician would not delay his or her

decision to relocate his or her practice pending the receipt of a favorable advisory opinion. Moreover, according to the commenter, the availability of an advisory opinion has limited utility because only the relocation requirement in § 411.357(t)(1) may be waived by the Secretary. The commenter suggested that CMS should be given more latitude through the advisory opinion process to approve retention payment agreements.

Response: The advisory opinion process is the vehicle for CMS to use in determining whether the relocation requirement in this exception will be waived for a particular retention payment arrangement. We believe that the modifications to § 411.357(t) may alleviate many of the commenter's concerns regarding a hospital's ability to offer a retention payment to a physician in a manner timely enough to affect the physician's decision to relocate out of the hospital's geographic service area. With respect to the commenter's suggestion that CMS be given more latitude to approve retention payment agreements, we are not convinced that additional changes to this exception would pose no risk of program abuse.

U. Community-Wide Health Information System

In Phase II, using our authority under section 1877(b)(4) of the Act, we created a new exception for community-wide health information systems (69 FR 16113). If certain conditions are met, § 411.357(u) permits compensation in the form of items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health. We are making no changes to this exception.

Comment: We received 13 comments regarding the community-wide health information system exception, all of which supported the new exception in § 411.357(u). Several commenters recommended further clarification of the definition of a ''community'' and of ''community-wide health information system.'' Several commenters recommended that hospitals be allowed to provide to physicians items and services needed for non-clinical functions. Commenters also raised questions about patient access and whether physicians may be charged to use a system. Several commenters suggested that hospitals be able to provide access to health information to physicians only, rather than all residents of the community. Two commenters urged that ''maximum flexibility'' be allowed. A few commenters recommended that interoperability should be encouraged.

Response: Subsequent to the receipt of the public comments, on October 11, 2005, we published a notice of proposed rulemaking creating an exception for electronic prescribing technology as required by section 101 of the MMA (70 FR 59182). In addition, in that same notice, using our authority under section 1877(b)(4) of the Act, we proposed an exception for electronic health records software and information technology and training services. After taking into account public comments, on August 8, 2006, we published a final rule promulgating these two exceptions (71 FR 45140). The exception for electronic prescribing items and services appears in § 411.357(v) and the exception for electronic health records software and information technology and training services appears in § 411.357(w). We are republishing both exceptions with nonsubstantive technical changes in this Phase III final rule. In addition to requiring compliance with criteria designed to safeguard against program and patient abuse, both exceptions provide that neither the donor nor any person on the donor's behalf may take any action to limit or restrict the use, compatibility or interoperability of the items or services. The electronic health records exception in § 411.357(w) requires interoperability at the time the remuneration is provided to the physician. Neither exception requires community-wide application.

At this time, we are not making any changes to, or issuing any further guidance concerning, the community-wide health information systems exception while we observe how the new exceptions for electronic prescribing and electronic health records technology in § 411.357 (v) and (w), respectively, are received. We are continuing to consider the issues that commenters raised and, if appropriate, we will issue clarifications and changes in a future rulemaking.

X. Reporting Requirements—§ 411.361

Section 1877(f) of the Act sets forth certain reporting requirements for all entities providing covered items or services for which payment may be made under Medicare. The required information must be provided in a form, manner, and at such times that the Secretary specifies. Section 1877(g)(5) of the Act provides that any person who is required, but fails, to meet one of these reporting requirements is subject to a civil money penalty of not more than $10,000 for each day for which reporting is required to have been made.

Section 411.361 of our regulations, as modified in Phase II, states that the information that we may require to be furnished can include the following—

(1) The name and Unique Physician Identification Number (UPIN) of each physician who has a financial relationship with the entity;

(2) The name and UPIN of each physician with an immediate family member (as defined at § 411.351) who has a financial relationship with the entity;

(3) The covered items and services provided by the entity; and

(4) With respect to each physician identified under (1) and (2), the nature of the financial relationship (including the extent and/or value of the ownership or investment interest or the compensation arrangement).

In Phase II, we—

- Specifically excluded from the definition of ''reportable financial relationships'' ownership or investment interests in publicly-traded securities and mutual funds if such interests satisfy the requirements of the exceptions in § 411.356(a) or (b), respectively. This exclusion from the definition of reportable financial relationships for publicly-traded securities and mutual funds is limited to *shareholder information*; contractual arrangements concerning these ownership or investment interests are reportable financial relationships.
- Modified § 411.361(c)(4) to specify that the information required to be reported is only that information that the entity knows or should know in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain to comply with IRS and Securities and Exchange Commission rules and other rules under the Medicare and Medicaid programs.

We are making no substantive changes to § 411.361 in this Phase III final rule. However, we are revising § 411.361(c) to account for the transition from the UPIN to the National Provider Identifier (NPI).

Comment: One commenter sought clarification of our statement in Phase II that, to the extent we are obligated under the Freedom of Information Act (FOIA), 5 U.S.C. 552, to disclose records we have received pursuant to the physician self-referral reporting requirements, we cannot maintain the records as confidential (69 FR 17934). The commenter believes that most such records will be exempt from disclosure under Exemption 4 of the FOIA, 5

U.S.C. 552(b)(4), as they will involve confidential business information.

Response: The commenter is correct that Exemption 4 of the FOIA protects confidential business information from required disclosure. Moreover, the Trade Secrets Act, 18 U.S.C. 1905, prohibits Federal agencies from disclosing confidential business information, absent a law or regulation permitting such disclosure. We agree that much of the information that we may receive pursuant to our reporting requirements under the physician self-referral regulations will be exempt from disclosure under the FOIA and prohibited from disclosure by the Trade Secrets Act. However, when we receive a FOIA request for information reported to us, we must evaluate whether the particular information is exempt or prohibited from disclosure. (Generally, information that is exempt from disclosure under the FOIA is also prohibited from disclosure by the Trade Secrets Act.) We cannot state categorically, however, that all information that we receive will be confidential business information within the meaning of the FOIA and the Trade Secrets Act.

Comment: A commenter suggested that we exclude from the definition of ''reportable financial relationship'' compensation arrangements that qualify under any of the following exceptions: Medical staff incidental benefits (§ 411.357(m)); nonmonetary compensation (§ 411.357(k)); professional courtesy (§ 411.357(s)); or referral services (§ 411.357(q)). According to the commenter, treating these compensation arrangements as ''reportable financial relationships'' would require a hospital to furnish the required information for virtually all physicians on its medical staff (and perhaps for others as well), which would create an unnecessary burden for the hospital. Another commenter asserted that an entity's obligation under our reporting requirements is staggering because of the breadth of the physician self-referral statute. According to this commenter, the most acute burdens relate to the requirement in § 411.361(c)(2) to maintain records of financial relationships with family members of physicians. The commenter further asserted that most DHS entities do not have a means to catalog all such financial relationships, as they have no reason to create records of transactions that are at fair market value. The commenter suggested that various types of financial relationships involving immediate family members of physicians (such as charitable donations by family members or fair market value lease arrangements) be excepted from the reporting requirements. A third commenter also expressed concern that the inclusion of financial relationships with immediate family members of physicians imposed a substantial burden on DHS entities. This commenter suggested that if basic information, such as the UPIN of each physician who has a reportable financial arrangement with the entity, the covered items or services provided by the entity, and the nature of the financial arrangement for each such physician is provided, CMS could verify that exceptions are met and it would not be necessary in many cases for the entity to report information pertaining to immediate family members who have financial relationships with the DHS entities. Where such information is needed from the immediate family members of physicians, the commenter asserted that 30 days is an unreasonable amount of time in which to provide the information, and suggested that extensions of at least 90 days should be available.

Response: We decline to adopt the commenters' suggestions for the reasons stated in Phase II (69 FR 17934). There, we stated that we are concerned that an entity could decide that one or more of its financial relationships falls within an exception, fail to retain data concerning those financial relationships, and thereby prevent the government from reviewing the arrangements to determine if they qualify for an exception. In particular, we disagree that, where the financial relationship that triggers the physician self-referral statute is between an immediate family member of a physician and the DHS entity, it is not necessary for the entity to maintain information concerning the financial relationship and to report it upon our direction to do so. We fail to see how reporting information pertaining only to physicians who have financial relationships provides us with assurance that financial relationships concerning immediate family members meet one or more of the exceptions.

Section 411.361(e) provides that entities must be given at least 30 days to provide the required information. Where we agree that the nature or scope of the request for information is such that the information cannot reasonably be furnished within 30 days, we will extend the time for supplying the information.

Comment: A commenter requested that we create an exception to the reporting requirements for the situation in which a DHS entity seeks to obtain the required information but was denied access to it, such as where a physician has a reportable financial relationship solely by virtue of the hospital's financial arrangement with an immediate family member.

Response: We fail to see the basis for the commenter's concern. An entity that has a financial relationship with a physician or an immediate family member of the physician should have its own records of the details of such relationship.

XI. Miscellaneous (Other)

A. Specialty Hospital Moratorium

Section 507(a) of the MMA amended the hospital and rural provider ownership exceptions to the physician self-referral prohibition. Section 507 of the MMA specified that, for the 18-month period beginning on December 8, 2003 and ending on June 7, 2005, physician ownership and investment interests in ''specialty hospitals'' would not qualify for the whole hospital exception. Section 507 of the MMA further specified that, for the same 18-month period, the exception for physician ownership or investment interests in rural providers would not apply in the case of specialty hospitals located in rural areas. For purposes of section 507 of the MMA only, a ''specialty hospital'' was defined as a hospital in one of the 50 States or the District of Columbia that is primarily or exclusively engaged in the care and treatment of one of the following: (1) Patients with a cardiac condition; (2) patients with an orthopedic condition; (3) patients receiving a surgical procedure; or (4) patients receiving any other specialized category of services that the Secretary designates as being inconsistent with the purpose of permitting physician ownership and investment interests in a hospital. The term ''specialty hospital'' did not include any hospital determined by the Secretary to be in operation or ''under development'' as of November 18, 2003, and ''for which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date.''

Phase II modified the hospital ownership exception to reflect the MMA moratorium provisions. We received several comments on Phase II regarding the implementation of the 18-month moratorium on referrals of Medicare patients to specialty hospitals by physician investors.

Comment: One commenter suggested that, during the 18-month moratorium, any entity applying to receive a Medicare provider agreement as a hospital should be required to submit, as part of the application process, the

information required under § 411.361(c)(1) through (c)(4).

Response: The commenter's suggestion is moot as the moratorium ended on June 7, 2005. However, as we noted in the Secretary's August 8, 2006 final Report to Congress on specialty hospitals, which was required by section 5006 of the DRA, we are exploring changes to the enrollment form for hospitals (the CMS–855A) to capture information regarding whether an applicant hospital is, or is projected to be, a specialty hospital.

Comment: A commenter noted that Phase II defined a specialty hospital as a hospital that is primarily or exclusively engaged in the care and treatment of patients with a cardiac condition, patients with an orthopedic condition, or patients receiving a surgical procedure, but that no clear guidance exists as to what ''primarily engaged in'' means.

Response: For purposes of implementing the 18-month moratorium imposed by section 507 of the MMA, we considered a hospital to be ''primarily engaged'' in the care and treatment of cardiac, orthopedic, or surgical patients if 45 percent of the hospital's Medicare cases were (or were projected to be) in Major Diagnostic Category (MDC) 5, Diseases and Disorders of the Circulatory System (cardiac), MDC 8, Diseases and Disorders of the Musculoskeletal System and Connective Tissue (orthopedic), or were surgical in nature (surgical). As noted in response to the previous comment, we are exploring changes to the CMS–855A to enable us better to determine whether an applicant hospital is a specialty hospital. We may define ''primarily engaged'' for that purpose.

Comment: A commenter noted that, in Phase II, we defined specialty hospital for purposes of the 18-month moratorium to exclude a hospital for which the number of physician investors at any time on or after November 18, 2003 is no greater than the number of investors as of such date. The commenter stated that this requirement unfairly restricted any group practice that had invested in a specialty hospital prior to November 18, 2003 from increasing the number of its physician owners. It suggested that we interpret section 507 of the MMA to mean that there is no increase in physician investors, notwithstanding an increase in the number of physician equity owners in a group practice, if the group practice owned its interest in the specialty hospital prior to November 18, 2003 and the group was not formed for the purpose of investing in the hospital.

Response: For purposes of implementing the 18-month moratorium, we considered there to be an increase in the number of physician investors in a specialty hospital if a group practice that had an investment interest in a specialty hospital increased the number of physician equity owners in the group at any time on or after November 18, 2003 (and there was no corresponding decrease in the specialty hospital's investors). The suggested interpretation by the commenter does not comport with the plain language of section 507 of the MMA.

B. Physician Certification Requirements for Home Health Services—§ 424.22

Section 903 of the Omnibus Reconciliation Act of 1980 amended sections 1814(a) and 1835(a) of the Act to require the Secretary to issue regulations prohibiting a physician from certifying the need for home health services, or establishing and reviewing home health plans of treatment if the physician had a ''significant ownership interest in, or a significant financial or contractual relationship with, a home health agency.'' In October 1982, we published a rule (47 FR 47388) interpreting the prohibition to apply to physicians having, among other things: (1) a direct or indirect ownership interest of 5 percent or more in a home health agency; or (2) direct or indirect business transactions with the home health agency that totaled more than $25,000 or 5 percent of the agency's operating expenses, whichever was less. The 1982 regulatory provision, which was ultimately codified in § 424.22(d), was superseded by the physician self-referral prohibition when the prohibition became applicable in 1995 to physician referrals for home health services.

In Phase I, we amended the home health certification requirement in § 424.22(d) to provide that a physician may not certify the need for home health services or establish or review a plan of treatment if his or her ''financial relationship'' (as defined in the physician self-referral regulations) with the home health agency did not satisfy the requirements of an exception under the physician self-referral law. In Phase II, we republished § 424.22(d) without change, and we received no comments on this provision. This Phase III final rule makes no substantive change to § 424.22(d), although we are revising the provision to reference more explicitly the regulatory exceptions.

XII. Provisions of the Final Rule

A summary of the major changes to the regulations in this Phase III final rule are discussed below. No major regulatory changes were made to § 411.352 (Group Practices), § 411.353 (Prohibition on Certain Referrals by Physicians and Limitations on Billing), or § 411.356 (Exceptions to the Referral Prohibition Related to Ownership or Investment Interests). However, certain provisions of these sections were clarified in this preamble.

Three definitions are added at § 411.351 (''downstream contractor,'' ''physician organization,'' and ''rural area''). Also, in the definition of ''fair market value,'' we are not retaining the safe harbor regarding hourly payments for a physician's personal services.

Section 411.354 defines ''financial relationships'' for purposes of the physician self-referral law. A new provision was added in § 411.354(b)(3)(v) which specifies that an ownership interest in an entity [the whole hospital or a subdivision (that is, portion) of the hospital] does not include a security interest taken by a physician in equipment sold to the entity and financed with a loan by the physician to the entity. However, the security interest is a compensation arrangement.

A new ''stand in the shoes'' provision was added to § 411.354(c)(2) under which a physician is deemed to ''stand in the shoes'' of his or her physician organization (defined at § 411.351 as a ''physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements of § 411.352.'' A physician who stands in the shoes of his or her physician organization is deemed to have the same compensation arrangements with the DHS entity that the physician organization has with the DHS entity. As a result, many compensation arrangements that were analyzed under Phase II as indirect compensation arrangements are now analyzed as direct compensation arrangements that must comply with an applicable exception for direct compensation arrangements.

The Phase III changes to the general exceptions in § 411.355 for both ownership/investment interests and compensation arrangements are concentrated in the exceptions for academic medical centers and intra-family rural referrals in § 411.355(e) and (j), respectively. With respect to the academic medical centers exception, we clarified that the total compensation from *each* academic medical center component to a faculty physician must be set in advance and not determined in a manner that takes into account the volume or value of the physician's

referrals or other business generated by the referring physician within the academic medical center. In addition, when determining whether the majority of physicians on the medical staff of a hospital affiliated with an academic medical center consists of faculty members, the affiliated hospital must include or exclude all individual physicians holding the same class of privileges at the affiliated hospital.

We amended the exception for intra-family rural referrals to include an alternative test to determine whether a physician may refer a patient to an immediate family member for DHS. Specifically, if, in light of the patient's condition, no other person or entity is available to furnish the DHS in a timely manner within 45 minutes transportation time from the patient's home, a physician is not prohibited from making a referral for the DHS to an immediate family member or to an entity with which the immediate family member has a financial relationship, provided that all other conditions of the exception are satisfied. The Phase II 25-mile test remains an option for complying with the exception.

Section 411.357 sets out the exceptions for various compensation arrangements. The revisions to the exceptions for physician recruitment in § 411.357(e) and retention payments in underserved areas in § 411.357(t) are significant.

The physician recruitment exception protects certain remuneration that is provided by a hospital to a physician as an inducement for the physician to relocate his or her medical practice into the ''geographic area served by the hospital,'' which we defined in Phase II as the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. Under the revised definition of ''geographic area served by the hospital,'' a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients may recruit a physician into the geographic area composed of *all* of the contiguous zip codes from which it draws its inpatients, provided that all other requirements of the exception are satisfied. In addition, the revised definition sets forth a special optional rule for rural hospitals under which a rural hospital may determine its geographic service area using the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients or, if the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, its service area may include certain noncontiguous zip codes. A rural hospital may also recruit physicians to an area outside the geographic area served by the hospital if the Secretary has determined in an advisory opinion that the area into which the physician is to be recruited has a demonstrated need for the recruited physician, provided that all other requirements of the exception are satisfied.

In the case of an income guarantee provided by a hospital to a physician who relocates his or her practice into a rural area or HPSA and joins a physician practice to replace a physician who retired, died, or relocated (from the service area) during the previous 12-month period, the costs allocated by the physician practice to the recruited physician may be either: (1) the actual additional incremental costs attributable to the recruited physician; or (2) the lower of a per capita allocation or 20 percent of the practice's aggregate costs.

This Phase III final rule also clarifies that a physician must move his or her medical practice from a location outside of the geographic area served by the hospital to a location within the geographic area served by the hospital. In addition, we have revised the exception to provide that the relocation requirement will not apply to a physician who: (1) for at least 2 years immediately preceding the recruitment arrangement, was employed on a full-time basis by a Federal or State bureau of prisons (or similar entity operating correctional facilities), the Department of Defense or Veterans Affairs, or facilities of the Indian Health Service, provided that he or she had no private medical practice during the same time period; or (2) the Secretary has determined in an advisory opinion not to have an established medical practice that serves a significant number of patients who are or could become patients of the recruiting hospital. In the case of recruitment assistance provided by a hospital to a physician who joins a physician practice, we have revised the exception to prohibit the physician practice from imposing on the recruited physician any practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital. Finally, the exception in § 411.357(e) is now applicable to a rural health clinic in the same manner as it applies to a hospital (or federally qualified health center).

We have expanded the exception in § 411.357(t) for retention payments in underserved areas to permit a hospital to make a payment to retain a physician on its medical staff even if the physician does not have a *bona fide* firm, written recruitment offer, provided that the physician certifies in writing that, among other things, he or she has a *bona fide* opportunity for future employment that would require the physician to move his or her medical practice at least 25 miles to a location outside the geographic area served by the hospital, and certain other conditions are satisfied. We have also expanded the retention payments exception to permit retention payments in the case of a physician with a *bona fide* firm, written offer of employment from, or a *bona fide* opportunity for future employment with, an academic medical center or physician organization. Also, we have expanded the exception to permit a hospital to make a retention payment to a physician whose current medical practice is not located in a HPSA. Under the revised exception, a retention payment may be made to a physician whose current medical practice is located in a rural area or an area with demonstrated need for the physician, as determined by the Secretary in an advisory opinion.

Changes to the remaining exceptions found in § 411.357 include—

- Under the personal service arrangements exception in § 411.357(d), allowing a ''holdover'' personal service arrangement on terms similar to those in the exceptions for the rental of office space and equipment;
- Under the nonmonetary compensation exception in § 411.357(k), in certain circumstances, upon repayment of nonmonetary compensation in excess of the applicable limit, deeming the nonmonetary compensation to be within the limit, and allowing an entity with a formal medical staff to hold one local medical staff appreciation event per year;
- Under the exception for charitable donations by a physician in § 411.357(j), clarifying that the donation may neither be solicited nor *offered* in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity;
- Under the professional courtesy exception in § 411.357(s), eliminating the requirement that the entity offering the professional courtesy inform the insurer in writing of the reduction of any coinsurance obligation on the part of the recipient of the professional courtesy, and clarifying that the exception is applicable only to entities that have formal medical staffs;
- Under the fair market value compensation exception in § 411.357(l),

clarifying that the exception is applicable to both compensation provided to a physician from an entity and compensation provided to an entity from a physician; and,

• Under the compliance training exception in § 411.357(o), permitting the provision of training programs for which CME is available, provided that the primary purpose of the program is compliance training.

XIII. Technical Corrections

1. Web site Change

Because the address of the physician self-referral Web site has changed, we are correcting the references to our Web site in the definition of ''List of CPT/HCPCS Codes'' at § 411.351, the ''nonmonetary compensation'' exception in § 411.357(k), and the ''medical staff incidental benefits'' exception in § 411.357(m).

[REG TEXT—Change]

2. Typographical Error

We are correcting typographical and other errors that appeared in Phase II. For example, we are removing a typographical error (''sbull'') in § 411.355(a)(2). In addition, we are correcting § 411.357(m)(1) to state that medical staff incidental benefits must be ''offered'' to all members of the medical staff. In Phase II, we intended to change ''offered'' to ''provided'' only in § 411.357(m)(2), but the change was inadvertently made to paragraph (m)(1) as well.

3. CMS Manuals

Because CMS has begun re-numbering and posting its manuals on the Internet, we are correcting the citations to the manuals in § 411.351 (the definitions of entity, *locum tenens* physician, parenteral and enteral nutrients, equipments and supplies, and physician in the group practice).

4. Nonmonetary Compensation

We are revising the section heading of § 411.357(k) to remove the reference to ''up to $300.'' This change will make the section heading consistent with the provisions of § 411.357(k).

5. Simplification of Regulatory Text

We made several non-substantive grammatical and editorial revisions to the regulatory text. For example, we revised the introductory language in § 411.355(g) concerning EPO and other dialysis related drugs to make it easier to read. We also substituted ''nonmonetary'' for ''non-monetary'' throughout the regulations. A similar change is being made to § 424.22 to simplify language concerning home health services. We have simplified references in the recruitment exception to a recruited physician joining a ''physician or physician practice.'' Because ''joining a physician'' is necessarily synonymous with ''joining a physician practice,'' we have simplified the regulation text so that it now refers only to ''joining a physician practice.''

6. Statutory References

Under the definition of *''Does not violate the anti-kickback statute''* at § 411.351, the statutory references to the anti-kickback statute have been corrected from sections 1128(a)(7) and 1128a(b)(7) of the Act to sections 1128A(a)(7) and 1128(b)(7) of the Act, respectively.

7. References to the Reassignment Rules

In the definition of ''physician in the group practice,'' we updated the reference to the reassignment rules from § 424.80(b)(3) to § 424.80(b)(2). We also updated the reference to the reassignment rules in the in-office ancillary services exception in § 411.355(b)(3)(v) from § 424.80(b)(6) to § 424.80(b)(5).

8. National Provider Identifier

We revised the Reporting Requirements provision in § 411.361(c) to account for the transition from the Unique Physician Identification Number (UPIN) to the National Provider Identifier (NPI) by inserting the following phrase: ''and/or the national provider identifier (NPI).'' Specific references to the NPI are found in § 411.361(c)(1) and (c)(2).

9. Advisory Opinions

We are revising § 411.370(a) to remove the sunset provision that had formerly applied to our authority to issue advisory opinions because section 543 of the Medicare, Medicaid, and SCHIP Benefits and Improvement Protection Act of 2000, Pub. L. 106–554, extended the time period indefinitely for our authority to issue advisory opinions.

XIV. 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 before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues—

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we previously solicited public comment on each of these issues for the following sections of the regulation that contain information collection requirements.

Group Practice (§ 411.352)

The burden associated with § 411.352 was discussed in detail in both Phase I and Phase II (66 FR 949 and 69 FR 16118–16119, respectively). Section 411.352 sets out the requirements that must be met in order to qualify as a group practice. Section 411.352(d) provides that substantially all of the patient care services of the physicians who are members of the group must be furnished and billed through the group practice. The burden associated with this requirement is the time and effort necessary to collect, document, and maintain the information outlined in § 411.352(d). We believe that the documentation requirements in this section are usual and customary business practices. The burden associated with this requirement, therefore, is not subject to the PRA as stated in 5 CFR 1320.3(b)(2) because 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 are considered to be usual and customary business practices and are not subject to the PRA. In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.352(i) addresses the special rule for productivity bonuses and profit shares. The burden associated with the requirements in this section is the time and effort associated with collecting and maintaining the information listed under § 411.352(i)(2) and (i)(3). The burden associated with the recordkeeping requirements in § 411.352(i) is not subject to the PRA, as stated in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent

that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Financial Relationship, Compensation, and Ownership or Investment Interest (§ 411.354)

Both Phase I (66 FR 949) and Phase II (69 FR 16119) contain detailed discussions of the information collection requirements in § 411.354. Section 411.354(d)(4) permits a physician's compensation from a *bona fide* employer or under a managed care or other contract to be conditioned on the physician's referrals to a particular provider, practitioner, or supplier if, among other things, the requirement to make referrals is set forth in a written agreement signed by the parties. Specifically, the burden associated with this requirement in § 411.354(d)(4)(iv)(A) is the time and effort necessary to set forth the required referrals provision in a written agreement signed by both parties. The burden associated with this requirement is not subject to the PRA as stated in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

General Exceptions to the Referral Prohibition Related to Both Ownership/Investment and Compensation (§ 411.355)

The burden associated with § 411.355 was discussed in detail in both Phase I (66 FR 949) and Phase II (69 FR 16119). Section 411.355(e) addresses the exception for services provided by an academic medical center. Essentially, § 411.355(e)(1)(iii)(B) states that the relationship of the components of the academic medical center must be set forth in written agreement(s) or other written document(s) that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components. The burden associated with these requirements is not subject to the PRA, as stated in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Exceptions to the Referral Prohibition Related to Compensation Arrangements (§ 411.357)

Section 411.357(a) addresses the rental of office space. Under § 411.357(a)(1), the rental or lease agreement associated with payments for the use of office space made by a lessee to a lessor must be set out in writing, signed by the parties, and specify the premises covered. The burden associated with these requirements is the time and effort necessary to draft, sign, and maintain the written agreement. The burden associated with this requirement is not subject to the PRA as stated in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(b) requires that the payments made by a lessee to a lessor for the use of equipment meet certain conditions. Specifically, § 411.357(b)(1) requires that a rental or lease agreement be set out in writing, signed by the parties, and specify the equipment covered by the agreement. The burden associated with this requirement is the time and effort associated with drafting, signing, and maintaining the written agreement. The burden associated with this requirement is not subject to the PRA as stated in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(d) addresses personal service arrangements. Section 411.357(d)(1)(i) requires that each personal service arrangement be set out in writing, signed by the parties, and specify the services covered by the arrangement. In addition, § 411.357(d)(1)(ii) requires that the written agreement cover all of the services to be furnished by the physician or his or her immediate family member, or both. This requirement is satisfied if all separate arrangements with the physician and his or her immediate family member incorporate each other by reference or cross-reference a master list of contracts. The burden associated with both § 411.357(d)(1)(i) and (ii) is not subject to the PRA as stated under 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(e) addresses physician recruitment. Specifically, § 411.357(e)(1)(i) requires that all arrangements for remuneration provided by a hospital to recruit a physician that is intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff must be set out in writing and signed by both parties. In addition, § 411.357(e)(4)(i) provides that, in the case of certain recruitment arrangements in which the recruited physician joins a physician practice, the written agreement must be signed by the hospital, the recruited physician, and the physician practice. The burden associated with these requirements is the time and effort associated with drafting, signing, and maintaining the written agreement. The burden associated with this requirement is not subject to the PRA as stated under 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(e)(4)(iv) imposes a recordkeeping requirement. Records of the actual costs and the passed through amounts must be maintained for a period of at least 5 years and made available to the Secretary upon request. The burden associated with this requirement is the time and effort associated with maintaining the required documentation. The burden associated with this collection is not subject to the PRA as it meets the requirements set forth in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(l)(1) requires that all arrangements pertaining to fair market value compensation be set forth in writing. In addition, the written agreement must be signed by the parties and must cover identifiable items or services that are the subject of the arrangement. The burden associated with this requirement is the time and effort necessary to draft, sign, and maintain the written agreement. The burden associated with these

requirements is not subject to the PRA as it meets the requirements set forth in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(p) sets forth an exception for indirect compensation arrangements. The exception requires the arrangement to be set out in a writing that is signed by the parties and specifies the services covered by the arrangement. The burden associated with this requirement is the time and effort necessary to draft, sign, and maintain the written agreement. The burden associated with these requirements is not subject to the PRA as it meets the requirements set forth in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(q) sets forth an exception for remuneration that meets all of the conditions set forth in the voluntary anti-kickback safe harbor at § 1001.952(f). Under § 1001.952(f), the referral service must make certain standard disclosures to each person seeking a referral and must maintain a written record certifying each disclosure. The burden associated with this requirement is the time and effort necessary to draft, sign, and maintain the disclosures. The burden associated with these requirements is not subject to the PRA as it meets the requirements set forth in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(r) sets forth an exception for obstetrical malpractice insurance subsidies that satisfy all of the conditions set forth in the voluntary anti-kickback safe harbor at § 1001.952(o). Under § 1001.952(o)(1), such subsidies must be made in accordance with a written agreement. The burden associated with this requirement is the time and effort necessary to draft, sign, and maintain the agreement. Under § 1001.952(o)(2), the physician receiving the subsidy must certify that for the initial coverage period, he or she has a reasonable basis for believing that at least 75 percent of his or her obstetrical patients will either reside in a HPSA or medically underserved area, or be part of a medically underserved population, and the physician must make a similar certification for subsequent coverage periods. The burden associated with the requirement for a written agreement is not subject to the PRA as it meets the requirements set forth in 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit. The burden associated with the physician certification requirement is considered to be a usual and customary business practice and, as set forth in 5 CFR 1320.3(b)(2), is not subject to the PRA. In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that information is collected during conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(s) addresses professional courtesy. Specifically, § 411.357(s)(3) requires that an entity have a written policy approved by the entity's governing body in order to extend professional courtesy. The burden associated with this requirement is the time and effort associated with drafting and maintaining the written policy. The burden associated with this requirement is not subject to the PRA as stated under 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(t), under this Phase III final rule, protects payments made by a hospital to a physician on its medical staff to retain the physician's medical practice in an underserved area if certain conditions are satisfied. The exception requires, among other things, that the physician: (1) have a *bona fide* firm written recruitment offer (or offer of employment) from an unrelated hospital (which includes a rural health clinic or federally qualified health center), academic medical center, or physician organization that specifies, among other things, the remuneration being offered; or (2) provide a written certification of a verifiable employment opportunity. Both options require documentation that the new employment would require the physician to move the location of his or her medical practice at least 25 miles and outside of the geographic area served by the hospital, rural health clinic, or federally qualified health center making the retention payment. The burden associated with this requirement is considered to be a usual and customary business practice and, as set forth in 5 CFR 1320.3(b)(2), is not subject to the PRA. In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(v) sets forth an exception for certain arrangements involving the donation of nonmonetary remuneration consisting of electronic prescribing items and services necessary and used solely to receive and transmit electronic prescription information. Section 411.357(v)(7) requires that such arrangements be set forth in a written agreement that is signed by all parties, specifies the items or services being provided and the donor's cost of the items and services, and covers all of the electronic prescribing items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The burden associated with these requirements is the time and effort associated with drafting, signing, and maintaining the necessary documentation. The burden associated with these requirements is not subject to the PRA as stated under 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Section 411.357(w) addresses certain arrangements involving the donation of nonmonetary remuneration consisting of electronic health records software and information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records. Specifically, § 411.357(w)(7) requires that the arrangement be set forth in a written agreement that is signed by the parties and that specifies the items and services being provided, the donor's cost of the items, and the amount of the physician's contribution. The agreement must cover all of the electronic health records items and services to be provided by the donor. The burden associated with these

requirements is the time and effort associated with drafting, signing, and maintaining the necessary documentation. The burden associated with these requirements is not subject to the PRA as stated under 5 CFR 1320.3(b)(2). In addition, the burden is not subject to the PRA under 5 CFR 1320.4(a) to the extent that the information is collected during the conduct of a criminal or civil action, or during the conduct of an administrative action, investigation or audit.

Reporting Requirements (§ 411.361)

The burden associated with this section was discussed in detail in Phase II (69 FR 16054). The burden associated with the requirements in this section is not subject to the PRA as stated under both 5 CFR 1320.3(b)(2) and 5 CFR 1320.4(a). However, this section does contain requirements that are not exempt from the PRA. As stated in Phase II, we quantified the burden associated with the reporting requirements in § 411.361(c) through (e) (69 FR 16119–16121). While these requirements are subject to the PRA, they are currently approved under OMB control number 0938–0846, with an expiration date of November 30, 2007.

We have submitted a copy of this final rule to OMB for its review of the aforementioned information collection requirements.

XV. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of Phase III of this rulemaking 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 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

While we cannot specify in advance the aggregate economic impact of this rule, we do not believe that the impact will approach $100 million or more annually. This Phase III final rule does not unsettle existing financial relationships or create further restrictions on financial relationships between physicians and health care facilities. Indeed, physicians and DHS entities have been complying with the requirements set forth in the physician self-referral prohibition for many years, specifically in regard to clinical laboratory services since 1992 and to referrals for all other DHS since 1995.

Under Phase I, the physician self-referral prohibition was interpreted narrowly while the exceptions were interpreted broadly. Phase I also established additional regulatory exceptions for legitimate arrangements that would otherwise violate the prohibition. Phase I covered the following—

- Sections 1877(a) and 1877(b) of the Act (the general prohibition and the exceptions applicable to both ownership and compensation arrangements);
- The statutory definitions at section 1877(h) of the Act;
- Certain additional regulatory definitions; and
- New regulatory exceptions promulgated using the Secretary's authority under section 1877(b)(4) of the Act for certain arrangements involving the following—
  - Academic medical centers;
  - Implants furnished by an ambulatory surgery center;
  - EPO and certain dialysis-related outpatient prescription drugs;
  - Preventive screening tests, immunizations, and vaccines;
  - Eyeglasses and contact lenses after cataract surgery;
  - Nonmonetary compensation up to $300;
  - Fair market value compensation;
  - Medical staff incidental benefits;
  - Risk-sharing arrangements;
  - Compliance training; and
  - Indirect compensation arrangements.

Phase II was issued as an interim final rule with comment period on March 26, 2004. Under Phase II, we clarified certain regulatory definitions, broadened certain established exceptions, and created additional regulatory exceptions. Phase II also addressed the public comments provided on the Phase I regulations. Phase II covered the following—

- All provisions of section 1877 of the Act (namely, the exceptions for ownership and investment interests and the exceptions for various compensation arrangements);
- Additional regulatory definitions; and
- Additional new regulatory exceptions promulgated using the Secretary's authority under section 1877(b)(4) of the Act for certain arrangements involving the following—
  - Temporary noncompliance with an applicable exception;
  - Intra-family rural referrals;
  - Charitable donations by a physician;
  - Referral services;
  - Obstetrical malpractice insurance subsidies;
  - Professional courtesy;
  - Retention payments in underserved areas; and
  - Community-wide health information systems.

This Phase III final rule primarily clarifies aspects of Phase I and Phase II based on public comments and, again, like Phase I and Phase II, increases the flexibility of the rule's application by expanding the breadth of the exceptions while continuing to protect against program and patient abuse. Phase III covers all of the provisions in section 1877 of the Act except those related to advisory opinions and civil monetary penalties. Among other things, this Phase III final rule—

- Eliminates the proposed safe harbor within the fair market value definition for physician compensation;
- Adds three new regulatory definitions;
- Considers a physician to ''stand in the shoes'' of a physician organization of which he or she is a member;
- Adds an alternative 45-minute transportation time test to the intra-family rural referrals exception;
- Adds a holdover provision in the exception for personal service arrangements on terms similar to those in the space and equipment lease contexts;
- Expands the geographic area into which a rural hospital may recruit a physician;
- With respect to a physician who is recruited to join another physician or practice in a rural area or HPSA to replace another physician who retired, died, or relocated within the previous 12-month period, permits the allocation of costs by the physician or practice to the recruited physician not to exceed either (A) the actual additional incremental costs attributable to the recruited physician, or (B) the lower of a per capita allocation or 20 percent of the practice's aggregate costs;
- Allows practice restrictions that do not unreasonably restrict the recruited physician from practicing in the geographic area served by the hospital;
- Expands the nonmonetary compensation exception to allow entities to avoid what would otherwise be noncompliance with the exception in

certain circumstances, and to allow an entity with a formal medical staff to provide one local medical staff appreciation event per year; and

• Adds a written certification option as an alternative to the requirement for a *bona fide* written offer under the exception for retention payments in underserved areas.

This Phase III final rule generally does not require existing financial relationships to be restructured; it merely further clarifies the language of Phase I and Phase II, and provides additional flexibility under the regulatory exceptions to enable parties to adjust noncompliant arrangements. Wherever possible, this Phase III final rule attempts to accommodate legitimate financial relationships while reducing the regulatory burden and continuing to protect against program and patient abuse. For these reasons, we conclude that this is not a major rule with an economically significant effect of $100 million in any 1 year.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Currently, there are approximately 1.1 million physicians, other health care practitioners, and medical suppliers that receive Medicare payment (*http://www.cms.hhs.gov/CapMarketUpdates/Downloads/2006CMSstat.pdf*).

For purposes of the RFA, according to the latest numbers from the Small Business Administration's North American Industrial Classification System, approximately 100 percent of offices of physicians in the United States are considered small businesses according to the Small Business Administration's size standards with total revenues of $9 million or less and are considered small entities. Individuals and States are not included in the definition of a small entity. We determined that this Phase III final rule does not have a significant impact on small businesses because it does not increase regulatory burden, but rather reduces it. As noted above, this Phase III final rule generally does not require existing financial relationships to be restructured; it provides clarifications of the provisions found in Phase I and Phase II and provides additional flexibility under the regulatory exceptions to enable parties to adjust noncompliant arrangements. Overall, this Phase III final rule is very accommodating to legitimate financial relationships while reducing the regulatory burden and continuing to protect against program and patient abuse.

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. The impact of this rule on small rural hospitals is minimal. In fact, several provisions of the rule benefit small rural hospitals by giving them more flexibility to maintain operations and remain competitive in an increasingly global health care market.

Several provisions of this Phase III final rule benefit rural hospitals and rural health clinics. For example, the rule modifies the physician recruitment exception with respect to a hospital located in a rural area by expanding the geographic area into which a rural hospital may recruit a physician. Under the revised exception, a rural hospital may recruit a physician into an area composed of the lowest number of contiguous zip codes (and in some circumstances, noncontiguous zip codes) from which the hospital draws at least 90 percent of its inpatients. In addition, we have modified the recruitment exception to permit a hospital to offer a more generous income guarantee to a physician who is recruited into a rural area or HPSA to replace a physician who retired, relocated, or died within the previous 12 months. The exception for physician recruitment is also expanded to include rural health clinics. Small rural hospitals also benefit under this rule from the significant expansion of their ability to offer retention payments to physicians. In summary, this Phase III final rule does not have a substantial negative 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. As discussed above, the revisions made to the Phase I and Phase II rules by this Phase III final rule will have an insignificant financial impact. As such, there are no anticipated expenditures under this rule that would result in expenditures to State, local or tribal governments, in the aggregate, or to the private sector, that would rise above 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 requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not anticipate that this Phase III final rule will have a substantial effect on State or local governments, nor do we believe that this final rule preempts State law or draws Federalism issues into question.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because, for the reasons identified above, we have determined, and we certify, that this Phase III final rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals. For the benefit of the public, we discuss below the anticipated effects of the rule and the alternative regulatory options we considered.

B. Anticipated Effects

This Phase III final rule primarily affects physicians and health care entities that furnish certain items and services (''designated health services'') to Medicare beneficiaries. We believe that this Phase III final rule addresses many of the industry's primary concerns with the existing regulatory scheme, is consistent with the statute's goals and directives, and protects beneficiaries of Federal health care programs. In particular, we have attempted to preserve the core statutory prohibition while providing sufficient flexibility to minimize the impact of the rule on many common business arrangements. For the reasons stated above, we do not anticipate that this rule will have a significant economic impact on a substantial number of small entities. Nevertheless, we wish to inform the public of what we regard as the major effects of this rulemaking. We discuss below some of the possible economic effects upon physicians and DHS entities. We also briefly discuss the effects of the rules on the Medicare and Medicaid programs as well as Medicare beneficiaries.

1. Effects on Physicians

A physician can have a financial relationship with an entity either through an ownership or investment

interest in the entity, or through a compensation arrangement with the entity. Financial relationships include both direct and indirect ownership and investment interests and direct and indirect compensation arrangements. A physician who has (or whose immediate family member has) a financial relationship with an entity that does not qualify for an exception is prohibited under section 1877 of the Act from referring Medicare patients to that entity for the provision of DHS. The primary statutory sanctions for violating the physician self-referral prohibition are nonpayment of claims for DHS furnished as the result of a prohibited referral and the corresponding obligation to refund any amounts collected on those claims. These sanctions target the entities that furnish DHS, including physician group practices. Referring physicians may be sanctioned with the imposition of civil monetary penalties (CMPs) only for knowing violations of the statutory prohibition. Nevertheless, although referring physicians are not the primary targets of the sanctions for violating the statute, their financial relationships with DHS entities must comply with the statute and implementing regulations. Accordingly, this Phase III final rule may affect a physician's or group practice's decision to enter into a particular financial relationship and the manner in which the arrangement is structured.

We have made every effort in Phase I, Phase II, and Phase III of this rulemaking to address the concerns of physicians and physician group practices while remaining faithful to the statute. We discuss below the major provisions of this rule that affect physicians.

Two major changes under this Phase III final rule directly affect physicians. In Phase II, we clarified that a referring physician may be treated as ''standing in the shoes'' of his or her wholly-owned PC and we solicited comments on whether to permit a physician to ''stand in the shoes'' of a group practice of which he or she is a member. In this final rule, we are adopting a broader ''stand in the shoes'' provision than the provision proposed in Phase II. Essentially, a physician is deemed to stand in the shoes of his or her ''physician organization,'' which is defined to include a physician practice or group practice as well as a professional corporation of which the physician is the sole owner. A physician who stands in the shoes of a physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. For physicians, this will require some compensation arrangements to comply with an exception for direct compensation arrangements, rather than the indirect compensation arrangements exception. In general, the new stand in the shoes provision will ease compliance by simplifying the analysis of arrangements in which a physician organization is interposed between the referring physician and the entity furnishing DHS.

The second major change relates to revisions to the physician recruitment exception. For hospitals located in rural areas, we have expanded the geographic area into which they may recruit a physician. Under the revised exception, a rural hospital may recruit a physician into an area composed of the lowest number of contiguous zip codes (and in some circumstances, noncontiguous zip codes) from which the hospital draws at least 90 percent of its inpatients. In addition, we have modified the recruitment exception to permit a hospital to offer a more generous income guarantee to a physician who is recruited into a rural area or HPSA to replace a physician who retired, relocated, or died within the previous 12 months. This change will make it easier for such physicians and physician practices to recruit new physicians.

This Phase III final rule also allows a physician practice to impose on a recruited physician practice restrictions that do not unreasonably restrict the ability of the recruited physician to practice in the geographic area served by the recruiting hospital. Allowing certain kinds of practice restrictions makes it more likely that physician practices will take on new physicians and, as a result, hospitals will be able to attract new physicians and satisfy what would otherwise be unmet health care needs of their communities.

Beyond the adoption of the more expansive ''stand in the shoes'' provision, and the revisions to the physician recruitment exception, the effect of the remaining changes on physicians under the Phase III final rule are relatively minor. Some of these changes include—

- Not retaining the safe harbor within the fair market value definition for hourly payments to physicians;
- Clarifying that group practices can compensate members, employed physicians, and other physicians in the group by directly taking into account the volume and value of items and services that are provided ''incident to'' the physicians' professional services, in certain circumstances; and
- Expanding the exception for retention payments in underserved areas to permit retention payments to be made in the case of a physician who does not have a *bona fide* written offer of recruitment or employment, provided that the physician certifies that he or she has a *bona fide* opportunity for future employment and the arrangement satisfies all other conditions of the exception.

All of these changes ease the burden and cost of complying with the statutory prohibition by creating or implementing clear rules in such a way that the parties can determine more easily and with greater certainty whether their financial relationships comply with an exception. In addition, by expanding some definitions and exceptions, a greater number of legitimate arrangements can comply with the statute.

2. Effects on Other Health Care Providers and Suppliers

As we stated above, the physician self-referral rules affect entities that furnish DHS by preventing them from receiving payment for services that they furnish as a result of a physician's prohibited referral. Entities may also be subject to other sanctions, including fines and exclusion from Federal health care programs, if they knowingly submit a claim in violation of the prohibition. While all physicians and DHS entities are subject to this rule, we lack the data to determine the number of entities whose financial relationships with physicians must be terminated or revised to comply with this Phase III final rule. However, we believe that the number will be fewer than we had anticipated in the prior physician self-referral rules for two reasons—

- First, hospitals and other DHS entities were required to restructure any non-compliant financial arrangements after Phase I and Phase II became effective (January 4, 2002 and July 26, 2004, respectively); and
- Second, this Phase III final rule does not adopt any changes that significantly narrow existing exceptions, or which would require termination or substantial modification of existing arrangements. As with Phase I and Phase II, we have interpreted the prohibition narrowly and the exceptions broadly under Phase III.

We have made every effort in Phase I, Phase II, and in Phase III of this rulemaking to address the concerns of health care providers and suppliers while remaining faithful to the statute. We discuss below the major provisions of this rule that affect health care providers and suppliers.

This Phase III final rule makes two substantive changes to the nonmonetary compensation exception that affect health care providers and suppliers: (1) The revised exception allows physicians to repay certain excess nonmonetary compensation within the same calendar year in which the excess compensation was received, thereby preserving compliance with the exception; and (2) entities are allowed, without regard to the nonmonetary compensation limit, to provide one local medical staff appreciation event per year for the entire medical staff (such as a holiday party).

The Phase III final rule also—

- Revises the exception for charitable donations by a physician to clarify that the donation may neither be solicited nor offered in any manner that takes into account the volume or value of referrals;
- Revises the exception for compliance training programs to permit entities to provide compliance training programs for which CME is available, provided that compliance training is the primary purpose of the program; and
- Allows a hospital, rural health clinic, or federally qualified health center to make a retention payment to a physician if the hospital receives a written certification from the physician, in lieu of documentation of a written offer, that he or she has a *bona fide* opportunity for future employment that would require the physician to relocate his or her medical practice at least 25 miles and outside of the geographic area served by the entity.

Again, to the extent that expanded exceptions permit additional legitimate arrangements to comply with the law, Phase III reduces the potential costs of restructuring such arrangements, and the consequences of noncompliance may be avoided entirely.

3. Effects on the Medicare and Medicaid Programs

Section 1877 of the Act was enacted to address over-utilization, anti-competitive behavior, and other program abuses that occur when physicians have financial relationships with certain entities to which they refer Medicare or Medicaid patients. Physician financial arrangements may have some anti-competitive effects to the extent that those relationships discourage other providers from entering a market in which patients are primarily referred to physician-owned entities or DHS entities that maintain generous compensation arrangements with physicians. Anti-competitive behavior can increase program costs if the DHS entities with which physicians have financial relationships are favored over other, more cost-efficient providers or providers that furnish higher quality care. Over-utilization increases program costs because it causes Medicare (or Medicaid) to pay for more items or services than are medically necessary.

We expect this Phase III final rule to generate savings to the program by minimizing anti-competitive business arrangements as well as over-utilization or other program abuse, similar to the effects of Phase I and Phase II. For example, we declined to eliminate the requirement in many exceptions that the arrangement at issue comply with the anti-kickback statute. We believe this requirement is necessary to protect the Medicare and Medicaid programs by preventing individuals or entities with fraudulent intent from paying for referrals.

Phase III continues to balance the risk of program and patient abuse with the need to support legitimate business arrangements. For example, we are not excluding DHS ordered by anesthesiologists pursuant to a consultation from the definition of a referral under Phase III, because we are not satisfied that this modification poses no risk of program or patient abuse. While we cannot gauge with certainty the extent of these savings to the programs at this time, this Phase III final rule reflects our continued efforts to prohibit arrangements that have the potential to increase utilization improperly or promote anti-competitive behavior.

4. Effects on Beneficiaries

We have sought to ensure that this rule will not adversely impact the medical care of Federal health care program beneficiaries. In most cases, this Phase III final rule should not require substantial changes in delivery arrangements. This Phase III final rule makes no significant changes that have the potential to impede patient access to health care facilities and services. In fact, as noted above under the ''Effects on the Medicare and Medicaid Programs,'' we believe that this final rule will help minimize anti-competitive behavior that can affect where a beneficiary receives health care services and possibly the quality of the services furnished. We believe the protections included under this Phase III final rule will minimize the number of medically unnecessary tests performed on, and items or services ordered for, Federal health care program beneficiaries.

C. Alternatives Considered

After reviewing the voluminous number of comments we received, we considered in Phase I and Phase II many alternatives to accommodate the practical problems that commenters raised. As noted throughout the Phase III preamble, we have considered alternatives raised in comments received on Phase II. We have modified the regulations to accommodate those alternatives that comport with the statutory language and intent.

For example, we received many comments suggesting that we revise our restrictions on retention payments to physicians in underserved areas in § 411.357(t). Under Phase II, this exception protected retention payments made only: (1) By a hospital whose geographic service area was located in a HPSA; and (2) to a physician with a firm, written recruitment offer from an unrelated hospital or federally qualified health center (provided that certain other conditions were satisfied). Some commenters requested that we broaden the exception to permit retention payments when the recruitment offer is made by any entity, including a group practice. In addition, a number of commenters requested that we eliminate the requirement for a written offer; they suggested that the exception be revised to permit a retention payment made on the basis of a ''good faith belief'' that the physician may be recruited by another entity.

After reviewing the comments, we decided to permit retention payments made in the case of a *bona fide* written recruitment offer from or written offer of employment with a hospital, academic medical center, or physician organization (which is defined to include a physician or group practice). We considered broadening the exception to permit retention payments made in the case of a recruitment or employment offer from any DHS entity, but rejected that alternative as unnecessarily broad and potentially subject to abuse.

In addition, after reviewing the comments, we recognized that it is commonplace for hospitals to become cognizant of a verbal offer received by a physician and that, in order to ensure that hospitals can compete fairly, we should permit hospitals to act based upon a written certification provided by the physician. We considered the ''good faith belief'' standard suggested by the commenters, but rejected it because it would be too difficult to enforce and would be subject to abuse. Instead, we added a new option in § 411.357(t)(2) to permit retention payments in the

absence of a written offer where a physician provides a written certification stating that the physician has a *bona fide* opportunity for future employment with a hospital, academic medical center, or physician organization that would require relocation of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The physician's certification must detail the opportunity presented (such as income and benefits), the steps taken by the physician to effectuate the employment opportunity, and other information sufficient for the hospital to verify the offer. We believe that our changes to the retention payments exception strike an appropriate balance between the industry's need for greater flexibility in making retention payments and our need to protect the Medicare and Medicaid programs from abuse while ensuring access to care in underserved areas.

Many commenters to both the Phase I and Phase II rules requested clarification of the definition of ''indirect compensation arrangement.'' In Phase II, we clarified that a referring physician may be treated as ''standing in the shoes'' of his or her wholly-owned PC when the only intervening entity between the referring physician and the DHS entity is his or her PC. Phase II did not make any changes with respect to the issue of indirect compensation arrangements that are created when a group practice is the only intervening entity between a DHS entity and the referring physician. However, we did solicit comments in Phase II on whether to permit a physician to ''stand in the shoes'' of a group practice of which he or she is a member. Since the publication of the Phase II interim final rule and in light of the comments we have received, we have concluded that it is in the best program integrity interests of the Medicare and Medicaid programs to adopt a broader ''stand in the shoes'' provision. In this Phase III final rule, we have modified the regulations to deem a direct compensation arrangement to exist when the only intervening entity between a referring physician and a DHS entity is a group practice or other physician organization. This will require some compensation arrangements to be analyzed for compliance with an exception for direct compensation arrangements, rather than the exception for indirect compensation arrangements exception.

We considered defining a ''physician organization'' to include entities other than a physician, physician practice, or group practice, but we have rejected that alternative because we are concerned about the potential for abuse and believe that such an expansion of the ''stand in the shoes'' doctrine would benefit from additional public comment.

We considered a number of alternatives suggested by commenters regarding the recruitment exception. The Phase II rule modified the physician recruitment exception to allow hospitals to recruit physicians into the geographic area served by the hospital, provided that certain conditions are satisfied. We defined ''geographic area served by the hospital'' to be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. Several commenters objected to the restriction on recruiting only into the ''geographic area served by the hospital,'' stating that the definition of that term prevents hospitals from recruiting physicians into outlying parts of their service area, where there is likely to be greater need. Additionally, some commenters pointed out that the restriction hurt rural hospitals and was very difficult for federally qualified health centers to satisfy.

Based on the comments we received, we revised the exception to permit a rural hospital to recruit a physician into an area composed of the lowest number of contiguous zip codes (and in some circumstances, noncontiguous zip codes) from which the hospital draws at least 90 percent of its inpatients. We considered expanding the definition of ''geographic area served by the hospital'' to permit all hospitals to recruit physicians into a broader geographic area, but we rejected that alternative on the grounds that, in many cases, such recruitment arrangements would not be necessary to ensure access to care and may be abusive.

As these examples demonstrate, our approach in this Phase III final rule is to address as many of the industry's concerns as possible. As noted throughout this preamble, we considered a variety of suggestions and alternatives, selecting only those that are consistent with the statute's goals and directives and that will protect Federal health care program beneficiaries' access to services.

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 411

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, 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 follows:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102, 1860 D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

■ 2. Section 411.350 is revised to read as follows:

§ 411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered services under Medicare report information concerning ownership, investment, or compensation arrangements in the form, in the manner, and at the times specified by CMS.

(d) This subpart does not alter an individual's or entity's obligations under—

(1) The rules regarding reassignment of claims (§ 424.80);

(2) The rules regarding purchased diagnostic tests (§ 414.50);

(3) The rules regarding payment for services and supplies incident to a physician's professional services (§ 410.26); or

(4) Any other applicable Medicare laws, rules, or regulations.

■ 3. Section 411.351 is revised to read as follows—

§ 411.351 Definitions.

As used in this subpart, unless the context indicates otherwise:

Centralized building means all or part of a building, including, for purposes of this subpart only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building or a mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider or supplier (for example, a diagnostic imaging facility) is not a centralized building for purposes of this subpart. This provision does not preclude a group practice from providing services to other providers or suppliers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body, as specifically identified by the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are clinical laboratory services for purposes of this subpart. Any service not specifically identified as a clinical laboratory service on the List of CPT/HCPCS Codes is not a clinical laboratory service for purposes of this subpart.

Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:

(1) The physician's opinion or advice regarding evaluation or management or both of a specific medical problem is requested by another physician.

(2) The request and need for the consultation are documented in the patient's medical record.

(3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided that the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

(1)(i) Clinical laboratory services.

(ii) Physical therapy, occupational therapy, and speech-language pathology services.

(iii) Radiology and certain other imaging services.

(iv) Radiation therapy services and supplies.

(v) Durable medical equipment and supplies.

(vi) Parenteral and enteral nutrients, equipment, and supplies.

(vii) Prosthetics, orthotics, and prosthetic devices and supplies.

(viii) Home health services.

(ix) Outpatient prescription drugs.

(x) Inpatient and outpatient hospital services.

(2) Except as otherwise noted in this subpart, the term ''designated health services'' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, ambulatory surgical center services or SNF Part A payments), except to the extent the services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS).

Does not violate the anti-kickback statute, as used in this subpart only, means that the particular arrangement—

(1)(i) Meets a safe harbor under the anti-kickback statute, as set forth at § 1001.952 of this title, ''Exceptions'';

(ii) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the particular arrangement (for example, the entity furnishing DHS) with respect to the particular arrangement (and not a similar arrangement), provided that the arrangement is conducted in accordance with the facts certified by the requesting party and the opinion is otherwise issued in accordance with part 1008 of this title, ''Advisory Opinions by the OIG''; or

(iii) Does not violate the anti-kickback provisions in section 1128B(b) of the Act.

(2) For purposes of this definition, a favorable advisory opinion means an opinion in which the OIG opines that—

(i) The party's specific arrangement does not implicate the anti-kickback statute, does not constitute prohibited remuneration, or fits in a safe harbor under § 1001.952 of this title; or

(ii) The party will not be subject to any OIG sanctions arising under the anti-kickback statute (for example, under sections 1128A(a)(7) and 1128(b)(7) of the Act) in connection with the party's specific arrangement.

Downstream contractor means a ''first tier contractor'' as defined at § 1001.952(t)(2)(iii) or a ''downstream contractor'' as defined at § 1001.952(t)(2)(i).

Durable medical equipment (DME) and supplies has the meaning given in section 1861(n) of the Act and § 414.202 of this chapter.

Electronic health record means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

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).)

Entity means—

(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it—

(i) Is the person or entity to which CMS makes payment for the DHS, directly or upon assignment on the patient's behalf; or

(ii) Is the person or entity to which the right to payment for the DHS has been reassigned in accordance with § 424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at § 1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).

(2) A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier under § 424.80(b)(1) and (b)(2) of this chapter, with respect to any DHS provided by that supplier.

(3) For purposes of this subpart, ''entity'' does not include a physician's practice when it bills Medicare for a diagnostic test in accordance with § 414.50 of this chapter (Physician billing for purchased diagnostic tests) and section 30.2.9 of the CMS Internet-only Manual, publication 100–04, Claims Processing Manual, Chapter 1 (general billing requirements), as amended or replaced from time to time.

Fair market value means the value in arm's-length transactions, consistent with the general market value. ''General market value'' means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), ''fair market value'' means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

Home health services means the services described in section 1861(m) of the Act and part 409, subpart E of this chapter.

Hospital means any entity that qualifies as a ''hospital'' under section 1861(e) of the Act, as a ''psychiatric hospital'' under section 1861(f) of the Act, or as a ''critical access hospital'' under section 1861(mm)(1) of the Act, and refers to any separate legally organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills. However, a ''hospital'' does not include entities that perform services for hospital patients ''under arrangements'' with the hospital.

HPSA means, for purposes of this subpart, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in part 5 of this title).

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

''Incident to'' services or services ''incident to'' means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, § 410.26 of this chapter, and sections 60, 60.1, 60.2, and 60.3 of the CMS Internet-only Manual, publication 100–02, Medicare Benefit Policy Manual, Chapter 15 (covered medical and other health services), as amended or replaced from time to time.

Inpatient hospital services means those services defined in section 1861(b) of the Act and § 409.10(a) and (b) of this chapter and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient critical access hospital services, as defined in section 1861(mm)(2) of the Act. ''Inpatient hospital services'' do not include emergency inpatient services provided by a hospital located outside of the U.S. and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter, or emergency inpatient services provided by a nonparticipating hospital within the U.S., as authorized by section 1814(d) of the Act and described in part 424, subpart G of this chapter. ''Inpatient hospital services'' also do not include dialysis furnished by a hospital that is not certified to provide end-stage renal dialysis (ESRD) services under subpart U of part 405 of this chapter. ''Inpatient hospital services'' include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. ''Inpatient hospital services'' do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists if Medicare reimburses the services independently and not as part of the inpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Interoperable means able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually, as published

in the **Federal Register**, and is posted on the CMS Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp#TopOfPage*.

Locum tenens physician means a physician who substitutes (that is, ''stands in the shoes'') in exigent circumstances for a physician, in accordance with applicable reassignment rules and regulations, including section 30.2.11 of the CMS Internet-only Manual, publication 100–04, Claims Processing Manual, Chapter 1 (general billing requirements), as amended or replaced from time to time.

Member of the group or member of a group practice means, for purposes of this subpart, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a *locum tenens* physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes ''patient care services'' to the group as defined in this section. An independent contractor or a leased employee is not a member of the group (unless the leased employee meets the definition of an ''employee'' under this § 411.351).

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (s)(2)(C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient critical access hospital services, as defined in section 1861(mm)(3) of the Act. ''Outpatient hospital services'' do not include emergency services furnished by nonparticipating hospitals and covered under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. ''Outpatient hospital services'' include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. ''Outpatient hospital services'' do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Outpatient prescription drugs means all drugs covered by Medicare Part B or Part D.

Parenteral and enteral nutrients, equipment, and supplies means the following services (including all HCPCS level 2 codes for these services):

(1) *Parenteral nutrients, equipment, and supplies*, meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in section 108.2 of the National Coverage Determinations Manual, as amended or replaced from time to time; and

(2) *Enteral nutrients, equipment, and supplies,* meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in section 108.2 of the National Coverage Determinations Manual, as amended or replaced from time to time.

Patient care services means any task(s) performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters or generally benefit a particular practice. Patient care services can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.

Physical therapy, occupational therapy, and speech-language pathology services means those particular services so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are physical therapy, occupational therapy, and speech-language pathology services for purposes of this subpart. Any service not specifically identified as physical therapy, occupational therapy or speech-language pathology on the List of CPT/HCPCS Codes is not a physical therapy, occupational therapy, or speech-language pathology service for purposes of this subpart. The list of codes identifying physical therapy, occupational therapy, and speech-language pathology services for purposes of this regulation includes the following:

(1) *Physical therapy services*, meaning those outpatient physical therapy services (including speech-language pathology services) described in section 1861(p) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Assessments, function tests, and measurements of strength, balance, endurance, range of motion, and activities of daily living;

(ii) Therapeutic exercises, massage, and use of physical medicine modalities, assistive devices, and adaptive equipment;

(iii) Establishment of a maintenance therapy program for an individual whose restoration potential has been reached; however, maintenance therapy itself is not covered as part of these services; or

(iv) Speech-language pathology services that are for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

(2) *Occupational therapy services,* meaning those services described in section 1861(g) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities;

(ii) Evaluation of an individual's level of independent functioning;

(iii) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; or

(iv) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act.

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must

contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in § 424.80(b)(2) of this chapter (see also section 30.2.11 of the CMS Internet-only Manual, publication 100-04, Claims Processing Manual, Chapter 1 (general billing requirements), as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

Physician incentive plan means any compensation arrangement between an entity (or downstream contractor) and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Physician organization means a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements of § 411.352.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of services.

Professional courtesy means the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these items and services that are covered by Medicare):

(1) *Orthotics,* meaning leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

(2) *Prosthetics,* meaning artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

(3) *Prosthetic devices,* meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(4) *Prosthetic supplies,* meaning supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Radiation therapy services and supplies means those particular services and supplies, including (effective January 1, 2007) therapeutic nuclear medicine services and supplies, so identified on the List of CPT/HCPCS Codes. All services and supplies so identified on the List of CPT/HCPCS Codes are radiation therapy services and supplies for purposes of this subpart. Any service or supply not specifically identified as radiation therapy services or supplies on the List of CPT/HCPCS Codes is not a radiation therapy service or supply for purposes of this subpart. The list of codes identifying radiation therapy services and supplies is based on section 1861(s)(4) of the Act and § 410.35 of this chapter.

Radiology and certain other imaging services means those particular services so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are radiology and certain other imaging services for purposes of this subpart. Any service not specifically identified as radiology and certain other imaging services on the List of CPT/HCPCS Codes is not a radiology or certain other imaging service for purposes of this subpart. The list of codes identifying radiology and certain other imaging services includes the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, computerized axial tomography, magnetic resonance imaging, nuclear medicine (effective January 1, 2007), or other imaging services. All codes identified as radiology and certain other imaging services are covered under section 1861(s)(3) of the Act and § 410.32 and § 410.34 of this chapter, but do not include—

(1) X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice; and

(2) Radiology procedures that are integral to the performance of a nonradiological medical procedure and performed)—

(i) During the nonradiological medical procedure; or

(ii) Immediately following the nonradiological medical procedure when necessary to confirm placement of an item placed during the nonradiological medical procedure.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, if—

(i) The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and

(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.

(3) Can be in any form, including, but not limited to, written, oral, or electronic.

Referring physician means a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made

by another person or entity. A referring physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity.

(3) A payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured plan) and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

Rural area means an area that is not an urban area as defined at § 412.62(f)(1)(ii) of this chapter.

Same building means a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior loading docks or parking garages. For purposes of this section, the ''same building'' does not include a mobile vehicle, van, or trailer.

Specialty hospital means a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act) that is primarily or exclusively engaged in the care and treatment of one of the following:

(1) Patients with a cardiac condition;

(2) Patients with an orthopedic condition;

(3) Patients receiving a surgical procedure; or

(4) Any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital. A ''specialty hospital'' does not include any hospital—

(1) Determined by the Secretary to be in operation before or under development as of November 18, 2003;

(2) For which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(3) For which the type of categories described above is no different at any time on or after such date than the type of such categories as of such date;

(4) For which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(5) That meets such other requirements as the Secretary may specify.

Transaction means an instance or process of two or more persons or entities doing business. An isolated financial transaction means one involving a single payment between two or more persons or entities or a transaction that involves integrally related installment payments provided that—

(1) The total aggregate payment is fixed before the first payment is made and does not take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician; and

(2) The payments are immediately negotiable or are guaranteed by a third party, or secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

■ 3a. Section 411.352 is revised to read as follows:

§ 411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) *Single legal entity.* The group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may be organized or owned (in whole or in part) by another medical practice, provided that the other medical practice is not an operating physician practice (and regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this subpart, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a single legal entity may itself own subsidiary entities. A group practice operating in more than one State will be considered to be a single legal entity notwithstanding that it is composed of multiple legal entities, provided that—

(1) The States in which the group practice is operating are contiguous (although each State need not be contiguous to every other State);

(2) The legal entities are absolutely identical as to ownership, governance, and operation; and

(3) Organization of the group practice into multiple entities is necessary to comply with jurisdictional licensing laws of the States in which the group practice operates.

(b) *Physicians.* The group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners), as defined at § 411.351.

(c) *Range of care.* Each physician who is a member of the group, as defined at § 411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(d) *Services furnished by group practice members.* (1) Except as otherwise provided in paragraphs (d)(3), (d)(4), (d)(5), and (d)(6) of this section, substantially all of the patient care services of the physicians who are members of the group (that is, at least

75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. *Patient care services* must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (For example, if a physician practices 40 hours a week and spends 30 hours a week on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

(2) The data used to calculate compliance with this *substantially all* test and related supportive documentation must be made available to the Secretary upon request.

(3) The *substantially all* test set forth in paragraph (d)(1) of this section does not apply to any group practice that is located solely in a HPSA, as defined at § 411.351.

(4) For a group practice located outside of a HPSA (as defined at § 411.351), any time spent by a group practice member providing services in a HPSA should not be used to calculate whether the group practice has met the *substantially all* test, regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the *start up* period (not to exceed 12 months) that begins on the date of the initial formation of a new group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the *substantially all* test requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5) does not apply when an existing group practice admits a new member or reorganizes.

(6)(i) If the addition to an existing group practice of a new member who would be considered to have relocated his or her medical practice under § 411.357(e)(2) would result in the existing group practice not meeting the *substantially all* test set forth in paragraph (d)(1) of this section, the group practice will have 12 months following the addition of the new member to come back into full compliance, provided that—

(A) For the 12-month period the group practice is fully compliant with the *substantially all* test if the new member is not counted as a member of the group for purposes of § 411.352; and

(B) The new member's employment with, or ownership interest in, the group practice is documented in writing no later than the beginning of his or her new employment, ownership, or investment.

(ii) This paragraph (d)(6) does not apply when an existing group practice reorganizes or admits a new member who is not relocating his or her medical practice.

(e) *Distribution of expenses and income.* The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this section prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS under § 411.352(i).

(f) *Unified business.* (1) The group practice must be a unified business having at least the following features:

(i) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries); and

(ii) Consolidated billing, accounting, and financial reporting.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues derived from DHS under § 411.352(i).

(g) *Volume or value of referrals.* No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in § 411.352(i).

(h) *Physician-patient encounters.* Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) *Special rule for productivity bonuses and profit shares.* (1) A physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed, or services ''incident to'' such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services ''incident to'' the physician's personally performed services).

(2) Overall profits means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. Overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. The share of overall profits will be deemed *not* to relate directly to the volume or value of referrals if *one* of the following conditions is met:

(i) The group's profits are divided per capita (for example, per member of the group or per physician in the group).

(ii) Revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group.

(3) A productivity bonus must be calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. A productivity bonus will be deemed not to relate directly to the volume or value of referrals of DHS if one of the following conditions is met:

(i) The bonus is based on the physician's total patient encounters or relative value units (RVUs). (The methodology for establishing RVUs is set forth in § 414.22 of this chapter.)

(ii) The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer.

(iii) Revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her

total compensation from the group practice.

(4) Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(2) and (i)(3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

■ 4. Section 411.353 is revised to read as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff. However, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing.* An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) *Denial of payment.* Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

(d) *Refunds.* An entity that collects payment for a designated health service that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis, as defined at § 1003.101 of this title.

(e) *Exception for certain entities.* Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal and State laws, rules, and regulations.

(f) *Exception for certain arrangements involving temporary noncompliance.* (1) Except as provided in paragraphs (f)(2), (f)(3), and (f)(4) of this section, an entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The financial relationship between the entity and the referring physician fully complied with an applicable exception under § 411.355, § 411.356, or § 411.357 for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception;

(ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance; and

(iii) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), and the claim or bill otherwise complies with all applicable Federal and State laws, rules, and regulations.

(2) Paragraph (f)(1) of this section applies only to DHS furnished during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with an exception.

(3) Paragraph (f)(1) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) Paragraph (f)(1) does not apply if the exception with which the financial relationship previously complied was § 411.357(k) or (m).

■ 4a. Section 411.354 is revised to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships.* (1) *Financial relationship* means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) *Types of financial relationships.* (i) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).

(ii) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) *Ownership or investment interest.* An ownership or investment interest in the entity may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to, stock, stock options other than those described in § 411.354(b)(3)(ii), partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

(i) An interest in a retirement plan;

(ii) Stock options and convertible securities received as compensation until the stock options are exercised or the convertible securities are converted to equity (before this time the stock options or convertible securities are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section);

(iv) An ''under arrangements'' contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS ''under arrangements'' with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section); or

(v) A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest is a compensation arrangement as defined in paragraph (c) of this section).

(4) An ownership or investment interest that meets an exception set forth in § 411.355 or § 411.356 need not also

meet an exception for compensation arrangements set forth in § 411.357 with respect to profit distributions, dividends, or interest payments on secured obligations.

(5)(i) An *indirect ownership or investment interest* exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) An indirect ownership or investment interest exists even though the entity furnishing DHS does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

(iii) Notwithstanding anything in this paragraph (b)(5), common ownership or investment in an entity does not, in and of itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor.

(iv) An indirect ownership or investment interest requires an unbroken chain of ownership interests between the referring physician and the entity furnishing DHS such that the referring physician has an indirect ownership or investment interest *in* the entity furnishing DHS.

(c) *Compensation arrangement.* A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An ''under arrangements'' contract between a hospital and an entity providing DHS ''under arrangements'' to the hospital creates a compensation arrangement for purposes of these regulations. A compensation arrangement does not include the portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term ''remuneration'' at § 411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(1)(i) A direct compensation arrangement exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities.

(ii) A physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization. In such situations, for purposes of this section, the physician is deemed to stand in the shoes of the physician organization.

(2) An *indirect compensation arrangement* exists if—

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(iv) For purposes of paragraph (c)(2)(i), a physician is deemed to ''stand in the shoes'' of his or her physician organization.

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv), a physician who ''stands in the shoes'' of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. For purposes of applying the exceptions in § 411.355 and § 411.357 to arrangements described in paragraphs (c)(1)(i) and (c)(2)(i), the ''parties'' to the arrangements are considered to be the entity furnishing DHS and the physician organization (including all members, employees, or independent contractor physicians).

(ii) The provisions of paragraphs (c)(1)(ii) and (c)(2)(iv) need not apply during the original term or current renewal term of an arrangement that satisfied the requirements of § 411.357(p) as of September 5, 2007.

(d) *Special rules on compensation.* The following special rules apply only to compensation under section 1877 of the Act and subpart J of this part:

(1) Compensation is considered ''set in advance'' if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(2) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account ''the volume or value of referrals'' if the compensation

is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of DHS.

(3) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account ''other business generated between the parties,'' provided that the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which are not considered ''other business generated'' by the referring physician).

(4) A physician's compensation from a *bona fide* employer or under a managed care contract or other contract for personal services may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets all of the following conditions. The compensation arrangement:

(i) Is set in advance for the term of the agreement.

(ii) Is consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals).

(iii) Otherwise complies with an applicable exception under § 411.355 or § 411.357.

(iv) Complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set forth in a written agreement signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(v) The required referrals relate solely to the physician's services covered by the scope of the employment or the contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment or contract.

■ 5. Section 411.355 is revised to read as follows:

§ 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in § 411.353 does not apply to the following types of services:

(a) *Physician services.* (1) Physician services as defined in § 410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at § 411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at § 411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of paragraph (a) of this section, ''physician services'' include only those ''incident to'' services (as defined at § 411.351) that are physician services under § 410.20(a) of this chapter.

(b) *In-office ancillary services.* Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN)), that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) An individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.

(2) They are furnished in one of the following locations:

(i) The same building (as defined at § 411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), *or* (b)(2)(i)(C) of this section are satisfied:

(A)(*1*) The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; and

(*2*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week. The 30 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(B)(*1*) The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(*3*) The referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(C)(*1*) The referring physician is present and orders the DHS during a patient visit on the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section *or* the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished during occupancy of the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section;

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(*3*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS.

(ii) A centralized building (as defined at § 411.351) that is used by the group practice for the provision of some or all

of the group practice's clinical laboratory services.

(iii) A centralized building (as defined at § 411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

(3) They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a ''physician in the group practice'' (as defined at § 411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (b)(3)(iv) of this section under a billing number assigned to the physician, group practice, or entity, provided that the billing arrangement meets the requirements of § 424.80(b)(5) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) For purposes of paragraph (b) of this section, DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purpose of ambulating, a patient uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the ''same building'' requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards set forth in § 424.57(c) of this chapter.

(v) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(vi) All other requirements of the in-office ancillary services exception in paragraph (b) of this section are met.

(5) A designated health service is ''furnished'' for purposes of paragraph (b) of this section in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) *Special rule for home care physicians.* In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the ''same building'' requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient's private home. For purposes of paragraph (b)(5) of this section only, a private home does not include a nursing, long-term care, or other facility or institution, except that a patient may have a private home in an assisted living or independent living facility.

(c) *Services furnished by an organization (or its contractors or subcontractors) to enrollees.* Services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(1) An HMO or a CMP in accordance with a contract with CMS under section 1876 of the Act and part 417, subparts J through M of this chapter.

(2) A health care prepayment plan in accordance with an agreement with CMS under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(6) A MCO contracting with a State under section 1903(m) of the Act.

(7) A prepaid inpatient health plan (PIHP) or prepaid ambulance health plan (PAHP) contracting with a State under part 438 of this chapter.

(8) A health insuring organization (HIO) contracting with a State under part 438, subpart D of this chapter.

(9) An entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

(d) [Reserved]

(e) *Academic medical centers.* (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—

(A) Is a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. (A ''component'' of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.) The components need not be separate legal entities;

(B) Is licensed to practice medicine in the State(s) in which he or she practices medicine;

(C) Has a *bona fide* faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital (as defined at § 411.355(e)(3)); and

(D) Provides either substantial academic services or substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing

academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services) is not precluded from qualifying under this paragraph (e)(1)(i)(D).

(ii) The compensation paid to the referring physician must meet all of the following conditions:

(A) The total compensation paid by each academic medical center component to the referring physician is set in advance.

(B) In the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided.

(C) The total compensation paid by each academic medical center component is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center.

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research or teaching and must be consistent with the terms and conditions of the grant.

(iv) The referring physician's compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(2) The ''academic medical center'' for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate) or an accredited academic hospital (as defined at § 411.355(e)(3));

(ii) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and

(iii) One or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions is made by physicians who are faculty members. The hospital for purposes of this paragraph (e)(2)(iii) may be the same hospital that satisfies the requirement of paragraph (e)(2)(i) of this section. For purposes of this paragraph, a faculty member is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. In meeting this paragraph (e)(2)(iii), faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physician professionals need not be counted. Any faculty member may be counted, including courtesy and volunteer faculty. For purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (for example, physicians holding courtesy privileges).

(3) An accredited academic hospital for purposes of this section means a hospital or a health system that sponsors four or more approved medical education programs.

(f) *Implants furnished by an ASC.* Implants furnished by an ASC, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices, and implanted DME that meet the following conditions:

(1) The implant is implanted by the referring physician or a member of the referring physician's group practice in an ASC that is certified by Medicare under part 416 of this chapter and with which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure paid by Medicare to the ASC as an ASC procedure under § 416.65 of this chapter.

(3) The arrangement for the furnishing of the implant does not violate the anti-kickback statute (section 1128B(b) of the Act).

(4) All billing and claims submission for the implants does not violate any Federal or State law or regulation governing billing or claims submission.

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to, and implanted in, the patient.

(g) *EPO and other dialysis-related drugs.* EPO and other dialysis-related drugs that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph, ''EPO and other dialysis-related drugs'' means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes; and ''furnished'' means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.

(2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the EPO and other dialysis-related drugs does not violate any Federal or State law or regulation governing billing or claims submission.

(4) The exception set forth in this paragraph does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) *Preventive screening tests, immunizations, and vaccines.* Preventive screening tests, immunizations, and vaccines that meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to CMS-mandated frequency limits.

(2) The arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the preventive screening tests, immunizations, and vaccines does not violate any Federal or State law or regulation governing billing or claims submission.

(4) The preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed as eligible for this exception on the List of CPT/HCPCS Codes.

(i) *Eyeglasses and contact lenses following cataract surgery.* Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in § 410.36(a)(2)(ii) and § 414.228 of this chapter, respectively.

(2) The arrangement for the furnishing of the eyeglasses or contact lenses does not violate the anti-kickback statute (section 1128B(b) of the Act).

(3) All billing and claims submission for the eyeglasses or contact lenses does not violate any Federal or State law or regulation governing billing or claims submission.

(j) *Intra-family rural referrals.* (1) Services provided pursuant to a referral from a referring physician to his or her immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, if all of the following conditions are met:

(i) The patient who is referred resides in a rural area as defined at § 411.351 of this subpart;

(ii) Except as provided in paragraph (j)(1)(iii) of this section, in light of the patient's condition, no other person or entity is available to furnish the services in a timely manner within 25 miles of or 45 minutes transportation time from the patient's residence;

(iii) In the case of services furnished to patients where they reside (for example, home health services or DME), no other person or entity is available to furnish the services in a timely manner in light of the patient's condition; and

(iv) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission;

(2) The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than 25 miles of or 45 minutes transportation time from (whichever test the referring physician utilized for purposes of paragraph (j)(1)(ii)) the patient's residence.

■ 6. Section 411.356 is revised to read as follows:

§ 411.356 Exceptions to the referral prohibition related to ownership or investment interests.

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly-traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers.

(2) They are in a corporation that had stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. ''Stockholder equity'' is the difference in value between a corporation's total assets and total liabilities.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities, for purposes of the services specified:

(1) A rural provider, in the case of DHS furnished in a rural area (as defined at § 411.351 of this subpart) by the provider. A ''rural provider'' is an entity that furnishes substantially all (not less than 75 percent) of the DHS that it furnishes to residents of a rural area and, for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), is not a specialty hospital.

(2) A hospital that is located in Puerto Rico, in the case of DHS furnished by such a hospital.

(3) A hospital that is located outside of Puerto Rico, in the case of DHS furnished by such a hospital, if—

(i) The referring physician is authorized to perform services at the hospital;

(ii) Effective for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), the hospital is not a specialty hospital; and

(iii) The ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.

■ 7. Section 411.357 is revised to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

For purposes of § 411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The term of the agreement is at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's *pro rata* share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the agreement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the agreement are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) A holdover month-to-month rental for up to 6 months immediately following the expiration of an agreement of at least 1 year that met the conditions of this paragraph (a) satisfies the requirements of this paragraph (a),

provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) A rental or lease agreement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee and is not shared with or used by the lessor or any person or entity related to the lessor.

(3) The agreement provides for a term of rental or lease of at least 1 year. To meet this requirement, if the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement.

(4) The rental charges over the term of the agreement are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(5) The agreement would be commercially reasonable even if no referrals were made between the parties.

(6) A holdover month-to-month rental for up to 6 months immediately following the expiration of an agreement of at least 1 year that met the conditions of this paragraph (b) satisfies the requirements of this paragraph (b), provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a *bona fide* employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

(3) The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(d) *Personal service arrangements.* (1) *General*—Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member can ''furnish'' services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at § 411.351, except that the regular physician need not be a member of a group practice).

(iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The term of each arrangement is for at least 1 year. To meet this requirement, if an arrangement is terminated during the term with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement.

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at § 411.351 of this subpart), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.

(vii) A holdover personal service arrangement for up to 6 months following the expiration of an agreement of at least 1 year that met the conditions of paragraph (d) of this section satisfies the requirements of paragraph (d) of this section, provided that the holdover personal service arrangement is on the same terms and conditions as the immediately preceding agreement.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined at § 411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled with the entity.

(ii) Upon request of the Secretary, the entity provides the Secretary with access to information regarding the plan (including any downstream contractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (d)(2) of this section.

(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined at § 422.208, the entity or any downstream contractor (or both) complies with the requirements concerning physician incentive plans set forth in § 422.208 and § 422.210 of this chapter.

(e) *Physician recruitment.* (1) Remuneration provided by a hospital to recruit a physician that is paid directly to the physician and that is intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by both parties;

(ii) The arrangement is not conditioned on the physician's referral of patients to the hospital;

(iii) The hospital does not determine (directly or indirectly) the amount of the remuneration to the physician based on the volume or value of any actual or anticipated referrals by the physician or

other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment or services contract that complies with § 411.354(d)(4)).

(2)(i) The ''geographic area served by the hospital'' is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. The geographic area served by the hospital may include one or more zip codes from which the hospital draws no inpatients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the hospital draws at least 75 percent of its inpatients.

(ii) With respect to a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the ''geographic area served by the hospital'' will be deemed to be the area composed of all of the contiguous zip codes from which the hospital draws its inpatients.

(iii) *Special optional rule for rural hospitals.* In the case of a hospital located in a rural area (as defined at § 411.351), the ''geographic area served by the hospital'' may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the ''geographic area served by the hospital'' may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital's inpatients resides, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients.

(iv) A physician will be considered to have relocated his or her medical practice if the medical practice was located outside the geographic area served by the hospital and—

(A) The physician moves his or her medical practice at least 25 miles and into the geographic area served by the hospital; or

(B) The physician moves his medical practice into the geographic area served by the hospital, and the physician's new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years, measured on an annual basis (fiscal or calendar year). For the initial ''start up'' year of the recruited physician's practice, the 75 percent test in the preceding sentence will be satisfied if there is a reasonable expectation that the recruited physician's medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.

(3) The recruited physician will not be subject to the relocation requirement of this paragraph, provided that he or she establishes his or her medical practice in the geographic area served by the recruiting hospital, if—

(i) He or she is a resident or physician who has been in practice 1 year or less;

(ii) He or she was employed on a full-time basis for at least 2 years immediately prior to the recruitment arrangement by one of the following (and did not maintain a private practice in addition to such full-time employment):

(A) A Federal or State bureau of prisons (or similar entity operating one or more correctional facilities) to serve a prison population;

(B) The Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or

(C) A facility of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service; or

(iii) The Secretary has deemed in an advisory opinion issued under section 1877(g) of the Act that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.

(4) In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

(i) The written agreement in paragraph (e)(1) is also signed by the party to whom the payments are directly made.

(ii) Except for actual costs incurred by the physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.

(iii) In the case of an income guarantee of any type made by the hospital to a recruited physician who joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician. With respect to a physician recruited to join a physician practice located in a rural area or HPSA, if the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated by the physician practice to the recruited physician do not exceed either—

(A) The actual additional incremental costs attributable to the recruited physician; or

(B) The lower of a *per capita* allocation or 20 percent of the practice's aggregate costs.

(iv) Records of the actual costs and the passed-through amounts are maintained for a period of at least 5 years and made available to the Secretary upon request.

(v) The remuneration from the hospital under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

(vi) The physician practice may not impose on the recruited physician practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.

(vii) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(5) Recruitment of a physician by a hospital located in a rural area (as defined at § 411.351) to an area outside the geographic area served by the hospital is permitted under this exception if the Secretary determines in an advisory opinion issued under section 1877(g) of the Act that the area has a demonstrated need for the recruited physician and all other requirements of this paragraph (e) are met.

(6) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, if all of the following conditions are met:

(1) The amount of remuneration under the isolated transaction is—

(i) Consistent with the fair market value of the transaction; and

(ii) Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties.

(2) The remuneration is provided under an agreement that would be commercially reasonable even if the physician made no referrals to the entity.

(3) There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in § 411.355 through § 411.357 and except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician.

(g) *Certain arrangements with hospitals.* Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as ''unrelated,'' remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. Remuneration relates to the furnishing of DHS if it—

(1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles;

(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or

(3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which DHS are furnished by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services furnished to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before, and has continued in effect without interruption since, December 19, 1989.

(3) With respect to the DHS covered under the arrangement, at least 75 percent of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with a written agreement that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(i) *Payments by a physician.* Payments made by a physician (or his or her immediate family member)—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for any other items or services that are furnished at a price that is consistent with fair market value, and that are not specifically addressed by another provision in § 411.355 through § 411.357 (including, but not limited to, § 411.357(l)). ''Services'' in this context means services of any kind (not merely those defined as ''services'' for purposes of the Medicare program in § 400.202 of this chapter).

(j) *Charitable donations by a physician. Bona fide* charitable donations made by a physician (or immediate family member) to an entity if all of the following conditions are satisfied:

(1) The charitable donation is made to an organization exempt from taxation under the Internal Revenue Code (or to a supporting organization);

(2) The donation is neither solicited, nor offered, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity; and

(3) The donation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(k) *Nonmonetary compensation.* (1) Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of $300 per calendar year, as adjusted for inflation in accordance with paragraph (k)(2) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(ii) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

(iii) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission.

(2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral Web site: *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.*

(3) Where an entity has inadvertently provided nonmonetary compensation to a physician in excess of the limit (as set forth in paragraph (k)(1) of this section), such compensation is deemed to be within the limit if—

(i) The value of the excess nonmonetary compensation is no more than 50 percent of the limit; and

(ii) The physician returns to the entity the excess nonmonetary compensation (or an amount equal to the value of the excess nonmonetary compensation) by the end of the calendar year in which the excess nonmonetary compensation was received or within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier.

(iii) Paragraph (k)(3) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) In addition to nonmonetary compensation up to the limit described in paragraph (k)(1) of this section, an entity that has a formal medical staff may provide one local medical staff appreciation event per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the limit in paragraph (k)(1).

(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a

physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352) for the provision of items or services (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement is set forth in an agreement that meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.

(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

(3) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(4) The arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

(5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) without regard to the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital web site or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital web site or in hospital advertising, meets the ''on campus'' requirement of this paragraph (m) of this section.

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) The compensation is of low value (that is, less than $25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value). The $25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–I for the 12 month period and the new limits on the physician self-referral web site: *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.*

(6) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(8) Other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have *bona fide* medical staffs may provide compensation under this paragraph (m) on the same terms and conditions applied to hospitals under this paragraph (m).

(n) *Risk-sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a MCO or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. For purposes of this paragraph (n), ''health plan'' and ''enrollees'' have the meanings set forth in § 1001.952(l) of this title.

(o) *Compliance training.* Compliance training provided by an entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity's local community or service area, provided that the training is held in the local community or service area. For purposes of this paragraph (o), ''compliance training'' means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, or reporting); specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or training regarding other Federal, State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided. For purposes of this paragraph, ''compliance training'' includes programs that offer continuing medical education credit, provided that compliance training is the primary purpose of the program.

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined at § 411.354(c)(2), if all of the following conditions are satisfied:

(1) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(q) *Referral services.* Remuneration that meets all of the conditions set forth in § 1001.952(f) of this title.

(r) *Obstetrical malpractice insurance subsidies.* Remuneration to the referring physician that meets all of the conditions set forth in § 1001.952(o) of this title.

(s) *Professional courtesy.* Professional courtesy (as defined at § 411.351) offered by an entity with a formal medical staff to a physician or a physician's immediate family member or office staff if all of the following conditions are met:

(1) The professional courtesy is offered to all physicians on the entity's *bona fide* medical staff or in such entity's local community or service area without regard to the volume or value of referrals or other business generated between the parties;

(2) The health care items and services provided are of a type routinely provided by the entity;

(3) The entity has a professional courtesy policy that is set out in writing and approved in advance by the entity's governing body;

(4) The professional courtesy is not offered to a physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need; and

(5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(t) *Retention payments in underserved areas.*

(1) *Bona fide written offer.* Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician has a *bona fide* firm, written recruitment offer or offer of employment from a hospital, academic medical center (as defined at § 411.355(e)), or physician organization (as defined at § 411.351) that is not related to the hospital making the payment, and the offer specifies the remuneration being offered and requires the physician to move the location of his or her medical practice at least 25 miles *and* outside of the geographic area served by the hospital making the retention payment.

(ii) The requirements of § 411.357(e)(1)(i) through § 411.357(e)(1)(iv) are satisfied.

(iii) Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the written recruitment offer or offer of employment.

(iv) The retention payment does not exceed the lower of—

(A) The amount obtained by subtracting the physician's current income from physician and related services from the income the physician would receive from comparable physician and related services in the written recruitment or employment offer, provided that the respective incomes are determined using a reasonable and consistent methodology, and that they are calculated uniformly over no more than a 24-month period; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) are satisfied.

(2) *Written certification from physician.* Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician furnishes to the hospital before the retention payment is made a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center (as defined at § 411.355(e)), or physician organization (as defined at § 411.351) that requires the physician to move the location of his or her medical practice at least 25 miles *and* outside the geographic area served by the hospital. The certification contains at least the following—

(A) Details regarding the steps taken by the physician to effectuate the employment opportunity;

(B) Details of the physician's employment opportunity, including the identity and location of the physician's future employer or employment location or both, and the anticipated income and benefits (or a range for income and benefits);

(C) A certification that the future employer is not related to the hospital making the payment;

(D) The date on which the physician anticipates relocating his or medical practice outside of the geographic area served by the hospital; and

(E) Information sufficient for the hospital to verify the information included in the written certification.

(ii) The hospital takes reasonable steps to verify that the physician has a *bona fide* opportunity for future employment that requires the physician to relocate outside the geographic area served by the hospital.

(iii) The requirements of § 411.357(e)(1)(i) through § 411.357(e)(1)(iv) are satisfied.

(iv) The retention payment does not exceed the lower of—

(A) An amount equal to 25 percent of the physician's current income (measured over no more than a 24-month period), using a reasonable and consistent methodology that is calculated uniformly; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) are satisfied.

(3) Remuneration provided under paragraph (t)(1) or (t)(2) must meet the following additional requirements:

(i)(A) The physician's current medical practice is located in a rural area or HPSA (regardless of the physician's specialty) or is located in an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The hospital does not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years.

(iii) The amount and terms of the retention payment are not altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(iv) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(4) The Secretary may waive the relocation requirement of paragraphs (t)(1) and (t)(2) of this section for payments made to physicians practicing in a HPSA or an area with demonstrated need for the physician through an advisory opinion issued in accordance with section 1877(g)(6) of the Act, if the

retention payment arrangement otherwise complies with all of the conditions of this paragraph.

(5) This paragraph (t) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(u) *Community-wide health information systems.* Items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that—

(1) The items or services are available as necessary to enable the physician to participate in a community-wide health information system, are principally used by the physician as part of the community-wide health information system, and are not provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician;

(2) The community-wide health information systems are available to all providers, practitioners, and residents of the community who desire to participate; and

(3) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(v) *Electronic prescribing items and services.* Nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to a physician who is a member of its medical staff;

(ii) Group practice (as defined at § 411.352) to a physician who is a member of the group (as defined at § 411.351); or

(iii) PDP sponsor or MA organization to a prescribing physician.

(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.

(4) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor's cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(w) *Electronic health records items and services.* Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, if all of the following conditions are met:

(1) The items and services are provided by an entity (as defined at § 411.351) to a physician.

(2) The software is interoperable (as defined at § 411.351) at the time it is provided to the physician. For purposes of this paragraph, software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the physician.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems.

(4) Before receipt of the items and services, the physician pays 15 percent of the donor's cost for the items and services. The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph, the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);

(ii) The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters, or total relative value units);

(iii) The determination is based on the total number of hours that the physician practices medicine;

(iv) The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the physician; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contribution; and

(iii) Covers all of the electronic health records items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(9) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(10) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.

(11) The electronic health records software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(12) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(13) The transfer of the items or services occurs and all conditions in this paragraph (w) are satisfied on or before December 31, 2013.

■ 8. Section 411.361 is revised to read as follows:

§ 411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing services for which payment may be made under Medicare must submit information to CMS or to the Office of Inspector General (OIG) concerning their reportable financial relationships (as defined in paragraph (d) of this section), in the form, manner, and at the times that CMS or OIG specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that furnish 20 or fewer Part A and Part B services during a calendar year, or to any Medicare covered services furnished outside the United States.

(c) *Required information.* The information requested by CMS or OIG can include the following:

(1) The name and unique physician identification number (UPIN) or the national provider identifier (NPI) of each physician who has a reportable financial relationship with the entity.

(2) The name and UPIN or NPI of each physician who has an immediate family member (as defined at § 411.351) who has a reportable financial relationship with the entity.

(3) The covered services furnished by the entity.

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent or value of the ownership or investment interest or the compensation arrangement) as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain to comply with the rules of the Internal Revenue Service and the Securities and Exchange Commission and other rules of the Medicare and Medicaid programs.

(d) *Reportable financial relationships.* For purposes of this section, a reportable financial relationship is any ownership or investment interest, as defined at § 411.354(b) or any compensation arrangement, as defined at § 411.354(c), except for ownership or investment interests that satisfy the exceptions set forth in § 411.356(a) or § 411.356(b) regarding publicly-traded securities and mutual funds.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information, upon request, within the time period specified by the request. Entities are given at least 30 days from the date of the request to provide the information. Entities must retain the information, and documentation sufficient to verify the information, for the length of time specified by the applicable regulatory requirements for the information, and, upon request, must make that information and documentation available to CMS or OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to $10,000 for each day following the deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to CMS or OIG under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

■ 9. Section 411.370 is amended by revising paragraph (a) to read as follows:

§ 411.370 Advisory opinions relating to physician referrals.

(a) *Period during which CMS accepts requests.* The provisions of § 411.370 through § 411.389 apply to requests for advisory opinions that are submitted to CMS during any time period in which CMS is required by law to issue the advisory opinions described in this subpart.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 10. 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).

Subpart B—Certification and Plan of Treatment Requirements

■ 11. In § 424.22, paragraph (d) is revised to read as follows:

§ 424.22 Requirements for home health services.

* * * * *

(d) *Limitation on the performance of certification and plan of treatment functions.* A physician who has a financial relationship, as defined at § 411.354 of this chapter, with a HHA may not certify or recertify the need for home health services or establish or review a plan of treatment for the HHA unless the financial relationship satisfies the requirements of one of the

exceptions set forth in § 411.355 through § 411.357 of this chapter.

(Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 4, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 11, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–4252 Filed 8–27–07; 3:45 pm]

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Federal Register

Wednesday,
September 5, 2007

Part III

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Hine's Emerald Dragonfly; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AU74

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Hine's Emerald Dragonfly

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are designating critical habitat for the Hine's emerald dragonfly (*Somatochlora hineana*) under the Endangered Species Act of 1973, as amended (Act). In total, approximately 13,221 acres (ac) (5,350 hectares (ha)) in 22 units fall within the boundaries of our critical habitat designation. The critical habitat units are located in Cook, DuPage, and Will Counties in Illinois; Alpena, Mackinac, and Presque Isle Counties in Michigan; and Door and Ozaukee Counties in Wisconsin.

DATES: This rule becomes effective on October 5, 2007.

FOR FURTHER INFORMATION CONTACT: John Rogner, Chicago Ecological Services Field Office, 1250 S. Grove, Suite 103, Barrington, IL 60010 (telephone: 847–381–2253, extension 11; facsimile: 847–381–2285).

SUPPLEMENTARY INFORMATION:

Background

It is our intent to discuss only those topics directly relevant to the designation of critical habitat in this rule. For information on the Hine's emerald dragonfly, please refer to our proposed critical habitat rule, which we published in the **Federal Register** on July 26, 2006 (71 FR 42442); the final listing determination, published on January 26, 1995 (60 FR 5267); or the Hine's Emerald Dragonfly (*Somatochlora hineana Williamson*) Recovery Plan (Service 2001).

Previous Federal Actions

For information about previous Federal actions for the Hine's emerald dragonfly, see our proposed critical habitat rule for the species (71 FR 42442). On March 20, 2007, we published a notice that included revisions to the proposed critical habitat, announced the availability of the draft economic analysis (DEA), and reopened the public comment period (72 FR 13061). Because we needed to meet our settlement agreement's deadline of submitting a final rule to the **Federal Register** by May 7, 2007, the comment period was reopened for only 14 days. Subsequently, we negotiated a new settlement agreement with the plaintiffs (The Center for Biodiversity *et al.*) to submit a final rule to the **Federal Register** by August 23, 2007. Therefore, on May 18, 2007, we published an additional notice that reopened the comment period on the proposal, revisions to the proposal, and the draft economic analysis for an additional 45 days (72 FR 28026). That comment period ended on July 2, 2007.

Summary of Comments and Recommendations

We requested written comments from the public on our proposed designation of critical habitat for the Hine's emerald dragonfly (71 FR 42442) and our draft economic analysis (72 FR 13061; 72 FR 28026). We contacted appropriate Federal, State, and local agencies; scientific organizations; and other interested parties and invited them to comment on the proposed rule. We also issued press releases and published legal notices in the Daily American Republic, Kansas City Star, Ozaukee News-Graphic, St. Ignace News, Door County Advocate, Alpena News, Ozaukee Press, and Joliet Herald News newspapers. We held one public hearing, on August 15, 2006, in Romeoville, Illinois.

During the comment period that opened on July 26, 2006, and closed on September 25, 2006, we received 35 comments directly addressing our proposed critical habitat designation: 6 from peer reviewers, 4 from Federal agencies, and 25 from organizations or individuals. During the comment periods from March 20, 2007 through April 3, 2007, and May 18, 2007 through July 2, 2007, we received 16 comments directly addressing the proposed critical habitat designation and the draft economic analysis. Of these latter comments, 2 were from Federal agencies and 14 were from organizations or individuals.

In total, 23 commenters supported the designation of critical habitat for the Hine's emerald dragonfly and 10 opposed the designation. Ten commenters, including three peer reviewers, supported exclusion of one or more particular units as identified in the proposed rule, and 5 commenters opposed exclusion of one or more particular units. Eighteen letters were either neutral or expressed both support of and opposition to certain portions of the proposal. Responses to comments are grouped by those received from peer reviewers, States, and the public, in the following sections. We grouped public comments into 10 general issues specifically relating to the proposed critical habitat designation and draft economic analysis. We have incorporated comments into this final rule as appropriate. We did not receive any requests for additional public hearings.

Peer Review

In accordance with our policy published on July 1, 1994 (59 FR 34270), and current Department of the Interior guidance, we solicited expert opinions from seven knowledgeable individuals with scientific expertise that included familiarity with the species, the geographic region in which the species occurs, and/or conservation biology principles. We received responses from six of the peer reviewers. We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding Hine's emerald dragonfly critical habitat. We have addressed peer reviewer comments in the following summary and have incorporated them into this final rule as appropriate.

The peer reviewers generally concurred with our methods and conclusions and provided additional information, clarifications, and suggestions to improve this final critical habitat rule. Three of the six peer reviewers specifically stated that they support our proposed designation of critical habitat, and one expressed concern that designation may be premature because the population status of the Hine's emerald dragonfly in Missouri and Michigan is not well understood. Information provided by peer reviewers included suggestions for conducting research on dispersal and habitat use that would better inform future Hine's emerald dragonfly conservation efforts, as well as comments on how to improve critical habitat rules. Peer reviewers also made suggestions and provided language to clarify biological information or make the proposed rule easier to understand. Several of the peer reviewers provided editorial comments that we have addressed in the body of this rule.

Peer Reviewer Comments

(1) *Comment:* One peer reviewer (as well as three other commenters) suggested that we should designate foraging areas (farmlands, pastures, old fields, ponds, and/or surface waters) as critical habitat.

Our response: Although adult Hine's emerald dragonflies have been observed foraging near or in these types of

habitats, the importance of such habitats in meeting the daily dietary needs of the dragonfly is still unknown. Dispersal areas are present in many of the designated critical habitat units, as they contain open areas that serve as corridors that are used by the dragonfly. In most of the units, dispersal areas are not limiting.

(2) *Comment:* One peer reviewer suggested that we use caution when accepting identifications of early instar (defined as the developmental stage on an insect between molts of its exoskeleton) larvae.

Our response: We agree that identifications of Hine's emerald dragonfly based on early instar larvae should be made with caution. Early instar larvae have been used in Missouri to document the presence of the species at new localities or to identify new Hine's emerald dragonfly breeding habitat. Identifications of early instar larvae were made by the two leading experts on Somatochlora species larvae: Dr. Tim Cashatt and Mr. Tim Vogt. These two experts wrote the definitive key to final instar larvae for the genus (Cashatt and Vogt 2001, pp. 94–97). These experts have also positively identified early instar larvae of Hine's emerald dragonfly by examining more larval specimens than any other recognized dragonfly larvae expert. Cashatt and Vogt (2001, pp. 94–97) confirmed early instar larvae identification by rearing some individuals to a final stage; this allowed preliminary determinations of the species to be confirmed. Identification of early instar larvae by these two recognized experts constitutes the best scientific data available.

(3) *Comment:* One peer reviewer commented that when the species' recovery plan was developed, the network of sites in Missouri was not known and, had the sites been known, this may have led to different recovery criteria, which may have influenced the identification of critical habitat from a scientific perspective.

Our response: Different recovery criteria may have been developed for Hine's emerald dragonfly had more sites been known in Missouri at the time the recovery plan was drafted. However, such changes to the species' recovery criteria would not have influenced our decision regarding designation of critical habitat in Missouri. We based the exclusion of Missouri sites on: (1) Current implementation of State and Federal management plans for the species; and (2) Missouri Department of Conservation's (MDC) implementation of successful conservation efforts on some private lands. The existing successful partnerships among State agencies and private property owners could be negatively affected by a critical habitat designation, and this could jeopardize future cooperative conservation efforts. We used all available data and information—including both the recovery plan and additional information gained since its development—to determine which areas are essential to the conservation of the Hine's emerald dragonfly. We will work with the Hine's Emerald Dragonfly Recovery Team in reevaluating recovery criteria when the overall status of the species is reexamined in a 5-year review.

(4) *Comment:* One peer reviewer commented that he is reluctant to assume that Hine's emerald dragonflies do not forage and roost in the forest canopy.

Our response: Hine's emerald dragonflies will use trees for roosting. Researchers have also observed Hine's emerald dragonflies foraging along the forest edge. Given that members of the genus *Somatochlora* commonly forage at treetop level along roads and utility rights of way, and dragonflies often perch in vegetation to avoid predation during their sensitive teneral stage (soft-bodied stage immediately after molt), it is possible that Hine's emerald dragonflies may utilize forest canopies to a greater extent than previously observed. There is no good information, however, to define the degree to which Hine's emerald dragonflies may use these habitats for foraging and roosting. We based our criteria to include up to 328 feet (ft) (100 meters (m)) of closed canopy forest around breeding habitat on observations made by one of the leading species experts (T. Vogt, Missouri Department of Natural Resources, in litt. March 2007); this is the best information we have available to date.

(5) *Comment:* One peer reviewer commented that in Missouri the small populations in identified sites may be elements of larger metapopulations. These individual elements, because they are so small, are probably extirpated fairly frequently even in the absence of human disturbance. For this reason, it would seem prudent to conserve suitable but currently unoccupied sites, since dispersal to such unoccupied sites must be important to the maintenance of the metapopulation. This does not necessarily mean that such sites should be designated as critical habitat for the species.

Our response: While the Hine's emerald dragonfly (*Somatochlora hineana Williamson*) Recovery Plan recognizes that the patchy nature of habitat in Illinois and Wisconsin suggests metapopulation in those two States, only three sites were known in Missouri at the time the Recovery Plan was written (Service 2001). We do not have adequate information to determine if the small populations of Hine's emerald dragonflies in Missouri are part of one or more metapopulations. Such a hypothesis is best tested by conducting various genetic analyses; genetic analyses of populations in Missouri will be initiated in the summer of 2007. Until such genetic analyses are conducted, it is difficult to assess the status of the Missouri populations of Hine's emerald dragonfly in relation to the overall distribution of the species.

(6) *Comment:* One peer reviewer stated that the rationales for exclusions are not easy to understand.

Our response: In this rule, we have attempted to further clarify the rationale for our exclusions and why these exclusions are important to the overall conservation of the Hine's emerald dragonfly.

(7) *Comment:* One peer reviewer commented that exclusion of the Missouri units based solely on the fact that the habitat is surrounded by contiguous forest does not seem justified. Without knowing anything about the dispersal ability of the species, that fact alone seems insufficient to conclude that such populations may not be important in the long-term survival of the species in Missouri.

Our response: We have described our reasons for excluding Missouri units from the critical habitat designation under the Exclusions section of this rule. We excluded those areas on the basis of existing conservation plans and partnerships, and not based on the fact that most sites are surrounded by contiguous, closed canopy forest.

(8) *Comment:* One peer reviewer suggested that we should include unoccupied habitat in areas that may serve as dispersal corridors or establish connectivity between sites in the critical habitat designation.

Our response: We attempted to include areas that will serve as dispersal corridors that are contiguous with occupied habitat within our critical habitat units. However, little is known about what factors are essential to enable the species to disperse. We designated areas that were occupied at the time of listing and not now occupied in order to allow for connectivity between units. We also included habitat out to the average dispersal distance of the species in order to maintain this dispersal capability. Not all unoccupied sites may be suitable for dispersal

corridors, however. We do not have enough scientific information to assess the importance of dispersal corridors to the conservation of the species. There are multiple reasons why Hine's emerald dragonflies may be absent from sites, even those that have all the necessary habitat requirements. Another peer reviewer noted that reasons such as interspecific interactions (e.g., with other dragonflies) could preclude Hine's emerald dragonflies in sites that have all the necessary habitat requirements. For example, in Missouri, the distribution of the Hine's emerald dragonfly may be dictated in part by the presence of large dragonfly predators that have been observed preying on individuals of the same genus (*Somatochlora*) as the Hine's emerald dragonfly.

(9) *Comment:* One peer reviewer stated that designation of critical habitat for the Hine's emerald dragonfly is premature because of the lack of knowledge on the status and population structure of the Hine's emerald dragonfly.

Our response: The Service is under a court order to complete the designation of critical habitat and submit a final rule to the **Federal Register** by August 23, 2007. Consequently, we must proceed with the critical habitat process for this species based on the best scientific data that is available, as required by the Act.

(10) *Comment:* One peer reviewer asked if management plans exist for any of the areas in Wisconsin identified in the proposal.

Our response: Lands owned by resource and conservation agencies in critical habitat units in Wisconsin do not have existing management plans that specifically address the Hine's emerald dragonfly. Those entities with conservation plans for their properties have included protective measures to conserve wetland habitat and thereby are helping to conserve the dragonfly. Those plans, however, do not specifically identify conservation measures for the Hine's emerald dragonfly.

(11) *Comment:* One peer reviewer recommended that research be conducted on dispersal, particularly female dispersal, and that we consider radio tracking, as has been done with Aeshnids (darners).

Our response: Research on dispersal is a task identified in the Hine's Emerald Dragonfly (*Somatochlora hineana* Williamson) Recovery Plan (Service 2001). The Hine's Emerald Dragonfly Recovery Team and species experts are assessing the feasibility of using a similar methodology as was used to radio track Aeshnids.

General Comments

Issue 1: Biological Justification and Methodology Used

(1A) *Comment:* Several individuals commented that the proposal did not address groundwater recharge areas.

Our response: In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, in determining what areas are critical habitat, we shall consider those physical and biological features that are essential to the conservation of the species. Some groundwater recharge areas may be included within a critical habitat unit if they co-occur with the biological and physical features essential to the conservation of Hine's emerald dragonfly. Any Federal actions that may affect critical habitat, irrespective of its location inside or outside of a critical habitat unit, are subject to section 7 consultation. This would include Federal actions that affect groundwater recharge to any of the critical habitat units.

(1B) *Comment:* One individual expressed that we did not show that the best available scientific data support the inclusion of the rail line in Illinois Units 1 and 2.

Our response: The rail line in Illinois Units 1 and 2 does not contain the primary constituent elements and, therefore, does not meet the definition of critical habitat. Therefore, we have not designated it as critical habitat. As stated in the proposal and this final rule, critical habitat does not include human-made structures existing on the effective date of a final rule and not containing one or more of the primary constituent elements. However, work performed on the rail line would be subject to the provisions of section 7 if that work could have adverse effects on designated critical habitat or the dragonfly.

(1C) *Comment:* One individual stated that it is not clear whether Wisconsin Unit 11 (containing Kellner's Fen) is sufficiently inclusive, and that this unit should also include the surrounding transitional habitat that may also contain primary constituent elements.

Our response: In designating critical habitat at Kellner's Fen, we used the same criteria we used for all the other units. We designated areas containing the primary constituent elements for the dragonfly, including wetland (fen) areas, shrubby areas, and 100 m into adjacent forest habitat. The map in the **Federal Register** is generalized, and does not show the habitat variations that actually exist within the unit.

(1D) *Comment:* One comment disputes the accuracy of the report's statement that adult dragonflies are active mid-June to mid-August.

Our response: According to the Recovery Plan (Service 2001), larvae begin to emerge as adult, possibly as early as late May in Illinois and late June in Wisconsin and continue to emerge through the summer (Vogt and Cashatt 1994; Mierzwa *et al.* 1997). The adults's know flight season lasts up to early October in Illinois (Voght and Cashatt 1994) and to late August in Wisconsin (Voght and Cashatt 1994). Fully adult Hine's emerald dragonflies can live at least 14 days and may live 4 to 6 weeks.

Issue 2: Procedural and Legal Compliance

(2A) *Comment:* Some commenters suggested that excluding Forest Service land was inappropriate as the Forest Service did not consult with the Service under section 7 of the Act. Two commenters mentioned a specific example, the Sprinkler Project on the Hiawatha National Forest, where they believed consultation was not completed. Further, the commenters suggested that designating critical habitat would ensure future consultation between the Service and Forest Service.

Our response: The Service has a cooperative relationship with the Hiawatha and Mark Twain National Forests, both of which are actively involved in endangered species management and recovery. Through this cooperative relationship, the Forest Service consistently consults on projects that may affect listed species, including the Hine's emerald dragonfly. The Forest Service recently completed section 7 consultation on Mark Twain's and Hiawatha's Land and Resource Management Plans. Several other informal and formal consultations have also been completed, including consultation on the Sprinkler Project in 2006. Section 7 consultation and conservation of Hine's emerald dragonfly will continue even with exclusion of Forest Service lands from critical habitat designation.

(2B) *Comment:* One individual commented that the proposed rule states that the conservation role of Hine's emerald dragonfly critical habitat units is to support ''viable core area populations,'' but that the proposed rule did not provide sufficient information to allow commenters to determine whether the proposed units actually contain areas that support such Hine's emerald dragonfly populations.

Our response: ''Viable'' means capable of living, developing, or reproducing under favorable conditions.

We have used the best scientific and commercial information available to determine what conditions are favorable to Hine's emerald dragonfly, and the proposal provided information on the physical and biological features essential to the conservation of the species. We identified areas that are known to contain these features, provided descriptions of the features in each unit, and are designating only those units that contain the features that are essential to the conservation of the species.

(2C) *Comment:* One commenter questioned the legality of the critical habitat designation in regards to takings.

Our response: The designation of critical habitat does not mean that private lands will be taken by the Federal government or that other legal uses will be restricted. We evaluated this rule in accordance with Executive Order (E.O.) 12630, and we believe that the critical habitat designation for the Hine's emerald dragonfly will not have significant takings implications. We do not anticipate that property values, rights, or ownership will be materially affected by the critical habitat designation.

Issue 3: Exclusions

(3A) *Comment:* Several commenters suggested that Michigan Units 1, 2, and 3 should not be excluded, because these units contain areas not covered by Federal or State management plans.

Our response: The entire acreage encompassed by Michigan Units 1 and 2, including some small areas of non-Federal land, are excluded from the final Hine's emerald dragonfly critical habitat designation. The non-Federal lands within these units are small in size relative to the unit's overall size. The larger landscapes in these two critical habitat units are managed by the Hiawatha National Forest. The Hiawatha National Forest's Land and Resource Management Plan provides for the management and protection of Hine's emerald dragonfly habitat that will facilitate the recovery of the species. Although those non-Federal lands may provide suitable habitat and primary constituent elements for colonizing dragonflies from adjacent National Forest land, their contribution to the overall recovery and conservation of the species is considered minute compared to the surrounding lands managed by the Hiawatha National Forest.

We have determined that adequate management and protection of Hine's emerald dragonfly habitat in Michigan Unit 3 is not provided by current State, Federal, or private management plans. Therefore, this unit was not excluded from the final critical habitat designation.

(3B) *Comment:* The Forest Plans for the Mark Twain and Hiawatha National Forests do not justify excluding these areas from critical habitat. Although the Forest Plan may address conservation of the Hine's emerald dragonfly, they would not provide for consultation with the Service on future Forest Service actions that may destroy or adversely modify the dragonfly's habitat. Furthermore, while the Service recognizes logging as a threat to the species, the Forest Service has recently proposed timber cutting to protect the species. Neither the Forest Service nor the Service has produced evidence that this logging proposed under the Hiawatha Forest Plan is likely to benefit the dragonfly.

Our response: The commenter is correct that a separate section 7 consultation addressing critical habitat would not be required in any excluded areas. However, as these excluded areas are currently occupied, activities that could impact Hine's emerald dragonfly (including its habitat) would still require a species-specific consultation. Based on the Forest Plans, the Forest Service not only has solidified its dedication to protect the Hine's emerald dragonfly and its habitat, but also has committed to help recover the species. The Forest Service commitment and ongoing partnership with us provide greater benefit to the species and its habitat than would critical habitat designation. Consequently, we disagree with the commenter that important breeding and foraging habitat for Hine's emerald dragonflies on the two national forests will not be protected without critical habitat designation.

If not conducted in a way that is sensitive to Hine's emerald dragonflies, logging could be detrimental to the species' habitat. At the same time, Hine's emerald dragonflies need open areas for foraging. Some areas on the Hiawatha National Forest adjacent to breeding habitat have closed canopies that could benefit from various forest management practices. Additionally, there are sites for Hine's emerald dragonflies on the Hiawatha and Mark Twain National Forests that would benefit from adding more direct dispersal corridors between breeding sites. Timber removal may be appropriate for such situations. National Forest land provides important Hine's emerald dragonfly breeding sites, and the maintenance, management, and protection of these areas will be achieved by implementing the Land and Resource Management Plans on the two forests.

(3C) *Comment:* One commenter stated that excluding habitat on lands owned by the State of Missouri would lead to no net conservation benefit to the Hine's emerald dragonfly. Designating CH would not harm our good working relationship with the MDC.

Our response: MDC owns and manages all fens on Missouri State lands with Hine's emerald dragonflies. The MDC currently implements various habitat management and conservation actions to sustain and enhance the species at these fens. Furthermore, MDC has recently updated its Conservation Area Plans and the Husman Fen Natural Area Plan to incorporate additional conservation measures for the Hine's emerald dragonfly that will ensure the long-term management and maintenance of fens. The benefits to the species resulting from conservation measures being implemented by MDC would exceed any benefit to the species gained from the designation of critical habitat. Additionally, in their comments on the proposal, MDC requested they be excluded from the critical habitat designation because they anticipate some negative effects of designation. Because of their implementation of management plans for the Hine's emerald dragonfly, we are able to accommodate this request.

(3D) *Comment:* One commenter expressed that the perception of public hostility does not justify excluding private property. That commenter believed that the lack of support from the general public was due to the Service's failure to properly educate private landowners on the minor impact of designating critical habitat on their property. The commenter stated that the exclusion of all private property in Missouri from critical habitat designation without a unit-by-unit consideration of conservation benefits and landowner amenability is arbitrary.

Our response: We have multiple examples where researchers have been denied access to private land to survey potentially new Hine's emerald dragonfly sites. In other cases, landowners who have documented Hine's emerald dragonflies on their property have been reluctant or apprehensive about taking advantage of multiple landowner incentive programs available to them due to false perceptions of critical habitat.

We, Hine's emerald dragonfly researchers, and personnel of the MDC's Private Land Services Division have extended considerable effort in providing private landowners with information on the Hine's emerald

dragonfly and outlining various landowner incentive programs. Despite the combined outreach efforts of multiple individuals, there is documented opposition by private landowners within the dragonfly's range in Missouri that is difficult to overcome. The designation of critical habitat on private property in Missouri would only exacerbate negative attitudes towards federally listed species.

We considered the conservation benefits of designating critical habitat for each unit under private ownership, as well as the benefits of excluding the area from critical habitat. We weighed the benefits of each, and concluded, using the discretion afforded to us under the Act, that actions for the conservation of the species would be best realized if the lands were excluded. Based on past experience and a strong working relationship between the MDC personnel and private landowners, we believe that private landowners are much more amenable to a partnership that emphasizes a cooperative working relationship rather than a fear of regulatory control.

(3E) *Comment:* One commenter expressed that Illinois Unit 2 should be excluded from the critical habitat designation, under section 4(b)(2) of the Act, because the substantial benefits of exclusion outweigh any potential benefits of designation and the exclusion will not result in the extinction of the species.

Our response: While the Service recognizes the cooperation of the landowners in Illinois Unit 2, formal conservation agreements or management plans have not been prepared for this unit and, therefore, the future management and protection of this unit are unknown. The landowners of this unit are in the very initial stages of developing a Habitat Conservation Plan for the species. This Habitat Conservation Plan, however, is not complete enough at this time to allow us to evaluate the conservation benefits to the species.

(3F) *Comment:* One commenter stated that Commonwealth Edison's right-of-way in Illinois Units 1–5 and 7 should be excluded because designation of these areas would put Commonwealth Edison's normal operations at severe risk. Another commenter expressed that in Illinois Units 1 and 2, the generating station, rail line, and land adjacent to those structures should be excluded.

Our response: To the greatest extent possible, we avoided including developed areas containing buildings, rail lines, electrical substations, and other urban infrastructure within critical habitat units. Where we have not been able to map out these structures we have excluded them by text. As stated in this rule, critical habitat does not include human-made structures existing on the effective date of a final rule not containing one or more of the primary constituent elements (see definition of ''primary constituent elements'' in subsequent section). Therefore, human-made structures including utility poles, power lines, rail lines, and the generating station are not included in the critical habitat designation. However, areas around the human-made structures that consist of habitat containing the primary constituent elements of Hine's emerald dragonfly habitat are included in the designation.

Although Commonwealth Edison has been a valued partner in the conservation of Hine's emerald dragonfly, and is one of the parties involved in the preparation of a Habitat Conservation Plan for the species, no management plans for their right of way currently exist.

(3G) *Comment:* Three commenters expressed that the life of a forest plan is likely shorter than the time it will take to recover the Hine's emerald dragonfly. They added that there is no guarantee that the forest plans would be in place or implemented in the future. Therefore, they question the exclusion of Forest Service land in Michigan and Missouri.

Our response: The intended cycle of National Forest plans is 10–15 years. The Mark Twain and Hiawatha National Forest Land and Resource Management Plans were approved in 2005 and 2006, respectively. As identified in the Hine's Emerald Dragonfly (*Somatochlora hineana* Williamson) Recovery Plan, anticipated recovery of the Hine's emerald dragonfly could occur as early as 2019 (Service 2001). While we concur that it is likely that current management plans for the Mark Twain and Hiawatha National Forests will expire before the Hine's emerald dragonfly can be recovered, we believe that the track record of cooperation between us and the two national forests outlines the Forest Service's commitment to the conservation of federally listed species under sections 7(a)(1) and 7(a)(2) of the Act. Once the current plans have expired, we are confident that both the Mark Twain and Hiawatha National Forests will complete consultation on the new plans. These consultations will further ensure that actions outlined in future land and resource management plans will not jeopardize the continued existence of any federally listed species, including the Hine's emerald dragonfly. We believe that standards and guidelines established for the Hine's emerald dragonfly will continue to contribute to the conservation of the species until it is recovered and removed from the list of federally protected species. If plans change such that it affects our balancing, we will reconsider whether to designate critical habitat in these areas.

(3H) *Comment:* One commenter expressed that we should exclude Illinois Units 1, 2, and 3 because of long-term stakeholder commitment and the Habitat Conservation Plan that is being written.

Our response: Though we are pleased with the progress made to date on the Habitat Conservation Plan, it is still far from complete. It is too early to judge its ultimate outcome. At this early stage, the developing Habitat Conservation Plan is not complete enough for us to evaluate whether habitat for the Hine's emerald dragonfly would be appropriately managed. Generally we do not consider excluding an area from critical habitat based on a draft Habitat Conservation Plan until the conservation measures have been determined, an environmental analysis has been completed and released for public review, and we have determined that issuing the associated incidental take permit would not result in a jeopardy or adverse modification finding for the species or its critical habitat. Therefore, we are not excluding Illinois Units 1, 2, and 3 at this time. When the Habitat Conservation Plan is completed, we will be able to evaluate its conservation benefits to the species and, if appropriate, revise the critical habitat designation to exclude this unit.

(3I) *Comment:* One commenter concluded that there is no reasonable basis for excluding privately owned sites in Missouri and designating Illinois Units 1 and 2. Excluding units in Missouri suggests that similarly situated parties are being treated differently.

Our response: Threats identified for the Hine's emerald dragonfly on private land in Missouri are addressed through close coordination among personnel with the MDC's Private Land Services Division or Regional Natural History biologists and private landowners. Additionally, MDC personnel work closely and proactively with the National Resources Conservation Service (NRCS) and the Service's Partners for Fish and Wildlife Program to initiate management and maintenance actions on privately owned fens occupied by the Hine's emerald dragonfly that benefit the species and alleviate potential threats.

One site on private property in Missouri is owned and managed by The

Nature Conservancy through the implementation of a site-specific plan (The Nature Conservancy 2006, pp. 1–4) that maintains fen habitat. One site under private ownership is a designated State Natural Area that is managed by the MDC through a site-specific plan (Missouri Natural Areas Committee 2007). This plan ensures that the integrity of the fen is maintained (Missouri Natural Areas Committee 2007). However, at this time there are no conservation plans in place for Illinois Units 1 and 2 that would guide the implementation of similar measures. In addition, Illinois Unit 1 is a publicly owned site.

(3J) *Comment:* One commenter was concerned with the exclusion of large areas of lands in Michigan and Missouri based solely on the existence of management plans. The commenter suggested that given the uncertainties surrounding funding and implementation, the Service should consider designating these areas. Another commenter opposed exclusion of Michigan Units because the Hine's emerald dragonfly is mobile, and designation of all possible habitat areas is necessary to support increased numbers of the species. Furthermore, the commenter suggested that, by excluding critical habitat areas, we spent more time and money on the designation process.

Our response: While available funding will likely impact the amount of Hine's emerald dragonfly conservation work that occurs in any one year, we are confident that the Forest Service will continue to place a high emphasis and priority on their obligation to contribute to the conservation of the species. In addition, State land management agencies in Missouri are committed to the implementation of recovery actions outlined in their management plans. Because of this commitment, land management agencies in Missouri and Michigan are already actively implementing conservation actions for the Hine's emerald dragonfly and fen habitat. The designation of critical habitat would not influence them to act more proactively.

In evaluating which areas to exclude, we requested and reviewed management plans and other relevant information. This analysis was conducted for all of the Hine's emerald dragonfly habitat areas we identified as meeting the definition of critical habitat. For excluded units, more time was spent on reviewing pertinent information, addressing public comments, and incorporating public input than for designated critical habitat units. This, however, was not due to the exclusion process, but rather to the amount of pertinent information available for these units (Forest Service Land and Resource Management Plans, other management plans, etc.) and the large number of public comments associated with exclusion. The evaluation and incorporation of relevant information and public comment was a necessary part of our critical habitat designation.

Issue 4: Economic Issues

(4A) *Comment:* The proposed critical habitat rule states that ''[t]o the extent that designation of critical habitat provides protection, that protection can come at significant social and economic cost'' (71 FR 42443). Two commenters contend that there is no evidence that ''social or economic'' costs apply to the Hine's emerald dragonfly critical habitat designation and that some private landowners have recognized that critical habitat designation poses no social or economic threat. Furthermore, the economic and social benefits of critical habitat designation are ignored.

Response: The draft economic analysis evaluates the potential economic costs associated with critical habitat designation, and also discuses the benefits of critical habitat designation. Based on our economic analysis, estimated future costs associated with conservation efforts for the dragonfly in areas designated as critical habitat range from $16.8 million to $47.9 million (undiscounted) over the next 20 years. The present value of these impacts, applying a 3 percent discount rate, is $13.4 million to $35.6 million ($0.9 million to $2.4 million annualized); or $10.7 million to $26.0 million, applying a 7 percent discount rate ($1.0 million to $2.5 million annualized).

The published economics literature has documented that social welfare benefits can result from the conservation and recovery of endangered and threatened species. In its guidance for implementing Executive Order 12866, OMB acknowledges that it may not be feasible to monetize, or even quantify, the benefits of environmental regulations due to either an absence of defensible, relevant studies or a lack of resources on the implementing agency's part to conduct new research. Rather than rely on economic measures, the Service believes that the direct benefits of the proposed rule are best expressed in biological terms that can be weighed against the expected cost impacts of the rulemaking. Critical habitat designation may also generate ancillary benefits. Critical habitat aids in the conservation of species specifically by protecting the primary constituent elements on which the species depends. To this end, critical habitat designation can result in maintenance of particular environmental conditions that may generate other social benefits aside from the preservation of the species. That is, management actions undertaken to conserve a species or habitat may have coincident, positive social welfare implications, such as the preservation of open space in a region. While they are not the primary purpose of critical habitat, these ancillary benefits may result in gains in employment, output, or income that may offset the direct, negative impacts to a region's economy resulting from actions to conserve a species or its habitat. It is often difficult to evaluate the ancillary benefits of critical habitat. To the extent that the ancillary benefits of the rulemaking may be captured by the market through an identifiable shift in resource allocation, they are factored into the overall economic impact assessment. For example, if habitat preserves are created to protect a species, the value of existing residential property adjacent to those preserves may increase, resulting in a measurable positive impact. Ancillary benefits that affect markets are not anticipated in this case and therefore are not quantified.''

(4B) *Comment:* One commenter suggested that the proposal was premature and legally deficient because it lacked an economic analysis.

Our response: Pursuant to the Act, and clarified in our implementing regulations at 50 CFR 424.19, we are required to, ''after proposing designation of [a critical habitat] area, consider the probable economic and other impacts of the designation upon proposed or ongoing activities.'' The purpose of the draft economic analysis is to determine and evaluate the potential economic effects of the proposed designation. In order to develop an economic analysis of the effects of designation critical habitat, we need to have identified an initial proposed critical habitat designation. Following publication of the critical habitat proposal for the Hine's emerald dragonfly, we developed a draft economic analysis of the proposed designation that was made available for public review and comment on March 20, 2007, for 14 days, and reopened for public review and comment on May 18, 2007, for 45 days. On the basis of information received during the public comment periods, we may, during the development of our final critical habitat determination, find that areas proposed are not essential, are appropriate for exclusion under section 4(b)(2) of the

Act, or are not appropriate for exclusion. An area may be excluded from critical habitat if it is determined that the benefits of such exclusion outweigh the benefits of including a particular area as critical habitat, unless the failure to designate such area as critical habitat will result in the extinction of the species. We have not, however, excluded any areas from the final designation based on economic reasons.

(4C) *Comment:* One commenter expressed that Midwest Generation's rail line and immediately adjoining areas in Illinois Units 1 and 2 should be excluded from critical habitat based on economic impacts, and they provided an independent economic analysis of alternative coal delivery systems.

Our response: On March 20, 2007, we issued an economic analysis that addressed these issues. As stated above and in the proposed rule ''critical habitat does not include human-made structures existing on the effective date of a final rule not containing one or more of the primary constituent elements.'' The rail line is not part of Illinois Units 1 and 2 because it was excluded by text from the proposal rule and from this final rule. Areas around the rail line that are not human-made but contain at least one primary constituent element are included. We determined that the relatively minor economic costs as described in the draft economic analysis do not justify excluding those areas from critical habitat.

(4D) *Comment:* One commenter expressed concerns about the effects of critical habitat designation on the future of the State snowmobile trail system in Door County, Wisconsin, and on improvements to, and installation of, new trails. Concerns include loss of the State trail corridor, which could bankrupt snowmobile clubs in the area, and loss of associated tourist revenue in Door County.

Our response: While the designation of critical habitat for the Hine's emerald dragonfly does not directly affect private landowners without a Federal nexus, it does alert them to the presence of an endangered species on their land and the need to ensure that their activities are consistent with the conservation of the species. Snowmobiling activity on upland areas in the winter will not affect the dragonfly, as adults are not flying in winter and the larval stage overwinters in crayfish burrows in wetlands. Construction and maintenance of snowmobile trails in upland locations at any time of year are not anticipated to affect the dragonfly. If construction and maintenance activities are planned in or near wetland areas occupied by the dragonfly, measures should be taken to preclude adversely affecting the wetlands or their hydrology. The Service's Green Bay Ecological Services Field Office can be contacted for guidance on ways to preclude harm to the dragonfly's habitat (by calling 920–866–1717). As we anticipate that snowmobiling activities will not be adversely affected by designation of critical habitat, we do not anticipate impacts to tourist revenues associated with snowmobiling in Door County.

(4E) *Comment:* One commenter stated that it was unclear from information in the economic analysis whether a determination had been made regarding exclusion of additional areas from the designation of critical habitat for all or some of the units in Illinois based on economic impact.

Our response: The purpose of the economic analysis is to identify and analyze the potential economic impacts associated with the proposed critical habitat designation for the Hine's emerald dragonfly. The economic analysis did not make a determination about any exclusions. The economic analysis is conducted to inform the Secretary's decision about exclusions. The final determination is made in this rule. Based on the information in the draft economic analysis and the comments received during the public comment period, we are not excluding any areas based on economic impacts.

(4F) *Comment:* One comment asserts that there is little (if any) economic activity in Alpena, Mackinac, or Presque Isle Counties in Michigan. The comment asserts that declining populations in these counties is evidence of minimal economic activity.

Our response: The methodology used to obtain land values is discussed in Section 2.1 of the economic analysis, and the land values for each potential critical habitat units are presented in Exhibit 2–3. These values reflect the level of actual economic activity in these counties. The land in the three Michigan counties that coincides with the study area is valued at $1,430 per ac in Alpena County; $4,380 per ac in Presque Isle County; and $1,510 per ac in Mackinac County. The land value estimates for economic impacts in these counties (for units MI 3, MI 4, MI 5, and MI 6) were obtained from local zoning and tax assessor officials in these counties. The price of land in the present constitutes the expected value of current and potential future values of that land. Each of the proposed critical habitat units are near waterfront access and roads, which may make them valuable now or in the future.

(4G) *Comment:* Two comments state that the economic analysis fails to define an appropriate baseline, specifically: (1) The analysis of future conservation measures as co-extensive is unjustified; and (2) the inclusion of past costs associated with the proposed critical habitat as consequences of the critical habitat designation is erroneous.

Our response: (1) The economic analysis includes co-extensive costs because courts and the public have asked to see us display all of the costs of critical habitat, whether or not these costs are co-extensive with other causes. (2) The economic analysis explains why past costs are included in the introduction of Chapter 1. The retrospective analysis of past costs is included to provide context for future costs, and in some cases to help predict them. The Service is not suggesting that these costs are a result of the critical habitat designation. Reporting of past costs is also reviewed in Section 1.4, where their inclusion is justified on the basis that past costs may have contributed to the efficacy of the Act in that area.

(4H) *Comment:* Two comments state that the economic analysis does not include benefits in the analysis. The unquantified benefits they list are: protection of ecosystem services; increased recreational and wildlife opportunities; reduced flood risks; concurrent conservation of other species; enhanced groundwater recharge; mosquito reduction; existence value of the dragonfly; protection of other species; wetland protection; decreased use of pesticides, chemicals, and herbicides; and potentially higher property values. One of the comments provides testimony of landowners who want to preserve the dragonfly on their property as evidence of existence value. This comment then proceeds to list several non-use valuation techniques. Another comment argues that the benefits should be expressed in monetary terms rather than in biological terms.

Our response: Potential benefits from critical habitat designation are discussed in Section 1.4 of the economic analysis, which recognizes the valuation methodologies discussed by the commenter. The section then describes the policy of the Service whereby benefits are expressed in biological terms. This section also discusses how ancillary benefits are not expected in the case of the Hine's Emerald Dragonfly. The Federal Office of Management and Budget (OMB) has acknowledged that it may not be

feasible to monetize or quantify benefits because there may be a lack of credible, relevant studies, or because the agency faces resource constraints that would make benefit estimation infeasible (U.S. OMB, ''Circular A–4,'' September 17, 2003, available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf.*).

(4I) *Comment:* One comment states that the economic analysis does not explain how the results of the analysis will be used in the critical habitat designation process.

Our response: In the introduction to Chapter 1, the Framework for Analysis states that the economic analysis will be used to weigh the benefits of excluding particular proposed critical habitat areas against the benefits of including them.

(4J) *Comment:* One comment states that the economic analysis does not consider the effects of other land use regulations that may affect how land can be developed or used, and that value losses attributed to critical habitat designation may be improperly attributed.

Our response: Land use regulations and how they affect land values are discussed in Section 2.1 of the economic analysis, in the context of Exhibit 2–3. First, the analysis explains that present land values will reflect the opportunities for development of that land. In this way, the present value of land incorporates all current and expected future regulatory constraints upon land use (Freeman 2003).

As an illustration, consider three identical parcels, one which housing can be built on with certainty, one which may or may not be subject to regulatory constraints that prohibit the construction of housing, and one where housing construction is absolutely prohibited. The price of the parcel where housing can be built (with certainty) will incorporate the option value for that housing and will sell for the highest price. The parcel where housing may or may not be built due to uncertainties about future regulation will sell for less than the parcel on which housing can be built with certainty, but will sell for more than the parcel where no housing can be built. The market price for land is net of the expected effect of current or future regulations. As described in Section 2.1 of the economic analysis, the GIS process for determining land values took into account zoning regulations and ownership types before determining land values from tax parcel records and interviews with zoning and planning officials. Impacts in this analysis are predicted using the best publicly available data for reasonably foreseeable land uses.

(4K) *Comment:* One comment argues that the assumption that the value of land is immediately lost is erroneous because there is imperfect information in markets.

Our response: Section 2.1 of the economic analysis provides an explanation of how real estate markets work, and how current prices are the market's best prediction of future land values. It is correct that all consumers are not perfectly informed about products in a marketplace. In the real estate market, a lack of knowledge can result in a higher or lower property value. In the case of a newly regulated market, this would mean that buyers would still be willing to pay too much for the property.

The goal of the analysis in Section 2.1 is to predict the market equilibrium outcome. Limited information among buyers may cause them to pay too much for the property in the short run, but once the market is informed, everyone will pay the true (lower) market equilibrium value. There are many studies that have empirically shown that, though there may be imperfect information among some potential buyers, real estate markets respond quickly to changes in land use regulation (Kiel 2005; Guttery *et al.* 2000). The assumptions used in this analysis are based on the best available information.

(4L) *Comment:* One comment states that the economic analysis improperly inflates the lost value of development because including all land values as lost development values assumes that these lands are certain to be developed, and there is no certainty that the land will be developed.

Our response: Section 2.1 of the economic analysis addresses this in its discussion of how real estate prices adjust to expectations about future property uses. This analysis does not assume that all lands are certain to be developed. The present price per parcel of land incorporates the expected value of potential current and future uses of that land, regardless of when, or if, the land is ever developed. If current and potential uses are taken away, or if the quality of the land declines, the price of the land parcel will decrease (Quigley and Rosenthal 2005; Kiel and McClain 1995). Even the perception that the quality of the land may change can affect real estate values (Kiel and McClain 1996). Land that can be developed will command a higher price because it could be developed (even if it is never developed), and it is that expected value that the analysis considers.

(4M) *Comment:* One comment states that the economic analysis fails to establish a proper baseline because it does not consider potential regulatory changes or changes in market demand. The comment does not specify what specific changes are likely other than potential changes due to global warming or peaked oil production. A similar comment suggests that the assumption that a dolomite mine in Illinois Unit 2 will close because of critical habitat designation does not consider the impact of unknown future events.

Our response: Section 2.1 of the economic analysis reviews the data sources and analytic procedures used to assess the potential value losses over the next 20 years. These data are the best data that are publicly available and as such provide the basis for the prediction of impacts for reasonably foreseeable land uses under expected future conditions. While costs attributable to critical habitat may result from other factors, we cannot speculate about future events. We must use the best information available to us at the time of the analysis.

(4N) *Comment:* One comment states that the economic analysis estimates of lost property values are incorrect because the analysis does not consider changes to the value of properties outside the study area. The comment argues that if some parcels of land are removed from the market, then other parcels of land will increase in value by the amount of the decrease in land value lost, so that the net economic effect will be zero change.

Our response: The potential for land use restrictions to affect neighboring properties is a valid concern. If there are no substitute parcels available in the vicinity of the parcel to be regulated (no other land that could be sold), then the price for land in that location will be driven up, and there will be a net gain for surrounding landowners, which could offset (fully or partially) the loss of value for the critical habitat units. However, if substitute parcels of land are plentiful in the vicinity of the critical habitat, then the consumer will have many options to choose from, and will not have to pay a higher price for substitute parcels, hence there will be no increase in surrounding land values (Quigley and Swoboda 2006).

Section 2.1 of the economic analysis discusses the possibility that the amount of land available for development in the vicinity of the study area could be very limited. However, the area of land under consideration for designation as well as the value of that

land indicates that there will not be a significant impact on the local real estate market. That is, the amount of land that could be removed from development is not believed to be enough to increase surrounding land values. Results from sampling multiple listing services in Michigan and Wisconsin indicate that limiting residential development on vacant parcels will not have a substantial impact on the local land markets. That is, prices of surrounding parcels are unlikely to change and it is unlikely that there will be welfare changes because there are many substitute parcels for the critical habitat units.

Sampling of Alpena County, Michigan found 146 parcels; the 50 sampled parcels had an average size of 24.5 ac, and an average asking price of approximately $68,000. Sampling of Mackinac County, Michigan found 229 parcels; the 50 sampled parcels had an average size of 5.8 acres, and an average asking price of approximately $90,000. Sampling of Presque Isle County, Michigan found 255 parcels; the 50 sampled parcels had an average size of 23 ac, and an average asking price of approximately $81,000. Sampling of the Door County (Wisconsin) Realtors Multiple Listing Service found approximately 550 vacant parcels of various sizes; the 50 sampled properties had an average size of 4.15 ac and an average asking price of approximately $66,000. This information is now included in Section 2.1.

(4O) *Comment:* One comment states that the limitation on resource extraction values in Illinois Unit 2 would not have had an effect because the losses in value would be offset by increases in values to competitors. The comment says that the analysis does not consider whether other companies will profit if Material Services Corporation cannot mine the parcel in critical habitat. The comment also argues that the DEA does not consider the fact that there may be lower cost companies that would profit more if the limitation were passed.

Our response: The magnitude of the dolomite deposits in Illinois Unit 2 relative to the rest of the Illinois dolomite market is discussed in Section 2.2.1 of the DEA. The annual revenue from the dolomite mine in Illinois Unit 2 is estimated to be $500,000. As noted in the report, the annual extraction of dolomite in Illinois has an approximate value of $470 million. Approximate dolomite revenues for Will County specifically (the county containing the mine in Illinois Unit 2) are $94 million. While losses of $500,000 per year to the mining company will be substantial, the expected revenues from this single mine are not significant relative to the entire market. That is, not allowing the dolomite in Illinois Unit 2 to be mined will not cause prices faced by competing companies to change; competitors will make no offsetting welfare gains (Just et al. 2004).

The commenter suggests that other companies may be able to compensate for decreased mining activity in Illinois Unit 2 by increasing operations at other facilities, and that there will be no net loss to society. The commenter is correct that any shortfall due to the mine being unable to operate will likely be made up by other places (especially since the magnitude of the mine is small relative to the overall market). There will still be, however, the lost resource value for the company that is not allowed to mine this specific property.

The comment also contends that another mine may have lower costs, and that increased operations at that mine may be more efficient. At this time, there are no publicly available data concerning different cost structures for dolomite mining companies.

(4P) *Comment:* One comment states that the DEA does not consider alternative uses for the land in Illinois Unit 2 if the mine is not allowed to operate. The comment suggests that there might be wildlife viewing values for the property, or that the limitation on the mine would make nearby house values increase.

Our response: The commenter makes a valid point; alternate land uses are not considered in this estimation for this proposed unit. In section 2.2.1 of the DEA, the analysis reports the mitigation costs of conservation that would be required to offset mining activities as well as the value lost if mining is not allowed. If mining is not allowed, there may be other uses for the property, but the values of the uses will be negligible compared to the lost mining resource value. It is unlikely that there could be significant economic benefits from preserving this parcel from mining. Visual inspection of Exhibit 1 in Appendix F shows that Illinois Unit 2 is located in an industrial corridor. In fact, the area proposed for the mine is surrounded by previously mined areas and industrial or transportation facilities. These location specifics make it unlikely that residential property values would be increased if the mine does not operate; there are no houses nearby and the effect of the industrial corridor that the mine is a part of will have a value dampening effect. There is not likely to be any increase in wildlife viewing values from a critical habitat designation, as the designation does not make any private land available to the public for wildlife viewing, nor does it increase the ability of the public to view wildlife on public lands where such viewing would be available even absent the designation.

(4Q) *Comment:* One comment states that the economic analysis fails to include other alternatives to deep water wells as potential means to offset decreases in the water table. This comment argues that water conservation measures and storm water conservation regulations should be included as alternative water management strategies in the analysis.

Our response: Section 3.1 of the DEA describes the threat of water depletion and Section 3.1.1 discusses residential consumption and the methodology that was taken to calculate estimated costs for deep aquifer well drilling. The section contends that one potential remedy for depletion of groundwater levels (and subsequent habitat impacts) is to drill municipal wells into the deep aquifer to meet current and future water demands, as discussed by the Service. Other adaptive behaviors may be feasible, but there are no publicly available data available to model them.

(4R) *Comment:* One comment states that the estimation of costs to drill deep aquifer wells assumes that these wells would not be drilled for population increases if critical habitat designation did not occur; and thus their inclusion inflates the cost estimates.

Our response: The argument that deep aquifer wells may be drilled regardless of the habitat designation is valid. The analysis does assume that new wells will be drilled in response to population growth. However, the analysis states that the presence of critical habitat could prompt new wells to be drilled into the deep aquifer instead of the upper aquifer. The estimated impact due to critical habitat designation is the projected difference between the cost of deep and upper aquifer wells for future population growth. Section 3.1.1 of the DEA discusses residential consumption of water and how population growth estimates are used to predict the number of new wells that will be needed. It is not known whether any new wells will be drilled, and if drilled, whether they will be drilled into the upper or lower aquifer (though upper aquifer wells are less expensive). It is for this reason that both a low (no deep aquifer well costs) estimate is included with a high estimate (which assumes all deep aquifer costs are in response to the dragonfly). The range of costs between the low (zero) and high estimates spans the potential costs for water use mitigation that may occur in these

proposed critical habitat units. The use of a range of estimates addresses the concerns about the uncertainty of whether deep aquifer wells would be drilled or not in response to population increases.

(4S) *Comment:* One comment states that the inclusion of invasive species control costs as co-extensive is inappropriate, since other species may have been affected.

Our response: The economic analysis discusses invasive species control measures and costs in Section 6.3. Invasive species control was listed as a threat to the species and a potential adverse affect to critical habitat in the proposed rule. Invasive species control has been ongoing in most critical habitat units and will continue regardless of the presence of Hine's emerald dragonfly or the designation of critical habitat.

(4T) *Comment:* One comment addresses the estimation of impacts from the Interstate-355 extension in Chapter 2 of the DEA. This comment states that ''total costs for I–355-related development activities range from a low of $11.8 million to a high of $18 million. This number includes opportunity costs to vehicles that have to slow down due to the presence of the dragonfly, since the Illinois Department of Transportation (IDOT) chose to build the road through dragonfly habitat * * *.'' The comment also states that the costs that are discussed will occur before the designation takes place. The comment then states that the DEA does not consider the possibility that IDOT could have decided to not build this road due to the presence of the dragonfly.

Our response: In Section 2.3.2 of the DEA, past costs are estimated to be $1.8 million (undiscounted), as shown in Exhibit 2–7. Future costs are estimated to be $2.3 million (undiscounted) as shown in Exhibit 2–8. The economic analysis does not address speed limits on roads through dragonfly habitat in this section. The costs for the interstate extension do not involve any traffic slowing costs, since the interstate extension is being built eight feet higher than it otherwise would be built to avoid dragonfly collisions (hence avoiding the need for a limited speed zone); see Section 2.3.2. The costs to build the roadway higher are included in the analysis. Opportunity costs from lost time due to speed limits to avoid take of dragonflies are estimated for other units—IL 7, WI 4, and WI 5. (The costs for the I–355 extension are in unit IL 4.)

The comment that these costs will be realized before designation is partially correct. Exhibit 2–7 displays the costs of mitigation and conservation through 2006. The costs in Exhibit 2–8 include costs incurred from 2007 through 2026. These costs include costs incurred in the current year, since this is an ongoing project, and costs may be incurred during the proposal period. Most of the dragonfly-specific costs are attributed to the future period (2007–2026).

The economic analysis does not provide economic estimates for a scenario in which the overpass is not built. The overpass construction was substantially underway when the proposed rule considering designation was published. Since the Illinois Toll-way Authority had made several conservation and mitigation efforts for the dragonfly, these impacts were included in the analysis.

(4U) *Comment:* One comment states that the economic analysis fails to include all the relevant information concerning travel time lost due to speed limitations on passenger trains in the analysis. Specifically, the comment states that the analysis does not include time lost for riders of METRA commuter trains, nor does it consider the value of passenger time lost (as well as additional fuel costs) for deceleration in preparation for, and acceleration after, the limited speed zone.

Our response: The commenter raises some valid concerns. The economic estimates (Section 5.1) were based upon the best publicly available data at the time. Newly available ridership information for METRA (which was initially omitted) and actual ridership information for AMTRAK (which had been overestimated by a factor of five by the AMTRAK source IEc contacted initially), and adding in the time value lost and additional fuel costs due for acceleration and deceleration, increases the vehicle slowing costs for Illinois unit 7 from $12.6 million to $13.7 million (undiscounted). This corresponds to an increase in costs from $9.7 million to $10.5 million (discounted at 3 percent), and from $7.1 million to $7.8 million (discounted at 7 percent). These cost increases are insufficient to change the rank orderings of units by level of impact for the high-end estimates (see Exhibit ES–6).

(4V) *Comment:* One comment states that the value of increased train carbon emissions from the deceleration and acceleration are also not quantified for these actions.

Our response: The commenter is correct; the economic analysis does not quantify increased emission levels due to deceleration and acceleration. The marginal quantities of emissions are not likely to be substantial. In addition, there is no emission trading market for mobile source diesel fuel emissions. In the absence of such a market, cost estimates for additional carbon pollution would be speculative.

(4W) *Comment:* One comment states that the economic analysis does not include the costs in increased traffic congestion from train riders switching to commuting by car that a speed limitation on AMTRAK and METRA commuter rail trains passing through Illinois Unit 7 would generate.

Our response: The commenter is correct. This comment is concerned with the estimation of values in Exhibit 5–3, Section 5.1 of the DEA. New calculations based on information obtained during the comment period quantified the increased delay for causing the AMTRAK and METRA to decelerate from 79 miles per hour (mph) to 15 mph, travel 15 miles per hour for one quarter mile, then accelerate back to a speed of 79 mph.

The estimated time delays are minimal and thus unlikely to be sufficient to cause many travelers to switch to automobile travel. The additional time taken for deceleration would be 36 seconds. The additional time taken for traveling 15 mph for one quarter mile (mi) would be 45 seconds. The increase in travel time for acceleration would be 40 seconds. The total (an additional two minutes and one second) of travel time is highly unlikely to cause train travelers to switch to travel by automobile, especially since the road that runs parallel to the track that would have the speed limits will be subject to the same speed limit as well; travel times on the roadway will increase by at least 3.25 minutes. These estimates, and their derivation, are discussed in Section 5.1

The economic literature on mode-split indicates that an increase in travel time on a commuter train is unlikely to cause much of a shift to car use. Mode-split studies measure how sensitive travelers are to changes in the cost of traveling. An increase of ten percent of travel time on a commuter train during peak commuting time will cause a one percent increase in demand for commuting by automobile (Lago and McEnroe 1981). The additional delay in unit IL 7 may cause a small increase in travel by car. However, the literature indicates that commuters who travel by rail are not very sensitive to small increases in travel times. The estimated change in demand cited above is illustrative of general behavior; there are no publicly available models or data for modeling this specific situation.

(4X) *Comment:* One comment questions the accuracy of projected cost estimates in Exhibit 4–8 relative to the

information provided. The comment is specifically concerned with the dates of anticipated costs from 2011–2014 and from 2007–2026.

Our response: The costs that the comment is concerned with are listed in Exhibit 4–8, Section 4.3 of the DEA. These estimates were obtained from documents provided by Midwest Generation concerning costs they have incurred and expect to incur for work done on the railroad line in Illinois Units 1 and 2. The calculations used to spread costs over the periods 2011–2014 and 2007–2026 were not presented in the draft economic analysis. These calculations are now included in Exhibit 4–8.

Future (long-term) rehabilitation costs from 2011 to 2014 are listed in a document submitted by Midwest Generation during the public comment period. The document is entitled ''List of Midwest Generation's Environmental Activities Associated with the Rail Line and HED Commitments.'' The end of the first paragraph of that document concludes: ''Long term maintenance items should be implemented in the four to seven year range * * *.'' Four years from the final rule is 2011 and seven years from the proposed rule is 2014. Accordingly, the long-term rehabilitation costs are spread over those years. These are the costs estimated to take place from 2011 to 2014.

(4Y) *Comment:* One comment states that railroad maintenance and culvert maintenance should not be considered threats. The comment states, ''The Service contends that this process is maintenance that the railroad would have to do regardless of the dragonfly, but recognizes that undercutting, combined with the construction of approximately 4 new French drains, and regular culvert maintenance may be potential options for mitigating the hydraulic pumping problem.''

Our response: Specific types of railroad maintenance, combined with undercutting, are listed in Section 5.2 of the DEA as mitigation measures that respond to the specific threat of the hydraulic pumping of sediments. As discussed in Chapter 4 of the DEA, maintenance activities may also pose threats to critical habitat. A clarifying sentence has been added to the referenced paragraph in the DEA: ''While regular maintenance may help mitigate the hydraulic pumping problem, maintenance activities may still pose a threat to critical habitat. An additional clarifying footnote was added following this sentence: ''There are types and methods of railroad maintenance that may be employed without threatening the dragonfly or its habitat; Section 4.3 addresses the additional costs of performing such dragonfly sensitive maintenance.''

(4Z) *Comment:* One comment states there is no concession stand in unit WI 5.

Our response: This apparent error occurs in Section 2.2.3 There is an interpretive center/gift store located in WI 5. This store is referred to as a ''concession'' in local zoning documents. This confusion has been clarified in the text.

Issue 5: Site-Specific Issues

(5A) *Comment:* Two commenters suggested that we designate multiple areas of unoccupied habitat in Michigan, including the Stonington Peninsula, Garden Peninsula, Munuscong Bay, Drummond Island, Pointe Aux Chenes River, Wilderness State Park, and others. Additionally, the commenters suggested we designate multiple areas in Michigan where the Hine's emerald dragonfly has been observed on site or within two mi of a known locality.

Our response: We did not designate unoccupied habitat listed by the commenters because there are no current or historic records documenting the presence of the species at these sites. In 2006, the Hiawatha National Forest conducted surveys on the Stonington Peninsula and did not document the presence of Hine's emerald dragonflies from this locality.

With regard to sites where the Hine's emerald dragonfly has been observed or where it was observed within a 2-mi radius, we used the methodology outlined under the section of this rule on ''Criteria Used to Identify Critical Habitat''. In drawing the outer boundary of a unit, we extended the unit boundary from the dragonfly larval habitat up to 100 meters where the PCEs are found unless we reached areas that did not contain the PCEs before that 100 meters, such as a closed canopy forest, roadway, or another natural or human-made break in habitat. This is to provide foraging areas for the species. A small number of dragonfly observations do not fall within a critical habitat unit. For instance, a one-time observation of a single foraging Hine's emerald dragonfly would not provide enough information to adequately determine the location of the core breeding habitat. We believe that there could be undiscovered Hine's emerald dragonfly breeding sites in Michigan, but using the best scientific data currently available, we have identified the six breeding areas in Michigan of which we are aware.

Issue 6: Effects of Critical Habitat Designation

(6A) *Comment:* One private landowner was concerned that the designation of critical habitat may affect current or planned activities. Specifically, the commenter was concerned about delays or disruptions to future plans to expand or enhance an existing rail line, which would require Federal permits.

Our response: Critical habitat designation does not preclude development. Section 7(a)(2) of the Act requires Federal agencies to consult with the Service to ensure that actions they fund, authorize, permit, or otherwise carry out will not jeopardize the continued existence of any listed species or adversely modify designated critical habitat. If the Federal action agency determines that a project may adversely affect a listed species or designated critical habitat, formal consultation is required. There is a designated period of time in which to consult (90 days), and beyond that, another set period of time for the Service to prepare a biological opinion (45 days). The analysis of whether the proposed action would likely jeopardize the continued existence of the species or adversely modify designated critical habitat is contained in the biological opinion. If a jeopardy or adverse modification determination is made, the biological opinion must identify any reasonable and prudent alternatives that could allow the project to move forward.

Issue 7: Philosophy on Utility of Critical Habitat

(7A) *Comment:* Two commenters expressed that they disagree with the statement in the proposal that critical habitat designations are driven by litigation and courts rather than biology. They argue that while many critical habitat designations are the result of litigation, it is only to the extent that the Service fails to meet its statutory obligation to designate critical habitat concurrently with listing and that it is a burden imposed by an unambiguous statutory mandate, not by litigation.

Our response: The section in the proposed rule that contained these statements (''The Role of Critical Habitat in Actual Practice of Administering and Implementing the Act'') has been removed from this final rule.

(7B) *Comment:* Two commenters suggested that critical habitat designation is strongly associated with species recovery and that the Service must consider the role of critical habitat in the recovery of the species.

Our response: We agree that we must consider the role of critical habitat in the recovery of species. The Ninth Circuit Court's decision in *Gifford Pinchot Task Force* v. *United States Fish and Wildlife Service*, 378 F.3d 1059 (9th Cir 2004) (hereinafter Gifford Pinchot) requires consideration of the recovery of species. Thus, under this court ruling, and our implementation of Section 7 of the Act, critical habitat designations may provide greater benefits to the recovery of a species. Also, we have found that critical habitat designations serve to educate landowners, State and local governments, and the public regarding the potential conservation value of the areas designated.

(7C) *Comment:* One commenter expressed that the Hawaii example in the proposal does not prove that excluding areas from critical habitat provides superior conservation benefits to designating critical habitat.

Our response: Each exclusion from critical habitat designation is considered on its own merits, after balancing the benefits of designation against the benefits of exclusion, and also considering whether the exclusion will result in the extinction of the species.

Issue 8: Unoccupied Habitat

(8A) *Comment:* Two commenters suggested that the Service consider designating areas that would contribute to the species' recovery through reintroduction, introduction, and augmentation efforts, as recommended in the species' recovery plan.

Our response: Although introductions and reintroductions were identified as being potentially important in the 2001 recovery plan, the Service acknowledged that additional surveys needed to be completed (Service 2001, p. 59). Since the recovery plan was written, additional Hine's emerald dragonfly breeding sites were identified in Illinois, Michigan, Missouri, and Wisconsin. Other unidentified sites may also exist in these States. Therefore, at this time we believe that introduction into unoccupied, potential habitat or reintroduction of dragonflies into additional historically occupied, but currently unoccupied, habitat may not be necessary to recover the species. As additional research is conducted on the population structure and status of the species, the Service will consider the necessity of introduction and reintroduction of the Hine's emerald dragonfly.

Issue 9: Mapping

(9A) *Comment:* Some commenters stated that the maps and descriptions of critical habitat units lacked sufficient detail to determine what essential features are included, what the surrounding land uses are, whether specific properties are included, and whether certain structures are included. Furthermore, they state that the maps should be provided in geological information system and aerial photography formats.

Our response: The scale of the maps prepared under the parameters for publication within the *Code of Federal Regulations* may not be detailed enough to allow landowners to determine whether their property is within the designation. Therefore, when the final rule is published, we will provide more detailed maps on our web site to better inform the public. We also provided contact information for anyone seeking assistance with the proposed critical habitat. Therefore, we believe we made every effort to provide avenues for interested parties to obtain information concerning our proposal and supporting information.

Issue 10: General Comments and Other Relevant Issues

(10A) *Comment:* One commenter stated that critical habitat designation is a ''waste of taxpayers' time and money.''

Our response: The designation of critical habitat for federally listed species is a requirement under section 4(a)(3)(A) of the Act.

(10B) *Comment:* One commenter expressed that the presence of habitat should have stopped the Interstate–355 (I–355) construction project. The commenter added that projects like the I–355 expansion project show that designation of critical habitat is justified.

Our response: If a species is listed or critical habitat is designated, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. As a result of this consultation, compliance with the requirements of section 7(a)(2) will be documented through the Service's issuance of: (1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or (2) a biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

The I–355 project required a permit from the Army Corp of Engineers, which established a Federal nexus, and was addressed under a formal consultation, pursuant to section 7(a)(2) of the Act. As part of that formal consultation, conservation measures were agreed to that require the project proponent to fund actions to conserve the Hine's emerald dragonfly and its habitat. The Service concluded that the I–355 project would not jeopardize the continued existence of the Hine's emerald dragonfly.

(10C) *Comment:* One commenter stated that the designation of critical habitat should recognize the importance of protecting genetic diversity through habitat conservation. Specifically, the Hine's emerald dragonfly population in Illinois may contain greater genetic diversity than the other populations. Thus, the importance of protecting habitats in this State is heightened.

Our response: Genetic analysis is identified as a task in the Hine's Emerald Dragonfly (*Somatochlora hineana* Williamson) Recovery Plan (Service 2001). We are attempting to acquire funding to complete genetic analysis in order to better understand the population structure of the species. The designation of critical habitat was based on the best available information. All currently occupied areas in Illinois are included in the critical habitat designation for this and other reasons.

(10D) *Comment:* Two commenters stated that the Service must address Executive Order 13211 and prepare a Statement of Energy Effects, if applicable. Also, the Service must offer an opportunity to comment on any Statement of Energy Effects before making a final determination on the designation.

Our response: Executive Order 13211 was addressed in the Economic Analysis that was announced in the Notice of Availability published on March 20, 2007, and is addressed again in this final rule.

(10E) *Comment:* One commenter is concerned that the proposal infers that Midwest Generation's train traffic is contributing to mortality of Hine's emerald dragonflies and that rail line operations are increasing sediment deposition.

Our response: Vehicular impacts to Hine's emerald dragonflies, including collisions resulting in mortality, have been documented in areas within the species' range. However, since Midwest Generation limits the speed of its trains to 4 to 6 mph in Illinois Units 1 and 2, we have determined that train traffic in these units is not resulting in direct mortality of Hine's emerald dragonflies.

We believe that sediment being released from the rail line ballast in

Illinois Units 1 and 2 may be impacting Hine's emerald dragonfly larval habitat. This potential threat is currently being assessed and will be addressed in the Habitat Conservation Plan under development for these units.

(10F) *Comment:* One commenter expressed that human-made structures should be a part of critical habitat.

Our response: We only include areas that contain at least one of the physical and biological features essential to the conservation of the species. Human-made structures are not essential features of the species' habitat.

Comments From States

Section 4(i) of the Act states, ''the Secretary shall submit to the State agency a written justification for his/her failure to adopt regulation consistent with the agency's comments or petition. Comments were received from the Illinois Department of Natural Resources (ILDNR), MDC, Michigan Department of Natural Resources (MIDNR) and Michigan Department of Environmental Quality (MIDEQ). Comments supporting the proposed rule were received from the ILDNR and MDC. Additional comments received from States regarding the proposal to designate critical habitat for the Hine's emerald dragonfly are addressed below.

(1) *State Comment:* The Michigan Department of Natural Resources commented that Michigan Units 3, 4, and 5 are partially owned by their agency. As these areas are owned by the State they are afforded protection under land management policies.

Our response: In general, we considered excluding State lands from the final critical habitat designation. Mud Lake/Snake Island Fens, a portion of Michigan Unit 3, is owned by MDNR and is a designated natural area. Much of Michigan Unit 4 is part of Thompson's Harbor State Park. A portion of Michigan Unit 5, approximately 65 acres, is state forest land and managed under Forest Certification Work Instructions. State ownership and the various designations bestowed upon these lands may afford some nonspecific protection for Hine's emerald dragonfly and its habitat. However, we only excluded State or Federal lands that had management plans identifying necessary management and protection efforts for Hine's emerald dragonfly or the PCEs. Therefore, Michigan Units 3, 4, and 5 are included in the final critical habitat designation.

(2) *State Comment:* The Michigan Department of Environmental Quality (MDEQ) emphasized that the State of Michigan has assumed the Federal Clean Water Act section 404 program that provides wetland fill permits. The MDEQ avers that a State, not a Federal, permit is issued; thus, section 7 consultation is not required. However, when reviewing a permit application that could affect a federally listed species or critical habitat, the MDEQ coordinates with the U.S. Environmental Protection Agency (USEPA) and the Service. The MDEQ may incorporate appropriate measures into a permit, thereby avoiding or minimizing impacts to listed species and addressing Federal concerns. The MDEQ cannot issue a permit over the objection of the USEPA Regional Administrator.

Our response: We appreciate MDEQ's dedication to and cooperation in conserving federally listed species. We agree that the approach outlined above is the process we currently use in reviewing section 404 permit applications under the state-assumed program in Michigan.

Summary of Changes From Proposed Rule

The area contained in Wisconsin Unit 1 has been amended. The map and the description of the area for Wisconsin Unit 1 were accurate in the proposed rule; however, the acreage for the unit was incorrect. The error was due to using information from an earlier, larger draft of the map for this unit. Therefore, the acreage has been corrected from 503 ac (204 ha) in the proposed rule to 157 ac (64 ha) in the final rule.

As discussed in the July 26, 2006, proposal (71 FR 42442), additional sites in Wisconsin were evaluated to determine if they contain the features that are essential for the conservation of the Hine's emerald dragonfly. Based on our evaluation of research results from 2006 fieldwork, we have determined that Kellner's Fen in Door County, Wisconsin, contains the features that are essential to the conservation of Hine's emerald dragonfly. Adult Hine's emerald dragonflies have been observed in this area and breeding habitat exists in this unit, although breeding has not yet been confirmed. We announced the proposed addition of this unit in the **Federal Register** on March 20, 2007, and are adding this unit to the critical habitat designation. The additional critical habitat unit, Wisconsin Unit 11, is described in the unit descriptions below.

We are excluding Michigan Units 1 and 2 (Hiawatha National Forest lands), and all Missouri Units (1–26), from the final designation of critical habitat because we believe that the benefits of excluding these specific areas from the designation outweigh the benefits of including the specific areas. We believe that the exclusion of these areas from the final designation of critical habitat will not result in the extinction of the Hine's emerald dragonfly. These exclusions are discussed in more detail in the Exclusions section below.

Critical Habitat

Critical habitat is defined in section 3 of the Act as—(i) the specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring any endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the prohibition against destruction or adverse modification of critical habitat with regard to actions carried out, funded, or authorized by a Federal agency. Section 7 requires consultation on Federal actions that are likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow government or public access to private lands. Section 7 is a purely protective measure and does not require implementation of restoration, recovery, or enhancement measures.

To be included in a critical habitat designation, the habitat within the area occupied by the species must first have features that are essential to the conservation of the species. Critical habitat designations identify, to the extent known using the best scientific

data available, habitat areas that provide essential life cycle needs of the species (areas on which are found the primary constituent elements, as defined at 50 CFR 424.12(b)).

Habitat occupied at the time of listing may be included in critical habitat only if the essential features thereon may require special management or protection. Thus, we do not include areas where existing management is sufficient to conserve the species. (As discussed below, such areas may also be excluded from critical habitat pursuant to section 4(b)(2).) Accordingly, when the best available scientific data do not demonstrate that the conservation needs of the species require additional areas, we will not designate critical habitat in areas outside the geographical area occupied by the species at the time of listing. An area currently occupied by the species but that was not occupied at the time of listing will likely, but not always, be essential to the conservation of the species and, therefore, is typically included in the critical habitat designation.

Our Policy on Information Standards Under the Act, published in the **Federal Register** on July 1, 1994 (59 FR 34271), and Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106–554; H.R. 5658) and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions represent the best scientific data available. They require Service biologists to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat. When determining which areas are critical habitat, we primarily use the listing package for the species. Additional information sources include the recovery plan for the species, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, or other unpublished materials and expert opinion or personal knowledge. All information is used in accordance with the provisions of Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658) and the associated Information Quality Guidelines issued by the Service.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Habitat is often dynamic, and species may move from one area to another over time. Furthermore, we recognize that designation of critical habitat may not include all of the habitat areas that may eventually be determined to be necessary for the recovery of the species. For these reasons, critical habitat designations do not signal that habitat outside the designation is unimportant or may not be required for recovery.

Areas that support populations, but are outside the critical habitat designation, will continue to be subject to conservation actions implemented under section 7(a)(1) of the Act and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard, as determined on the basis of the best available information at the time of the action. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCP), or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome.

Primary Constituent Elements

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, in determining which areas to designate as critical habitat, we consider those physical and biological features (PCEs) that are essential to the conservation of the species, and within areas occupied by the species at the time of listing, that may require special management considerations and protection. These include, but are not limited to space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, and rearing (or development) of offspring; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species.

The specific PCEs required for the Hine's emerald dragonfly are derived from the biological needs of this species as described in the proposed critical habitat designation published in the **Federal Register** on July 26, 2006 (71 FR 42442).

Primary Constituents for the Hine's Emerald Dragonfly

Pursuant to our regulations, we are required to identify the known physical and biological features (PCEs) essential to Hine's emerald dragonfly conservation. All areas designated as Hine's emerald dragonfly critical habitat are occupied, within the species' historic geographic range, and contain sufficient PCEs to support at least one life history function.

This designation is designed for the conservation of those areas containing PCEs necessary to support the life history functions that were the basis for the designation. Because not all life history functions require all the PCEs, not all critical habitat will contain all the PCEs.

Units occupied at the time of listing are designated based on sufficient PCEs being present to support one or more of the species' life history functions. All units designated for this species contain all PCEs and support multiple life processes.

Based on our current knowledge of the life history, biology, and ecology of the species and the requirements of the habitat to sustain the essential life history functions of the species, we have determined that the Hine's emerald dragonfly's PCEs are:

(1) For egg deposition and larval growth and development:

(a) Organic soils (histosols, or with organic surface horizon) overlying calcareous substrate (predominantly dolomite and limestone bedrock);

(b) Calcareous water from intermittent seeps and springs and associated shallow, small, slow flowing streamlet channels, rivulets, and/or sheet flow within fens;

(c) Emergent herbaceous and woody vegetation for emergence facilitation and refugia;

(d) Occupied burrows maintained by crayfish for refugia; and

(e) Prey base of aquatic macroinvertebrates, including mayflies, aquatic isopods, caddisflies, midge larvae, and aquatic worms.

(2) For adult foraging; reproduction; dispersal; and refugia necessary for roosting, resting, escape from male harassment, and predator avoidance (especially during the vulnerable teneral stage):

(a) Natural plant communities near the breeding/larval habitat which may include fen, marsh, sedge meadow, dolomite prairie, and the fringe (up to 328 ft (100m)) of bordering shrubby and forested areas with open corridors for movement and dispersal; and

(b) Prey base of small, flying insect species (*e.g.*, dipterans).

Each of the areas designated in this rule that were occupied at the time of listing has been determined to contain sufficient PCEs to provide for one or

more of the life history functions of the Hine's emerald dragonfly. In some cases, the PCEs exist as a result of ongoing Federal actions. As a result, ongoing Federal actions at the time of designation will be included in the baseline in any consultation conducted subsequent to this designation.

Criteria Used To Identify Critical Habitat

We are designating critical habitat in areas we have determined were occupied at the time of listing, and that contain sufficient PCEs to support life history functions essential to the conservation of the Hine's emerald dragonfly. Lands are designated based on sufficient PCEs being present to support the life processes of the species. All lands designated as critical habitat for this species contain all PCEs and support multiple life processes. We are also designating areas that were not occupied at the time of listing, but which were subsequently identified as being occupied, and which we have determined to be essential to the conservation of the Hine's emerald dragonfly.

To identify features that are essential to the conservation of the Hine's emerald dragonfly and areas essential to the conservation of the species, we considered the natural history of the species and the science behind the conservation of the species as presented in literature summarized in the Hine's Emerald Dragonfly (*Somatochlora hineana* Williamson) Recovery Plan (Service 2001).

We began our analysis of areas with features that are essential to the conservation of the Hine's emerald dragonfly by identifying currently occupied breeding habitat. We developed a list of what constitutes occupied breeding habitat with the following criteria: (a) Adults and larvae documented; (b) Larvae, exuviae (skin that remains after molt), teneral (newly emerged) adults, ovipositing females, and/or patrolling males documented; or (c) Multiple adults sighted and breeding conditions present. We determined occupied breeding habitat through a literature review of data in reports submitted during section 7 consultations and as a requirement from section 10(a)(1)(B) incidental take permits or section 10(a)(1)(A) recovery permits; published peer-reviewed articles; academic theses; and agency reports. We then determined which areas were occupied at the time of listing.

After identifying the core occupied breeding habitat, our second step was to identify contiguous habitat containing one or more of the PCEs within 2.5 mi (4.1 kilometers (km)) of the outer boundary of the core area (Mierzwa *et al.* 1995, pp.17–19; Cashatt and Vogt 1996, pp. 23–24). This distance, the average adult dispersal distance measured in one study, was selected as an initial filter for determining the outer limit of unit boundaries in order to ensure that the dragonflies would have adequate foraging and roosting habitat, corridors among patches of habitat, and the ability to disperse among subpopulations. However, based on factors discussed below, unit boundaries were significantly reduced in most cases based on the contiguous extent of PCEs and the presence of natural or human-made barriers. When assessing wetland complexes in Wisconsin and Michigan we determined that features that fulfill all of the Hine's emerald dragonfly's life history requirements are often within 1 mi (1.6 km) of the core breeding habitat; therefore, the outer boundary of those units is within 1 mi (1.6 km) of the core breeding habitat.

Areas not documented to be occupied at the time of listing but that are currently occupied are considered essential to the conservation of the species due to the limited numbers and small sizes of extant Hine's emerald dragonfly populations. Recovery criteria established in the recovery plan for the species (Service 2001, pp. 31–32) call for a minimum of three populations, each containing at least three subpopulations, in each of two recovery units. Within each subpopulation there should be at least two breeding areas, each fed by separate seeps and springs. Management and protection of all known occupied areas are necessary to meet these goals.

When determining critical habitat boundaries, we made every effort to avoid including developed areas such as buildings, paved areas, and other structures and features that lack the PCEs for the species. The scale of the maps we have prepared under the parameters for publication within the *Code of Federal Regulations* may not reflect the exclusion of all such developed areas. Any such structures and the land under them inadvertently left inside critical habitat boundaries shown on the maps of this final rule are excluded from this rule by text and are not designated as critical habitat. Therefore, Federal actions limited to these areas would not trigger section 7 consultation, unless they affect the species and/or PCEs in critical habitat.

Units were identified based on sufficient PCEs being present to support Hine's emerald dragonfly life processes. All units contain all PCEs and support multiple life processes.

A brief discussion of each area designated as critical habitat is provided in the unit descriptions below. Additional detailed documentation concerning the essential nature of these areas is contained in our supporting record for this rulemaking.

Special Management Considerations or Protections

When designating critical habitat, we assess whether the areas determined to be occupied at the time of listing contain the features essential to the conservation of the species and whether they may require special management considerations or protections. At the time of listing, the Hine's emerald dragonfly was known to occur in Illinois and Wisconsin. As discussed in more detail in the proposed critical habitat designation (July 16, 2006; 71 FR 42442) and in the unit descriptions below, we find that the areas we are designating may require special management considerations or protections due to threats to the species or its habitat. Such management considerations and protections include: management of invasive species and all terrain vehicle use and protection of habitat from threats of commercial and residential development, alteration of water regimes, contamination, and recreational activities.

Critical Habitat Designation

We are designating 22 units as critical habitat for the Hine's emerald dragonfly. The critical habitat areas described below constitute our best assessment at this time of areas determined to be occupied at the time of listing, that contain the PCEs essential for the conservation of the species, and that may require special management, and those additional areas not occupied at the time of listing but that have been determined to be essential to the conservation of the Hine's emerald dragonfly. Management and protection of all the areas is necessary to achieve the conservation biology principles of representation, resiliency, and redundancy (Shaffer and Stein 2000) as represented in the recovery criteria established in the recovery plan for the species.

Table 1 shows the units that were occupied at the time of listing and those that are currently occupied but were not identified at the time of listing. Table 2 identifies the areas that meet the definition of critical habitat but were excluded from final critical habitat based on their species-specific management plans or partnerships.

TABLE 1.—UNITS THAT WERE OCCUPIED BY THE HINE'S EMERALD DRAGONFLY AT THE TIME OF LISTING OR ARE CURRENTLY OCCUPIED

Unit	Occupied at time of listing	Occupied currently	Acres/hectares
Illinois Unit 1	X		419/170
Illinois Unit 2	X		439/178
Illinois Unit 3	X		337/136
Illinois Unit 4	X		607/246
Illinois Unit 5	X		326/132
Illinois Unit 6	X		387/157
Illinois Unit 7	X		480/194
Michigan Unit 3		X	50/20
Michigan Unit 4		X	959/388
Michigan Unit 5		X	156/63
Michigan Unit 6		X	220/89
Wisconsin Unit 1		X	157/64
Wisconsin Unit 2	X		814/329
Wisconsin Unit 3	X		66/27
Wisconsin Unit 4		X	407/165
Wisconsin Unit 5	X		3,093/1,252
Wisconsin Unit 6	X		230/93
Wisconsin Unit 7	X		352/142
Wisconsin Unit 8		X	70/28
Wisconsin Unit 9		X	1,193/483
Wisconsin Unit 10		X	2,312/936
Wisconsin Unit 11		X	147/59

TABLE 2.—AREAS DETERMINED TO MEET THE DEFINITION OF CRITICAL HABITAT FOR THE HINE'S EMERALD DRAGONFLY THAT WERE EXCLUDED FROM THE CRITICAL HABITAT DESIGNATION

Geographic area	Definitional areas (acres/hectares)	Area excluded from final designation (acres/hectares)	Reason*
Michigan Unit 1	9,452/3,825	All	1
Michigan Unit 2	3,511/1,421	All	1
Missouri Unit 1	90/36	All	1
Missouri Unit 2	34/14	All	1
Missouri Unit 3	18/7	All	2, 3
Missouri Unit 4	14/6	All	1
Missouri Unit 5	50/20	All	1
Missouri Unit 6	22/9	All	2, 3
Missouri Unit 7	33/13	All	1
Missouri Units 8, 9, 10	333/135	All	1, 2, 3
Missouri Unit 11	113/46	All	1, 2, 3
Missouri Unit 12	50/20	All	2, 3
Missouri Unit 13	30/12	All	2, 3
Missouri Unit 14	14/5	All	2, 3
Missouri Unit 15	11/4	All	2, 3
Missouri Unit 16	4/2	All	1
Missouri Units 17 and 18	224/91	All	1, 2, 3
Missouri Units 19 and 20	115/47	All	2, 3
Missouri Unit 21	6/2	All	1
Missouri Unit 22	32/13	All	1
Missouri Units 23 and 24	75/31	All	1
Missouri Unit 25	33/13	All	1
Missouri Unit 26	5/2	All	1
Total	14,269/5,774	14,269/5,774	

*1 = species specific management plan in place; 2 = potential loss of partnership with private land owner; 3 = existing strong working relationship between MDC and private land owners.

Table 3 provides the approximate area encompassed within each critical habitat unit determined to meet the definition of critical habitat for the Hine's emerald dragonfly.

TABLE 3.—CRITICAL HABITAT UNITS DESIGNATED FOR THE HINE'S EMERALD DRAGONFLY

Unit	State land (acres/ hectares)	Local and private land (acres/ hectares)	Total (acres/ hectares)
Illinois Unit 1	.....	419/170	419/170
Illinois Unit 2	.....	439/178	439/178
Illinois Unit 3	.....	337/136	337/136
Illinois Unit 4	.....	607/246	607/246
Illinois Unit 5	.....	326/132	326/132
Illinois Unit 6	.....	387/157	387/157
Illinois Unit 7	130/53	350/142	480/194
Michigan Unit 3	23/9	27/11	50/20
Michigan Unit 4	875/354	84/34	959/388
Michigan Unit 5	65/26	91/37	156/63
Michigan Unit 6	.....	220/89	220/89
Wisconsin Unit 1	42/17	115/47	157/64
Wisconsin Unit 2	32/13	782/316	814/329
Wisconsin Unit 3	.....	66/27	66/27
Wisconsin Unit 4	.....	407/165	407/165
Wisconsin Unit 5	816/330	2277/922	3,093/1,252
Wisconsin Unit 6	200/81	30/12	230/93
Wisconsin Unit 7	.....	352/142	352/142
Wisconsin Unit 8	.....	70/28	70/28
Wisconsin Unit 9	684/277	509/206	1,193/483
Wisconsin Unit 10	1512/612	800/324	2,312/936
Wisconsin Unit 11	.....	147/59	147/59
Total	4,379/1,772	8,842/3,578	13,221/5,350

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for the Hine's emerald dragonfly, below.

Illinois Unit 1—Will County, Illinois

Illinois Unit 1 consists of 419 ac (170 ha) in Will County, Illinois. This unit was occupied at the time of listing and includes the area where the Hine's emerald dragonfly was first collected in Illinois as well as one of the most recently discovered locations in the State. All PCEs for the Hine's emerald dragonfly are present in this unit. Adults and larvae are found within this unit. The unit consists of larval and adult habitat with a mosaic of upland and wetland communities, including fen, marsh, sedge meadow, and dolomite prairie. The wetlands are fed by groundwater that discharges into the unit from seeps and upwelling that have formed small, flowing streamlet channels that contain crayfish burrows. Known threats to the PCEs in this unit that may require special management include ecological succession and encroachment of invasive species; illegal all-terrain vehicles; utility and road construction and maintenance; management and land use conflicts; and groundwater depletion, alteration, and contamination. The majority of the unit is a dedicated Illinois Nature Preserve that is managed and leased by the Forest Preserve District of Will County. Although a current management plan is in place, it does not specifically address the Hine's emerald dragonfly or its PCEs. This unit also consists of a utility easement that contains electrical transmission and distribution lines and a railroad line used to transport coal to a power plant. In addition, a remaining small portion of this unit is located between a sewage treatment facility and the Des Plaines River. This unit is planned to be incorporated in a HCP that is being pursued by a large partnership, which includes the landowners of this unit. Though we are pleased with the progress made to date on the HCP, it is still far from complete. It is too early to judge its ultimate outcome.

Illinois Unit 2—Will County, Illinois

Illinois Unit 2 consists of 439 ac (178 ha) in Will County, Illinois. This unit was occupied at the time of listing and has repeated adult and larval observations. All PCEs for the Hine's emerald dragonfly are present in this unit. The unit consists of larval and adult habitat with a mosaic of plant communities including fen, marsh, sedge meadow, and dolomite prairie. The wetlands are fed by groundwater that discharges into the unit from seeps and upwelling that have formed small flowing streamlet channels that contain crayfish burrows. Known threats to the PCEs in this unit that may require special management include ecological succession and encroachment of invasive species; utility and road construction and maintenance; management and land use conflicts; and groundwater depletion, alteration, and contamination. The unit is privately owned and includes a utility easement that contains electrical transmission and distribution lines and a railroad line used to transport coal to a power plant. This unit is planned to be incorporated in a HCP that is being pursued by a large partnership, which includes the landowners of this unit. Though we are pleased with the progress made to date on the HCP, it is still far from complete. It is too early to judge its ultimate outcome.

Illinois Unit 3—Will County, Illinois

Illinois Unit 3 consists of 337 ac (136 ha) in Will County, Illinois. This unit was occupied at the time of listing and includes one of the first occurrences of Hine's emerald dragonfly known after the discovery of the species in Illinois. All PCEs for the Hine's emerald dragonfly are present in this unit. The unit consists of larval and adult habitat with a mosaic of upland and wetland communities including fen, sedge meadow, marsh, and dolomite prairie. The wetlands are fed by groundwater that discharges into the unit from seeps and upwelling that have formed small flowing streamlet channels that contain crayfish burrows. Known threats to the PCEs in this unit that may require special management include ecological

succession and encroachment of invasive species; utility and road construction and maintenance; management and land use conflicts; and groundwater depletion, alteration, and contamination. The majority of the unit is a dedicated Illinois Nature Preserve that is owned and managed by the Forest Preserve District of Will County. Although a current management plan is in place, it does not specifically address the Hine's emerald dragonfly. This unit also consists of a utility easement that contains electrical transmission and distribution lines. This unit is planned to be incorporated in a HCP that is being pursued by a large partnership, which includes the landowners of this unit. Though we are pleased with the progress made to date on the HCP, it is still far from complete. It is too early to judge its ultimate outcome.

Illinois Unit 4—Will and Cook Counties, Illinois

Illinois Unit 4 consists of 607 ac (246 ha) in Will and Cook Counties in Illinois. This unit was occupied at the time of listing and includes one of the first occurrences of Hine's emerald dragonfly that was verified after the discovery of the species in Illinois. All PCEs for the Hine's emerald dragonfly are present in this unit. Repeated observations of both adult and larval Hine's emerald dragonfly have been made in this unit. The unit consists of larval and adult habitat with a mosaic of upland and wetland communities including fen, sedge meadow, and dolomite prairie. The wetlands are fed by groundwater that discharges into the unit from seeps and upwelling that have formed small flowing streamlet channels that contain crayfish burrows. Known threats to the PCEs in this unit that may require special management include ecological succession and encroachment of invasive species; utility and road construction and maintenance; management and land use conflicts; and groundwater depletion, alteration, and contamination. The unit is owned and managed by the Forest Preserve District of Will County and the Forest Preserve District of Cook County. Construction of the Interstate 355 extension began in 2005 and the corridor for this project intersects this unit at an elevation up to 67 ft (20 m) above the ground to minimize potential impacts to Hine's emerald dragonflies. This unit also consists of a utility easement that contains electrical transmission lines.

Illinois Unit 5—DuPage County, Illinois

Illinois Unit 5 consists of 326 ac (132 ha) in DuPage County, Illinois. This unit was occupied at the time of listing and has repeated adult observations. All PCEs for the Hine's emerald dragonfly are present in this unit. The unit consists of larval and adult habitat with a mosaic of upland and wetland plant communities including fen, marsh, sedge meadow, and dolomite prairie. The wetlands are fed by groundwater that discharges into the unit from seeps and upwelling that have formed small flowing streamlet channels that contain crayfish burrows. Known threats to the PCEs in this unit that may require special management include ecological succession and encroachment of invasive species; utility and road construction and maintenance; management and land use conflicts; and groundwater depletion, alteration, and contamination. The majority of the unit is owned and managed by the Forest Preserve District of DuPage County. This unit also consists of a railroad line and a utility easement with electrical transmission lines.

Illinois Unit 6—Cook County, Illinois

Illinois Unit 6 consists of 387 ac (157 ha) in Cook County, Illinois. This unit was occupied at the time Hine's emerald dragonfly was listed. All PCEs for the Hine's emerald dragonfly are present in this unit. There have been repeated adult observations as well as observations of teneral adults and male territorial patrols suggesting that breeding is occurring within a close proximity. The unit consists of larval and adult habitat with a mosaic of upland and wetland plant communities including fen, marsh, and sedge meadow. The wetlands are fed by groundwater that discharges into the unit from seeps that have formed small flowing streamlet channels that contain crayfish burrows. Known threats to the PCEs in this unit that may require special management include ecological succession and encroachment of invasive species; utility and road construction and maintenance; management and land use conflicts; and groundwater depletion, alteration, and contamination. The area within this unit is owned and managed by the Forest Preserve District of Cook County.

Illinois Unit 7—Will County, Illinois

Illinois Unit 7 consists of 480 ac (194 ha) in Will County, Illinois. This unit was occupied at the time of listing and includes one of the first occurrences of Hine's emerald dragonfly known after the discovery of the species in Illinois. All PCEs for the Hine's emerald dragonfly are present in this unit. Adults and larvae have been found within this unit. The unit consists of larval and adult habitat with a mosaic of upland and wetland communities including fen, marsh, sedge meadow, and dolomite prairie. The wetlands are fed by groundwater that discharges into the unit from seeps and upwelling that have formed small flowing streamlet channels that contain crayfish burrows. Known threats to the PCEs in this unit that may require special management include ecological succession and encroachment of invasive species; utility and road construction and maintenance; management and land use conflicts; and groundwater depletion, alteration, and contamination. A portion of the unit is a dedicated Illinois Nature Preserve that is managed and owned by the ILDNR. This unit also consists of a railroad line and a utility easement that contains electrical distribution lines. This unit is planned to be incorporated in an HCP that is being pursued by a large partnership, which includes the landowners of this unit. Though we are pleased with the progress made to date on the HCP, it is still far from complete. It is too early to judge its ultimate outcome.

Michigan Unit 3—Mackinac County, Michigan

Michigan Unit 3 consists of 50 ac (20 ha) in Mackinac County on Bois Blanc Island in Michigan. This area was not known to be occupied at the time of listing but is currently occupied. All PCEs for the Hine's emerald dragonfly are present in this unit. The unit contains one breeding area for Hine's emerald dragonfly with male territorial patrols and more than 10 adults observed in 1 year. The unit contains a small fen that is directly adjacent to the Lake Huron shoreline and forested dune and swale habitat that extends inland. The unit contains seeps and small fens, some areas with marl. Threats to the unit include maintenance of utility and road right of way, and development of private lots and septic systems. Road work and culvert maintenance could change the hydrology of the unit. Approximately half of the unit is owned by the State of Michigan, the remaining portion of the area is owned by The Nature Conservancy or is subdivided private land. This unit is essential to the conservation of the species because it provides habitat essential to accommodate populations of the species to meet the conservation principles of redundancy and resiliency throughout the species range.

Michigan Unit 4—Presque Isle County, Michigan

Michigan Unit 4 consists of 959 ac (388 ha) in Presque Isle County in the

northern lower peninsula of Michigan. This area was not known to be occupied at the time of listing but is currently occupied. All PCEs for the Hine's emerald dragonfly are present in this unit. The unit contains one breeding area for Hine's emerald dragonfly, with female oviposition and adults observed in more than 1 year. The unit contains a fen with seeps and crayfish burrows present. The fen has stunted, sparse white cedar and marl flats dominated by spike rush (*Eleocharis*). The threats to Hine's emerald dragonflies in this unit are unknown. The majority of this unit is a State park owned by the MIDNR, the remainder of the unit is privately owned. This unit is essential to the conservation of the species because it provides habitat essential to accommodate populations of the species to meet the conservation principles of redundancy and resiliency throughout the species range.

Michigan Unit 5—Alpena County, Michigan

Michigan Unit 5 consists of 156 ac (63 ha) in Alpena County in the northern lower peninsula of Michigan. This area was not known to be occupied at the time of listing but is currently occupied. All PCEs for the Hine's emerald dragonfly are present in this unit. The unit contains one breeding area for Hine's emerald dragonfly, with adults observed in more than one year and crayfish burrows present. The unit contains a mixture of northern fen and wet meadow habitats that are used by breeding and foraging Hine's emerald dragonfly. Threats to this unit include possible hydrological modification due to outdoor recreational vehicle use and a nearby roadway. The majority of the site is privately owned and the remaining acreage is owned by the State of Michigan. This unit is essential to the conservation of the species because it provides habitat essential to accommodate populations of the species to meet the conservation principles of redundancy and resiliency throughout the species range.

Michigan Unit 6—Alpena County, Michigan

Michigan Unit 6 consists of 220 ac (89 ha) in Alpena County in the northern lower peninsula of Michigan. This area was not known to be occupied at the time of listing but is currently occupied. All PCEs for the Hine's emerald dragonfly are present in this unit. The unit contains one breeding area for Hine's emerald dragonfly, with male territorial patrols and adults observed. The unit contains a marl fen with numerous seeps and rivulets important for breeding and foraging Hine's emerald dragonfly. In the area of this unit, trash dumping, home development, and outdoor recreational vehicles were observed impacting similar habitat. The unit is owned by a private group. This unit is essential to the conservation of the species because it provides habitat essential to accommodate populations of the species to meet the conservation principles of redundancy and resiliency throughout the species range.

Wisconsin Unit 1—Door County, Wisconsin

Wisconsin Unit 1 consists of 157 acres (64 hectares) on Washington Island in Door County, Wisconsin. This unit was not known to be occupied at the time of listing but is currently occupied. All PCEs for the Hine's emerald dragonfly are present in this unit. Three adults were observed at this site in July 2000, as well as male territorial patrols and female ovipositioning behavior; crayfish burrows, seeps, and rivulet streams are present. The unit consists of larval and adult habitat including boreal rich fen, northern wet-mesic forest, emergent aquatic marsh on marl substrate, and upland forest. Known threats to the PCEs include loss of habitat due to residential development, invasive plants, alteration of the hydrology of the marsh (low Lake Michigan water levels can result in drying of the marsh), contamination of groundwater, and logging. A portion of one State Natural Area owned by the Wisconsin Department of Natural Resources occurs within the unit; the remainder of the unit is privately owned. This unit is essential to the conservation of the species because it provides habitat essential to accommodate populations of the species to meet the conservation principles of redundancy and resiliency throughout the species range.

Wisconsin Unit 2—Door County, Wisconsin

Wisconsin Unit 2 consists of 814 acres (329 hectares) in Door County, Wisconsin. This unit was occupied at the time of listing. All PCEs for the Hine's emerald dragonfly are present in this unit. The first adult recorded in Wisconsin was from this unit in 1987. Exuviae and numerous male and female adults have been observed in this unit. The unit, which encompasses much of the Mink River Estuary, contains larval and adult habitat including wet-mesic and mesic upland forest (including white cedar wetlands), emergent aquatic marsh, and northern sedge meadows. Known threats to the PCEs that may require special management include loss of habitat due to residential development, invasive plants, alteration of wetland hydrology, contamination of the surface and ground water, and logging. The majority of the land in this unit is owned by The Nature Conservancy and other private landowners with a small portion of the unit owned by the State. Forest areas with 100 percent canopy that occur greater than 328 ft (100 m) from the open forest edge of the unit are not considered critical habitat.

Wisconsin Units 3, 4, 5, 6, and 7—Door County, Wisconsin

Wisconsin Units 3 through 7 are located in Door County, Wisconsin and comprise the following areas: Unit 3 consists of 66 ac (27 ha); Unit 4 consists of 407 ac (165 ha); Unit 5 consists of 3,093 ac (1,252 ha); Unit 6 consists of 230 ac (93 ha); and Unit 7 consists of 352 ac (142 ha). Units 3, 5, 6, and 7 were occupied at the time of listing. Unit 4 was not known to be occupied at the time of listing but is currently occupied. All of the units are within 2.5 mi (4 km) of at least one other unit, making exchange of dispersing adults likely between units. All PCEs for the Hine's emerald dragonfly are present in all of the units. Adult numbers recorded from these units vary. Generally fewer than 8 adults have been observed at Units 4, 6, and 7 during any one season. A study by Kirk and Vogt (1995, pp. 13–15) reported a total adult population in the thousands in Units 3 and 5. Male and female adults have been observed in all the units. Adult dragonfly swarms commonly occur in Unit 5. Swarms ranging in size from 16 to 275 dragonflies and composed predominantly of Hine's emerald dragonflies were recorded from a total of 20 sites in and near Units 5 and 6 during 2001 and 2002 (Zuehls 2003, pp. iii, 19, 21, and 43). In addition, the following behaviors and life stages of Hine's emerald dragonflies have been recorded from the various units: Unit 3—mating behavior, male patrolling behavior, crayfish burrows, exuviae, and female ovipositioning (egg-laying); Unit 4—larvae and exuviae; Unit 5—teneral adults, mating behavior, male patrolling, larvae, female ovipositioning (egg-laying), and crayfish burrows; and Unit 6—mating behavior, evidence of ovipositioning, and crayfish burrows.

Unit 5 contains two larval areas, while Units 3, 4, 5, 6, and 7 each contain one larval area. Units 3 through 7 all include adult habitat, which varies from unit to unit but generally includes boreal rich fen, northern wet-mesic forest (including white cedar wetlands), upland forest, shrub-scrub wetlands,

emergent aquatic marsh, and northern sedge meadow. Known threats to the PCEs that may require special management include loss of habitat due to residential and commercial development, ecological succession, invasive plants, utility and road construction and maintenance, alteration of the hydrology of wetlands (e.g., via quarrying or beaver impoundments), contamination of the surface and ground water (e.g., via pesticide use at nearby apple/cherry orchards (Unit 7)), agricultural practices, and logging. The majority of the land in the unit is conservation land in public and private ownership; the remainder of the land is privately owned. Forest areas with 100 percent canopy that occur greater than 328 ft (100 m) from the open forest edge of the unit but that are too small for us to map out are not considered critical habitat. Unit 4 is essential to the conservation of the species because it provides habitat essential to accommodate populations of the species to meet the conservation principles of redundancy and resiliency throughout the species range.

Wisconsin Unit 8—Door County, Wisconsin

Wisconsin Unit 8 consists of 70 ac (28 ha) in Door County, Wisconsin and includes Arbter Lake. This unit was not known to be occupied at the time of listing but is currently occupied. All PCEs for the Hine's emerald dragonfly are present in this unit. Numerous male and female adults as well as ovipositing have been observed in this unit; crayfish burrows and rivulets are present. The unit consists of larval and adult habitat with a mix of upland and lowland forest, and calcareous bog and fen communities. Known threats to the PCEs include encroachment of larval habitat by invasive plants and alteration of local groundwater hydrology (e.g., via quarrying activities), contamination of surface and groundwater, and logging. Land in this unit is owned by The Nature Conservancy and other private landowners. This unit is essential to the conservation of the species because it provides habitat essential to accommodate populations of the species to meet the conservation principles of redundancy and resiliency throughout the species range.

Wisconsin Unit 9—Door County, Wisconsin

Wisconsin Unit 9 consists of 1,193 ac (483 ha) in Door County, Wisconsin associated with Keyes Creek. This unit was not known to be occupied at the time of listing but is currently occupied. All PCEs for the Hine's emerald dragonfly are present in this unit. Numerous male and female adults have been seen in this unit; ovipositing females have been observed. Crayfish burrows are present. The unit consists of larval and adult habitat with a mix of upland and lowland forest, scrub-shrub wetlands, and emergent marsh. Known threats to the PCEs are loss and/or degradation of habitat due to development, groundwater depletion or alteration, surface and groundwater contamination, alteration of the hydrology of the wetlands (e.g., via stream impoundment, road construction and maintenance, and logging). The majority of the land in this unit is a State Wildlife Area owned by the Wisconsin Department of Natural Resources with the remainder of the land privately owned. Forest areas with 100 percent canopy that occur greater than 328 ft (100 m) from the open forest edge of the unit are not considered critical habitat. This unit is essential to the conservation of the species because it provides habitat essential to accommodate populations of the species to meet the conservation principles of redundancy and resiliency throughout the species range.

Wisconsin Unit 10—Ozaukee County, Wisconsin

Wisconsin Unit 10 consists of 2,312 ac (936 ha) in Ozaukee County, Wisconsin, and includes much of Cedarburg Bog. This unit was not known to be occupied at the time of listing but is currently occupied. All PCEs for the Hine's emerald dragonfly are present in this unit. Numerous male and female adults have been seen in this unit including teneral adults; ovipositing females have been observed, as well as larvae. Crayfish burrows are present. The unit consists of larval and adult habitat with a mix of shrub-carr, ''patterned'' bog composed of forested ridges and sedge mats, wet meadow, and lowland forest. The majority of area in the unit is State land and the remainder of the land is privately owned. This unit is essential to the conservation of the species because it provides habitat essential to accommodate populations of the species to meet the conservation principles of redundancy and resiliency throughout the species range.

Wisconsin Unit 11—Door County, Wisconsin

Wisconsin Unit 11 consists of approximately 147 acres (59 hectares) in Door County, Wisconsin. This unit was not known to be occupied at the time of listing but is currently occupied. All PCEs for the Hine's emerald dragonfly are present in this unit. Adults have been observed in this unit over multiple years. Male patrolling behavior has been observed, and crayfish burrows are present. The unit consists of larval and adult habitat, including a floating sedge mat and lowland and upland conifer and deciduous forest. This unit is essential to the conservation of the species because it provides for the redundancy and resilience of populations in this portion of the species' range, where habitat is under threat from multiple factors. All land in the unit is privately owned. The northern portion of the unit is owned by the Door County Land Trust.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that actions they fund, authorize, or carry out are not likely to destroy or adversely modify critical habitat. Decisions by the 5th and 9th Circuit Court of Appeals have invalidated our definition of ''destruction or adverse modification'' (50 CFR 402.02) (see *Gifford Pinchot Task Force* v. *U.S. Fish and Wildlife Service*, 378 F.3d 1059 (9th Cir 2004) and *Sierra Club* v. *U.S. Fish and Wildlife Service et al.*, 245 F.3d 434, 442F (5th Cir 2001)), and we do not rely on this regulatory definition when analyzing whether an action is likely to destroy or adversely modify critical habitat. Under current national policy and the statutory provisions of the Act, we determine destruction or adverse modification is determined on the basis of whether, with implementation of the proposed Federal action, the affected critical habitat would remain functional (or retain the current ability for the PCEs to be functionally established) to serve its intended conservation role for the species.

Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. This is a procedural requirement only, as any conservation recommendations in a conference report or opinion are strictly advisory. However, once a species proposed for listing becomes listed, or proposed critical habitat is designated as final, the full prohibitions of section 7(a)(2) apply to any discretionary Federal action.

The primary utility of the conference procedures is to allow a Federal agency to maximize its opportunity to

adequately consider species proposed for listing and proposed critical habitat and to avoid potential delays in implementing their proposed action because of the section 7(a)(2) compliance process, if we list those species or designate critical habitat. We may conduct conferences either informally or formally. We typically use informal conferences as a means of providing advisory conservation recommendations to assist the agency in eliminating conflicts that the proposed action may cause. We typically use formal conferences when we or the Federal agency believes the proposed action is likely to jeopardize the continued existence of the species proposed for listing or adversely modify proposed critical habitat.

We generally provide the results of an informal conference in a conference report, while we provide the results of a formal conference in a conference opinion. We typically prepare conference opinions on proposed species or critical habitat in accordance with procedures contained at 50 CFR 402.14, as if the proposed species were already listed or the proposed critical habitat was already designated. We may adopt the conference opinion as the biological opinion when the species is listed or the critical habitat is designated, if no substantial new information or changes in the action alter the content of the opinion (see 50 CFR 402.10(d)).

If a species is listed or critical habitat is designated, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. As a result of this consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species or destroy or adversely modify critical habitat, we also provide reasonable and prudent alternatives to the project, if any are identifiable. We define ''Reasonable and prudent alternatives'' at 50 CFR 402.02 as alternative actions identified during consultation that:

- Can be implemented in a manner consistent with the intended purpose of the action;
- Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction;
- Are economically and technologically feasible; and
- Would, in the Director's opinion, avoid jeopardizing the continued existence of the listed species or destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, some Federal agencies may request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions may affect subsequently listed species or designated critical habitat.

Federal activities that may affect the Hine's emerald dragonfly or its designated critical habitat will require section 7 consultation under the Act. Activities on State, tribal, local or private lands requiring a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from us under section 10(a)(1)(B) of the Act) or involving some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency) are also subject to the section 7 consultation process. Federal actions not affecting listed species or critical habitat, and actions on State, tribal, local, or private lands that are not federally-funded, authorized, or permitted, do not require section 7 consultations.

Application of the ''Adverse Modification'' Standard

For the reasons described in the Director's December 9, 2004, memorandum, the key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species, or would retain its current ability for the primary constituent elements to be functionally established. Activities that may destroy or adversely modify critical habitat are those that alter the PCEs to an extent that appreciably reduces the conservation value of critical habitat for the Hine's emerald dragonfly. Generally, the conservation role of Hine's emerald dragonfly critical habitat units is to support viable core area populations.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation.

Activities that, when carried out, funded, or authorized by a Federal agency, may affect critical habitat and therefore result in consultation for the Hine's emerald dragonfly include, but are not limited to:

(1) Actions that would significantly increase succession and encroachment of invasive species. Such activities could include, but are not limited to, release of nutrients and road salt (NaCl; unless not using road salt would result in an increased degree of threat to human safety and alternative de-icing methods are not feasible) into the surface water or connected groundwater at a point source or by dispersed release (non-point source), and introduction of invasive species through human activities in the habitat. These activities can result in conditions that are favorable to invasive species and would provide an ecological advantage over native vegetation, fill rivulets and seepage areas occupied by Hine's emerald dragonfly larvae, reduce detritus that provides cover for larvae, and reduce flora and fauna necessary for the species to complete its life cycle. Actions that would increase succession and encroachment of invasive species could negatively impact the Hine's emerald dragonfly and the species' habitat.

(2) Actions that would significantly increase sediment deposition within the rivulets and seepage areas occupied by Hine's emerald dragonfly larvae. Such activities could include, but are not limited to, excessive sedimentation from livestock grazing, road construction, channel alteration, timber harvest, all terrain vehicle use, equestrian use, feral pig introductions, maintenance of rail lines, and other watershed and

floodplain disturbances. These activities could eliminate or reduce the habitat necessary for the growth and reproduction of Hine's emerald dragonflies and their prey base by increasing sediment deposition to levels that would adversely affect the organisms' ability to complete their life cycles. Actions that would significantly increase sediment deposition within rivulets and seepage areas could negatively impact the Hine's emerald dragonfly and the species' habitat.

(3) Actions that would significantly alter water quantity and quality. Such activities could include, but are not limited to, groundwater extraction; alteration of surface and subsurface areas within groundwater recharge areas; and release of chemicals, biological pollutants, or heated effluents into the surface water or groundwater recharge area at a point source or by dispersed release (non-point source). These activities could alter water conditions such that the conditions are beyond the tolerances of the Hine's emerald dragonfly and its prey base, and result in direct or cumulative adverse affects to these individuals and their life cycles. Actions that would significantly alter water quantity and quality could negatively impact the Hine's emerald dragonfly and the species' habitat.

(4) Actions that would significantly alter stream, streamlet, and fen channel morphology or geometry. Such activities could include but are not limited to, all terrain vehicle use, equestrian use, feral pig introductions, channelization, impoundment, road and bridge construction, mining, and loss of emergent vegetation. These activities may lead to changes in water flow velocity, temperature, and quantity that could negatively impact the Hine's emerald dragonfly and their prey base and/or habitats. Actions that would significantly alter channel morphology or geometry could negatively impact the Hine's emerald dragonfly and the species' habitat.

(5) Actions that would fragment habitat and impact adult foraging or dispersal. Such activities could include, but are not limited to, road construction, destruction or fill of wetlands, and high-speed railroad and vehicular traffic. These activities may adversely affect dispersal, resulting in reduced fitness and genetic exchange within populations and potentially mortality of individuals. Actions that would fragment habitat and impact adult foraging or dispersal could negatively impact the Hine's emerald dragonfly and the species' habitat.

Application of Exclusions Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary must designate and revise critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the Secretary is afforded broad discretion, and the Congressional record is clear that, in making a determination under the section, the Secretary has broad discretion as to which factors to use and how much weight will be given to any factor.

Under section 4(b)(2) of the Act, in considering whether to exclude a particular area from the designation, we must identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, determine whether the benefits of exclusion outweigh the benefits of designation. If we consider an exclusion, then we must determine whether excluding the area would result in the extinction of the species.

In the following sections, we address a number of general issues that are relevant to the exclusions we are considering. In addition, we are conducting an economic analysis of the impacts of the proposed critical habitat designation and related factors, which will be available for public review and comment when it is complete. Based on public comment on that document, the proposed designation itself, and the information in the final economic analysis, the Secretary may exclude from critical habitat additional areas beyond those identified in this assessment under the provisions of section 4(b)(2) of the Act. This is also addressed in our implementing regulations at 50 CFR 424.19.

Benefits of Designating Critical Habitat

Regulatory Benefits

The consultation provisions under section 7(a) of the Act constitute the regulatory benefits of critical habitat. As discussed above, Federal agencies must consult with us on actions that may affect critical habitat and must avoid destroying or adversely modifying critical habitat. Prior to our designation of critical habitat, Federal agencies consult with us on actions that may affect a listed species and must refrain from undertaking actions that are likely to jeopardize the continued existence of the species. Thus, the analysis of effects to critical habitat is a separate and different analysis from that of the effects to the species. Therefore, the difference in outcomes of these two analyses represents the regulatory benefit of critical habitat. For some species, and in some locations, the outcome of these analyses will be similar, because effects on habitat will often result in effects on the species. However, the regulatory standard is different: the jeopardy analysis looks at the action's impact on survival and recovery of the species, while the adverse modification analysis looks at the action's effects on the designated habitat's contribution to the species' conservation. This will, in many instances, lead to different results and different regulatory requirements.

Once an agency determines that consultation under section 7 of the Act is necessary, the process may conclude informally when we concur in writing that the proposed Federal action is not likely to adversely affect critical habitat. However, if we determine through informal consultation that adverse impacts are likely to occur, then we would initiate formal consultation, which would conclude when we issue a biological opinion on whether the proposed Federal action is likely to result in destruction or adverse modification of critical habitat.

For critical habitat, a biological opinion that concludes in a determination of no destruction or adverse modification may contain discretionary conservation recommendations to minimize adverse effects to primary constituent elements, but it would not contain any mandatory reasonable and prudent measures or terms and conditions. We suggest reasonable and prudent alternatives to the proposed Federal action only when our biological opinion results in an adverse modification conclusion.

We believe that in many instances the regulatory benefit of critical habitat is low when compared to voluntary conservation efforts or management plans. The conservation achieved through implementing HCPs or other habitat management plans is typically greater than what we achieve through multiple site-by-site, project-by-project, section 7 consultations involving consideration of critical habitat. Management plans may commit resources to implement long-term management and protection to

particular habitat for at least one and possibly additional listed or sensitive species. Section 7 consultations commit Federal agencies to preventing adverse modification of critical habitat caused by the particular project only, and not to providing conservation or long-term benefits to areas not affected by the proposed project. Thus, any HCP or management plan that considers enhancement or recovery as the management standard will often provide as much or more benefit than a consultation for critical habitat designation conducted under the standards required by the ninth circuit in the *Gifford Pinchot* decision.

In providing the framework for the consultation process, the previous section applies to all the following discussions of benefits of inclusion or exclusion of critical habitat.

The process of designating critical habitat as described in the Act requires that the Service identify those lands on which are found the physical or biological features essential to the conservation of the species which may require special management considerations or protection. In identifying those lands, the Service must consider the recovery needs of the species, such that the habitat that is identified, if managed, could provide for the survival and recovery of the species. Furthermore, once critical habitat has been designated, Federal agencies must consult with the Service under section 7(a)(2) of the Act to ensure that their actions will not adversely modify designated critical habitat or jeopardize the continued existence of the species. As noted in the Ninth Circuit's *Gifford Pinchot* decision, the Court ruled that the jeopardy and adverse modification standards are distinct, and that adverse modification evaluations require consideration of impacts to the recovery of species. Thus, through the section 7(a)(2) consultation process, critical habitat designations provide recovery benefits to species by ensuring that Federal actions will not destroy or adversely modify designated critical habitat.

The identification of those lands that are necessary for the conservation of the species can, if managed, provide for the recovery of a species and is beneficial. The process of proposing and finalizing a critical habitat rule provides the Service with the opportunity to determine lands essential for conservation as well as identify the primary constituent elements or features essential for conservation on those lands. The designation process includes peer review and public comment on the identified features and lands. This process is valuable to land owners and managers in developing conservation management plans for identified lands, as well as any other occupied habitat or suitable habitat that may not have been included in the Service's determination of essential habitat.

However, the designation of critical habitat does not require that any management or recovery actions take place on the lands included in the designation. Even in cases where consultation has been initiated under section 7(a)(2) of the Act, the end result of consultation is to avoid jeopardy to the species and adverse modification of its critical habitat, but not specifically to manage remaining lands or institute recovery actions on remaining lands. Conversely, management plans institute proactive actions over the lands they encompass intentionally to remove or reduce known threats to a species or its habitat and, therefore, implement recovery actions. We believe that the conservation of a species and its habitat that could be achieved through the designation of critical habitat, in some cases, is less than the conservation that could be achieved through the implementation of a management plan that includes species-specific provisions and considers enhancement or recovery of listed species as the management standard over the same lands. Consequently, implementation of any HCP or management plan that considers enhancement or recovery as the management standard will often provide as much or more benefit than a consultation for critical habitat designation conducted under the standards required by the Ninth Circuit in the *Gifford Pinchot* decision.

Conservation Partnerships on Non-Federal Lands

Most federally listed species in the United States will not recover without cooperation of non-Federal landowners. More than 60 percent of the United States is privately owned (National Wilderness Institute 1995), and at least 80 percent of endangered or threatened species occur either partially or solely on private lands (Crouse *et al.* 2002). Stein *et al.* (1995) found that only about 12 percent of listed species were found almost exclusively on Federal lands (90 to 100 percent of their known occurrences restricted to Federal lands) and that 50 percent of federally listed species are not known to occur on Federal lands at all.

Given the distribution of listed species with respect to land ownership, conservation of listed species in many parts of the United States is dependent upon working partnerships with a wide variety of entities and the voluntary cooperation of many non-Federal landowners (Wilcove and Chen 1998; Crouse *et al.* 2002; James 2002). Building partnerships and promoting voluntary cooperation of landowners are essential to our understanding the status of species on non-Federal lands, and necessary for us to implement recovery actions such as reintroducing listed species and restoring and protecting habitat.

Many non-Federal landowners derive satisfaction from contributing to endangered species recovery. We promote these private-sector efforts through the Department of the Interior's Cooperative Conservation philosophy. Conservation agreements with non-Federal landowners (HCPs, safe harbor agreements, other conservation agreements, easements, and State and local regulations) enhance species conservation by extending species protections beyond those available through section 7 consultations. In the past decade, we have encouraged non-Federal landowners to enter into conservation agreements, based on the view that we can achieve greater species conservation on non-Federal land through such partnerships than we can through regulatory methods (61 FR 63854; December 2, 1996).

Many private landowners, however, are wary of the possible consequences of attracting endangered species to their property. Mounting evidence suggests that some regulatory actions by the Federal Government, while well-intentioned and required by law, can (under certain circumstances) have unintended negative consequences for the conservation of species on private lands (Wilcove *et al.* 1996; Bean 2002; Conner and Mathews 2002; James 2002; Koch 2002; Brook *et al.* 2003). Many landowners fear a decline in their property value due to real or perceived restrictions on land-use options where threatened or endangered species are found. Consequently, harboring endangered species is viewed by many landowners as a liability. This perception results in anti-conservation incentives, because maintaining habitats that harbor endangered species represents a risk to future economic opportunities (Main *et al.* 1999; Brook *et al.* 2003).

According to some researchers, the designation of critical habitat on private lands significantly reduces the likelihood that landowners will support and carry out conservation actions (Main *et al.* 1999; Bean 2002; Brook *et al.* 2003). The magnitude of this outcome is greatly amplified in situations where active management

measures (such as reintroduction, fire management, control of invasive species) are necessary for species conservation (Bean 2002). We believe that the judicious use of excluding specific areas of non-federally owned lands from critical habitat designations can contribute to species recovery and provide a superior level of conservation than critical habitat alone.

The purpose of designating critical habitat is to contribute to the conservation of threatened and endangered species and the ecosystems upon which they depend. The outcome of the designation, triggering regulatory requirements for actions funded, authorized, or carried out by Federal agencies under section 7(a)(2) of the Act, can sometimes be counterproductive to its intended purpose on non-Federal lands. Thus the benefits of excluding areas that are covered by partnerships or voluntary conservation efforts can often be high.

Educational Benefits

A benefit of including lands in critical habitat is that designation of critical habitat serves to educate landowners, State and local governments, and the public regarding the potential conservation value of an area. This helps focus and promote conservation efforts by other parties by clearly delineating areas of high conservation value for the Hine's emerald dragonfly. In general, critical habitat designation always has educational benefits; however, in some cases, they may be redundant with other educational effects. For example, HCPs have significant public input and may largely duplicate the educational benefits of a critical habitat designation. A second benefit of including lands in critical habitat is that the designation of critical habitat would inform State agencies and local governments about areas that could be conserved under State laws or local ordinances.

Benefits of Excluding Lands With Approved Management Plans

The benefits of excluding lands within approved long-term management plans from critical habitat designation include relieving landowners, communities, and counties of any additional regulatory burden that might be imposed by critical habitat. Many conservation plans provide conservation benefits to unlisted sensitive species. Imposing an additional regulatory review as a result of the designation of critical habitat may undermine conservation efforts and partnerships in many areas. Designation of critical habitat within the boundaries of management plans that provide conservation measures for a species could be viewed as a disincentive to entities currently developing these plans or contemplating them in the future, because one of the incentives for undertaking conservation is greater ease of permitting where listed species will be affected. Addition of a new regulatory requirement would remove a significant incentive for undertaking the time and expense of management planning.

A related benefit of excluding lands within management plans from critical habitat designation is the unhindered, continued ability it gives us to seek new partnerships with future plan participants, including States, counties, local jurisdictions, conservation organizations, and private landowners, which together can implement conservation actions that we would be unable to accomplish otherwise. Designating lands within approved management plan areas as critical habitat would likely have a negative effect on our ability to establish new partnerships to develop these plans, particularly plans that address landscape-level conservation of species and habitats. By preemptively excluding these lands, we preserve our current partnerships and encourage additional conservation actions in the future.

Exclusions Under Section 4(b)(2) of the Act

We are excluding Michigan Units 1 and 2 (Hiawatha National Forest lands), and all Missouri units (1–26) from the final designation of critical habitat for the Hine's emerald dragonfly because we believe that the benefits of excluding these specific areas from the designation outweigh the inclusion of the specific areas. The conservation actions planned and implemented for the Hine's emerald dragonfly on Mark Twain National Forest, Hiawatha National Forest, Missouri state owned lands, and through MDC's coordination with private landowners in Missouri provide greater conservation benefit to the species than would designating these areas as critical habitat. We believe that the exclusion of these areas from the final designation of critical habitat will not result in the extinction of the Hine's emerald dragonfly. We reviewed relevant information concerning other critical habitat units to determine whether any other units, or portions thereof, should be excluded from the final designation. No other units were excluded from the final designation.

Federal Land Management Plans—Exclusions Under Section 4(b)(2) of the Act

Hiawatha National Forest, Michigan

Michigan units 1 and 2 are on Hiawatha National Forest lands. The Hiawatha National Forest contains 895,313 ac (362,320 ha) of land in the eastern portion of the Upper Peninsula of Michigan; it is broken into an east and west unit and contains a diversity of upland and wetland community types. In 2006, the Hiawatha National Forest revised its Land and Resource Management Plan (Hiawatha Forest Plan) (United States Department of Agriculture (USDA) 2006). The Hiawatha Forest Plan guides the National Forest's activities over the next 15 years. We completed a section 7 consultation for the Hiawatha Forest Plan that addresses federally listed resources, including the Hine's emerald dragonfly. We determined in our biological opinion resulting from that section 7 consultation that the implementation of the Plan would not jeopardize the continued existence of the Hine's emerald dragonfly.

The Hiawatha Forest Plan contains management direction that serves to protect and conserve Hine's emerald dragonfly breeding and foraging habitats. Several standards, guidelines, and objectives in the Hiawatha Forest Plan are pertinent to the Hine's emerald dragonfly (Table 4). Standards as listed in the Hiawatha Forest Plan are required courses of action. An amendment to the Forest Plan is required to change a standard and this would trigger consultation with us under section 7 of the Act. Guidelines are also strongly adhered to, and may only be modified if site-specific conditions warrant a modification and a rationale for a deviation is given in a National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) document. Again, section 7 consultation would be conducted, and the Service would review a guideline deviation if one or more listed species were likely to be impacted by the specific project. Standards and guidelines are not voluntary actions, but rather strong commitments by the Hiawatha National Forest to a particular management direction.

TABLE 4.—SUMMARY OF STANDARDS AND GUIDELINES IN THE HIAWATHA NATIONAL FOREST 2006 FOREST PLAN (USDA 2006) THAT PROTECT HINE'S EMERALD DRAGONFLY AND THEIR HABITAT

2006 Forest plan management direction	Conservation for Hine's emerald dragonfly
Protect all known Hine's emerald dragonfly breeding areas (standard) ..	Protect breeding areas.
Implement signed recovery plans for threatened and endangered species (standard).	Protect, restore, or enhance breeding areas; locate new sites; identify foraging habitat; encourage coordination.
Cross-country OHV travel prohibited except in designated OHV area (standard).	Protect breeding and foraging areas.
Wetland roads, or trail crossings, will preserve drainage (standard)	Protect breeding and foraging areas.
Motorized trails should be located away from Designated Wilderness and semi-primitive management areas (guideline).	Protect breeding and foraging areas; some breeding areas are within Designated Wilderness Area.
Manage wilderness Areas to protect biological and physical factors and Wilderness values while accommodating recreational use (guideline).	Protect breeding and foraging areas.
Vegetation management activities should be designed to minimize adverse impacts on recreation use and wildlife populations (guideline).	Protect, enhance or create new breeding and foraging areas.
Excavated soil material (including spoils, drilling mud, etc.) should be deposited in upland locations (guideline).	Protect breeding areas.
Clear-cutting should not occur next to woodland ponds (guideline)	Protect breeding and foraging areas.
Road obliteration will include removing bridges, culverts and fill from streams, floodplains and wetlands to re-establish natural drainage and restore wetlands (guideline).	Protect, enhance, or restore breeding and foraging areas.
Deference should be afforded to implementing conservation measures for federal threatened and endangered species when and where they conflict with conservation measures for unlisted species (guideline).	Protect breeding and foraging areas.
Non-native invasive plants within element occurrences of threatened and endangered and Regional Forester Sensitive Species should be eliminated or controlled (guideline).	Protect, enhance, or restore breeding and foraging areas.
For all threatened and endangered species, special closure orders may be used to protect known breeding areas, nests, and denning sites (guideline).	Protect breeding and foraging areas.
Spread of existing non-native invasive species is controlled using permissible mechanical, biological, and chemical controls (guideline).	Protect, enhance or restore breeding and foraging areas.
Habitat in Wilderness Areas may be manipulated to correct conditions resulting from human influence or to protect threatened and endangered species (guideline).	Enhance and restore existing habitat, create additional habitat; some breeding areas are located in a designated Wilderness Area.
In Candidate Research Natural Areas (CRNA), motorized use should be prohibited except for emergency or administrative situations (guideline).	Protect breeding and foraging areas; one breeding area is located within a CRNA.
Common variety mineral pits will not be developed (guideline)	Protect breeding and foraging areas.

Although multiple standards and guidelines within the Hiawatha Forest Plan relate to the Hine's emerald dragonfly, two key standards provide strong assurances that Hine's emerald dragonflies will be protected and managed on the Hiawatha National Forest. The standards are: (1) All Hine's emerald dragonfly breeding sites will be protected; and (2) signed recovery plans for federally threatened and endangered species will be implemented (USDA 2006, p. 26). These two standards provide greater benefit to the Hine's emerald dragonfly than critical habitat designation. While critical habitat designation triggers the prohibition of destruction or adverse modification of that habitat, it does not require specific actions to restore or improve habitat. The Hiawatha Forest Plan not only will prevent destruction of important Hine's emerald dragonfly habitat, but also would require additional conservation actions to help recover the species.

In addition, several activities show the Hiawatha National Forest's commitment to the Hine's emerald dragonfly and other listed species conservation. Over the last five years the Hiawatha National Forest has completed several dragonfly surveys that have led to the identification of at least two new Hine's emerald dragonfly breeding areas. In 2005, the Hiawatha National Forest hosted a Hine's emerald dragonfly workshop that provided critical education and outreach to Federal, State, and private field staff. They are also actively managing or protecting lands in an effort to help in the recovery of several other federally listed species including the piping plover and Kirtland's warbler.

We believe that the standards and guidelines outlined in the Hiawatha Forest Plan and the Forest's commitment to protect and recover federally listed species through section 7(a)(1) and 7(a)(2), adequately address identified threats to the Hine's emerald dragonfly and its habitat. The conservation measures as outlined above provide greater benefit to the Hine's emerald dragonfly than would designating critical habitat on the Hiawatha National Forest. Thus the relative benefits of designation of these lands would be diminished and limited.

(1) Benefits of Designation.

The primary effect of designating any particular area as critical habitat is the requirement for Federal agencies to consult with us pursuant to section 7 of the Act to ensure actions they carry out authorize, or fund do not destroy or adversely modify designated critical habitat. Absent critical habitat designation, Federal agencies remain obligated under section 7 to consult with us on actions that may affect a federally listed species to ensure such actions do not jeopardize the species' continued existence. The Forest Service routinely consults with us for activities on the Hiawatha National Forest that may affect federally listed species to ensure that the continued existence of such species is not jeopardized.

Designation of critical habitat may also provide educational benefits by informing land managers of areas essential to the conservation of the Hine's emerald dragonfly. In the case of Hiawatha National Forest, there is no

appreciable educational benefit because the Forest managers have already demonstrated their knowledge and understanding of essential habitat for the species through their active recovery efforts, consultation, and workshops. Furthermore, the benefits of including the Hiawatha National Forest in designated critical habitat are minimal because the Forest managers are currently implementing conservation actions for the Hine's emerald dragonfly that equal or exceed those that would be realized by designating critical habitat.

(2) Benefits of Exclusion.

The long standing cooperative working relationship between the Service and Hiawatha National Forest has lead to the identification and implementation of various recovery actions for listed species, including Hine's emerald dragonfly. With the 2006 Forest Plan revision, the Hiawatha National Forest reaffirmed and formalized their commitment to recovering endangered species by stating that they will implement the Recovery Plans for all listed species. The benefits of these recovery activities exceed the benefits of critical habitat designation. Exclusion would further enhance the cooperative working relationship with the Forest Service by focusing on activities that are designed to protect and recover Hine's emerald dragonfly.

(3) Benefits of Exclusion Outweigh the Benefits of Designation.

We believe that a critical habitat designation for the Hine's emerald dragonfly in areas being managed by the Hiawatha and Mark Twain Forest Plans would provide a relatively low level of additional regulatory conservation benefit to the species and its PCEs beyond what is already provided by existing section 7 consultation requirements due to the physical presence of the species. Any minimal conservation benefits that would be gained from consulting on critical habitat would be outweighed by the benefits of avoiding the additional costs (staff time and money) of designating and consulting on critical habitat. These costs, while not significant, are avoidable, create very little additional benefits to the species, and could be better used to effectuate conservation measures on the ground. As such, we find that the benefits of designating critical habitat for the Hine's emerald dragonfly on Hiawatha National Forest are small in comparison to the benefits of excluding these specific areas from the final designation. Further, exclusions will continue to enhance the partnership efforts with the Forest Service that are focused on conservation of the species on the Hiawatha National Forest.

(4) Exclusions Will Not Result in Extinction of the Species.

We believe that exclusion of Michigan units 1 and 2 in Hiawatha National Forest from critical habitat will not result in the extinction of the Hine's emerald dragonfly because current conservation efforts under the Land and Resource Management Plan for the Hiawatha National Forest adequately protect essential Hine's emerald dragonfly habitat and go beyond this to provide appropriate management to maintain and enhance the PCEs for the Hine's emerald dragonfly. If these units were designated as critical habitat, the designation would not have required the implementation of conservation efforts. As such, there is no reason to believe that this exclusion would result in extinction of the species. We therefore have excluded the Hiawatha and Mark Twain National Forests from the final designation of critical habitat for the Hine's emerald dragonfly under section 4(b)(2) of the Act.

Mark Twain National Forest, Missouri

Missouri units 1, 2, 3, 5, 7, 8 (in part), 11 (in part), 21, 23, 24, 25, and 26 are on U.S. Forest Service lands in Mark Twain National Forest. The Mark Twain National Forest contains approximately 1.5 million ac (607,028 ha) of land in southern and central Missouri. In 2005, Mark Twain National Forest revised its Land and Resource Management Plan (Mark Twain Forest Plan) (USDA 2005, Chapter 2, pp. 1–14). That Forest Plan, through implementation of the standards and guidelines established for the Hine's emerald dragonfly, addresses threats to the species on Mark Twain National Forest lands in Missouri. We completed a section 7 consultation for the Mark Twain Forest Plan that addresses federally listed resources, including the Hine's emerald dragonfly. We determined in our biological opinion that the implementation of the Mark Twain Forest Plan would not jeopardize the continued existence of the Hine's emerald dragonfly.

The 2005 Forest Plan contains specific direction for management of fen habitat and for fens with known or suspected populations of Hine's emerald dragonflies (Table 4). The Plan also contains standards and guidelines to protect soil productivity and water quality while implementing all management actions. An amendment to the Mark Twain Forest Plan is required to change a standard and this would trigger consultation with us under section 7 of the Act. Guidelines are also strongly adhered to and may only be modified if site-specific conditions warrant and rationale for a deviation is given in a NEPA document. Again section 7 would be conducted and the Service would review a guideline deviation if listed species were likely to be impacted by the specific project. Standards and guidelines are not voluntary actions, but rather strong commitments by the Mark Twain National Forest to a particular management direction. The specific standards and guidelines (USDA 2005, Chapter 2, p. 8) for the Hine's emerald dragonfly and its habitat are summarized in Table 5.

TABLE 5.—SUMMARY OF STANDARDS AND GUIDELINES IN THE MARK TWAIN NATIONAL FOREST 2005 FOREST PLAN (USDA 2005) THAT PROTECT HINE'S EMERALD DRAGONFLY AND THEIR HABITAT

2005 Forest plan management direction	Conservation for Hine's emerald dragonfly
Control nonnative, invasive and/or undesirable plant species in fen habitats through the most effective means possible while protecting water quality (standard).	Protect, enhance, or restore breeding and foraging areas.
Prescribed burns on fens that harbor known or suspected populations of Hine's emerald dragonfly must be scheduled to occur from November through April (standard).	Protect, restore, or enhance breeding and foraging areas.
Prohibit vehicle and heavy equipment use in fens, unless needed to improve Hine's emerald dragonfly habitat (standard).	Protect, restore, or enhance breeding and foraging areas.
Control unauthorized vehicle access to fens (standard)	Protect the species and its breeding and foraging habitat.
Restore local hydrology by eliminating old drainage ditches or other water diversionary structures when possible if such activities would not result in a loss of habitat (guideline).	Protect breeding and foraging areas.

TABLE 5.—SUMMARY OF STANDARDS AND GUIDELINES IN THE MARK TWAIN NATIONAL FOREST 2005 FOREST PLAN (USDA 2005) THAT PROTECT HINE'S EMERALD DRAGONFLY AND THEIR HABITAT—Continued

2005 Forest plan management direction	Conservation for Hine's emerald dragonfly
Fens that harbor known populations of Hine's emerald dragonfly should be prescribe burned to control invasion of woody species or as part of larger landscape restoration and enhancement projects (guideline).	Protect breeding and foraging areas.

The fen standards and guidelines prohibit mechanical disturbance, and establish buffer zones around fen edges. Certain management activities are prohibited or modified within the buffer zones. The fen standards and guidelines require new road design to maintain hydrologic functioning of fens and encourage relocation of roads or restoration of hydrology where existing roads interfere with natural water flow. The fen standards and guidelines encourage management of fire-dependent wetland communities with a fire regime similar to that with which the communities evolved (USDA 2005, Chapter 2, pp. 13–14).

Implementing the Mark Twain Forest Plan's standards and guidelines will maintain the natural hydrology, restore natural fire regimes, and control undesirable plant species to maintain breeding and foraging habitat identified for the Hine's emerald dragonfly on the Mark Twain National Forest. Additionally, prohibiting mechanical disturbance in fens will protect the integrity of crayfish burrows and maintain important larval habitat.

In addition to the 2005 Forest Plan, the Mark Twain National Forest completed a ''Threats Assessment of Fens Containing Hine's Emerald Dragonfly'' in September 2005. This assessment describes threats to individual fens and provides recommendations to eliminate or minimize those threats. Primary recommendations are to increase the use of prescribed fire at many fens, and construct fences to exclude all-terrain vehicles (ATVs) and feral hogs from a few of the locations. Potential disturbance due to equestrian use will be minimized through coordination with the appropriate U.S. Forest Service District Office; signs and fencing will be used, if necessary, to alleviate this threat. Effective removal and exclusion measures will minimize threats from feral hogs and beavers. In 2005, beavers were effectively removed from Missouri Unit 5 where floodwater associated with a beaver dam threatened the integrity of the adjacent fen.

We believe that the standards and guidelines outlined in the Mark Twain Forest Plan, guidelines identified in the U.S. Forest Service's 2005 Threats Assessment, and the agency's commitment to manage and maintain important fen habitat through section 7(a)(1) and 7(a)(2) consultation, adequately address identified threats to the Hine's emerald dragonfly and its habitat. The conservation measures as outlined above provide greater benefit to the Hine's emerald dragonfly than would designating critical habitat on the Mark Twain National Forest. Thus the relative benefits of designation of these lands are diminished and limited.

(1) Benefits of Designation.

The primary effect of designating any particular area as critical habitat is the requirement for Federal agencies to consult with us under section 7 of the Act to ensure actions they carry out, authorize, or fund do not destroy or adversely modify designated critical habitat. Absent critical habitat designation, Federal agencies remain obligated under section 7 to consult with us on actions that may affect a federally listed species to ensure such actions do not jeopardize the species' continued existence. The Forest Service routinely consults with us on activities on the Mark Twain National Forest that may affect federally listed species to ensure that the continued existence of such species is not jeopardized.

Designation of critical habitat may also provide educational benefits by informing land managers of areas essential to the conservation of the Hine's emerald dragonfly. In the case of Missouri, there is no appreciable educational benefit because the Mark Twain National Forest has already demonstrated its knowledge and understanding of essential habitat for the species through active recovery efforts and consultation. The Missouri public, particularly landowners with Hine's emerald dragonfly habitat on their lands, is also well informed about the Hine's emerald dragonfly.

Furthermore, the benefits of including the Mark Twain National Forest in designated critical habitat would be minimal because the Forest is currently implementing conservation actions for the Hine's emerald dragonfly and its habitat that are beyond those that would be realized if critical habitat were designated.

(2) Benefits of Exclusion.

The longstanding cooperative working relationship between the Service and the Mark Twain National Forest has lead to the identification and implementation of various recovery actions for listed species, including the Hine's emerald dragonfly. Mark Twain National Forest is actively implementing actions to conserve the Hine's emerald dragonfly on their lands, reinforcing their commitment to actions outlined in the Forest Plan. The benefits of these recovery activities exceed the benefits of critical habitat designation. Exclusion would further enhance the cooperative working relationship with the Forest Service by focusing on activities that are designed to protect and recover the Hine's emerald dragonfly.

(3) Benefits of Exclusion Outweigh the Benefits of Designation.

We find that the benefits of designating critical habitat for the Hine's emerald dragonfly in Mark Twain National Forest in Missouri are small in comparison to the benefits of exclusion. Exclusion will enhance the partnership efforts with the Forest Service focused on conservation of the species in the State, and will ensure conservation benefits for the species beyond those that could be required under a critical habitat designation.

(4) Exclusions Will Not Result in Extinction of the Species.

We believe that exclusion of Missouri units 1, 2, 3, 5, 7, 8 (in part), 11 (in part), 21, 23, 24, 25, and 26 in Mark Twain National Forest from critical habitat will not result in the extinction of the Hine's emerald dragonfly because current conservation efforts under the Land and Resource Management Plan for the Mark Twain National Forest adequately protect essential Hine's emerald dragonfly habitat and go beyond this to provide appropriate management to maintain and enhance the PCEs for the Hine's emerald dragonfly. If these units were designated as critical habitat, the designation would not have required the implementation of conservation efforts. As such, there is no reason to believe that this exclusion would result in extinction of the species.

State Land Management—Exclusions Under Section 4(b)(2) of the Act

We are excluding all State-owned land in Missouri under section 4(b)(2) of the Act based on conservation measures addressed in species-specific management plans for state-managed lands and Missouri's state-wide Hine's emerald dragonfly recovery plan. Missouri is the only state within the range of the Hine's emerald dragonfly that has management plans that specifically address conservation of the Hine's emerald dragonfly on state lands.

Missouri units 16, 17, 18, and 22 are under MDC ownership and Unit 14 is privately owned but managed by MDC. Threats identified on land owned and managed by MDC are feral hogs, habitat fragmentation, road construction and maintenance, all terrain vehicles, beaver dams, and management conflicts.

In regard to Hine's emerald dragonfly conservation, the MDC has:

(1) Developed management plans for the five conservation areas where the Hine's emerald dragonfly has been documented (Missouri Natural Areas Committee 2007; Missouri Department of Conservation 2007a, 1–4 pp.; 2007b, 1–3 pp.; 2007c, 1–4 pp.)

(2) Formulated best management practices (Missouri Department of Conservation 2007d, 1–2 pp.) and department guidelines (Missouri Department of Conservation 2007e, 1–3 pp.); and

(3) Developed a state-wide recovery plan for the Hine's emerald dragonfly (Missouri Department of Conservation 2007f, 1–33 pp.).

These plans provide for long-term management and maintenance of fen habitat essential for larval development and adjacent habitat that provides for foraging and resting needs for the species. Areas of management concern include the fen proper, adjacent open areas for foraging, adjacent shrubs, and a 328 ft (100 m) forest edge buffer to provide habitat for resting and predator avoidance. Based on initial groundwater recharge delineation studies by Aley and Aley (2004, p. 22), the 328 ft (100 m) buffer will also facilitate the maintenance of the hydrology associated with each unit. Actions outlined in area management plans and the state recovery plan for the Hine's emerald dragonfly address threats to habitat by preventing the encroachment of invasive woody plants (ecological succession), and by maintaining open conditions of the fen and surrounding areas with prescribed fire and stand improvement through various timber management practices.

In addition to site-specific plans, there is also a state-wide recovery plan (Missouri Department of Conservation 2007f) outlines objectives for conserving the Hine's emerald dragonfly on state managed and privately owned property in Missouri (Table 6). The recovery plan includes a budget for Fiscal Years 2006 to 2012, showing MDC's commitment to acquire the funds necessary to implement these actions. The MDC coordinated closely with the Service in developing the site-specific plans and the state-wide Hine's emerald dragonfly recovery plan and the recommended conservation measures within it. We believe that by implementing those recommended conservation actions in Missouri we can achieve recovery of the species in the state.

TABLE 6.—SUMMARY OF OBJECTIVES IN MDC'S RECOMMENDATIONS FOR RECOVERY OF HINE'S EMERALD DRAGONFLY AND OZARK FEN COMMUNITIES IN MISSOURI (FY08–FY12)

MDC recovery plan objective	Conservation benefit for Hine's emerald dragonfly
Maintain the natural integrity of Ozark fen communities by decreasing exotic, feral, domestic, and undesirable native animal and plant populations specifically when those populations threaten Ozark fens, associated natural communities, and habitats essential for the life requirements of the dragonfly.	Protect, restore, or enhance breeding and foraging areas.
Restore local hydrology and protect groundwater contribution areas by eliminating past drainage improvements and ensuring developments do not adversely affect fen recharge areas.	Protect, enhance, or restore breeding and foraging areas.
Prohibit vehicle operation in fens unless specifically authorized or prescribed for Ozark fen restoration actions and Hine's emerald dragonfly habitat improvement projects.	Protect breeding and foraging areas.
Ensure that recreational overuse does not impact Ozark fen communities.	Protect breeding and foraging areas.
Develop public outreach materials and solutions to advance the conservation of Hine's emerald dragonfly and Ozark fen communities.	Protect, enhance, or restore breeding and foraging areas.
Manage fire-dependent wetland communities with a fire regime similar to that in which the natural communities evolved and developed.	Protect, enhance, or restore breeding and foraging areas.
Monitor fen water quality, identify potential pollutants, and develop strategies to abate damages.	Protect, enhance, or restore breeding and foraging areas.
Increase connectivity within Ozark fen complexes	Enhance breeding and foraging areas.

Numerous agencies and groups are working together to alleviate threats to the Hine's emerald dragonfly in Missouri. These cooperating partners include conservation area managers, the MDC's Private Land Services (PLS) Division and Natural History biologists, MDC's Recovery Coordinator for the species, the Service, the Missouri Hine's Emerald Dragonfly Workgroup, and the Federal Hine's Emerald Dragonfly Recovery Team (Recovery Team).

We believe that management guidelines outlined in the conservation area plans and natural area plans, the BMPs, the state-wide recovery plan for the Hine's emerald dragonfly, and the close coordination among the various agencies mentioned above (plus other identified species experts as needed), adequately address identified threats to Hine's emerald dragonfly and its habitat on MDC lands. The conservation measures as outlined above provide greater benefit to the Hine's emerald dragonfly than would designating critical habitat on Missouri state-managed lands. Thus the relative benefits of designation of these lands are diminished and limited.

(1) Benefits of Designation.

The primary effect of designating any particular area as critical habitat is the requirement for Federal agencies to consult with us under section 7 of the Act to ensure actions they carry out, authorize, or fund do not destroy or adversely modify designated critical

habitat. Absent critical habitat designation, Federal agencies remain obligated under section 7 to consult with us on actions that may affect a federally listed species to ensure such actions do not jeopardize the species' continued existence.

Designation of critical habitat may also provide educational benefits by informing land managers of areas essential to the conservation of the Hine's emerald dragonfly. In the case of Missouri, there is no appreciable educational benefit because the MDC has already demonstrated its knowledge and understanding of essential habitat for the species through active recovery efforts and consultation.

Furthermore, the benefits of including State-managed lands in Missouri in designated critical habitat would be minimal because the land managers/landowners are currently implementing conservation actions for the Hine's emerald dragonfly and its habitat that are beyond those that could be required if critical habitat were designated.

(2) Benefits of Exclusion.

Excluding State-owned lands in Missouri from critical habitat designation will sustain and enhance the already robust working relationship between the Service and MDC. The State has a strong history of conserving the Hine's emerald dragonfly and other federally listed species. The MDC is committed to continued conservation for the Hine's emerald dragonfly through its state management plan for the species. The Service's willingness to work closely with MDC on innovative ways to manage federally listed species will continue to reinforce those conservation efforts.

(3) Benefits of Exclusion Outweigh the Benefits of Designation.

We find that the benefits of designating critical habitat for the Hine's emerald dragonfly on State lands in Missouri are small in comparison to the benefits of exclusion. Exclusion will enhance the partnership efforts with the MDC focused on conservation of the species in the State, and secure conservation benefits for the species beyond those that could be required under a critical habitat designation.

(4) Exclusions Will Not Result in Extinction of the Species.

We believe that excluding the Missouri units under MDC ownership (units 16, 17, 18, and 22) and Unit 14, that is privately owned but managed by MDC, from critical habitat would not result in the extinction of Hine's emerald dragonfly because current conservation efforts under the Conservation and Natural Area Plans and other Plans by the MDC adequately protect essential Hine's emerald dragonfly habitat and provide appropriate management to maintain and enhance the PCEs for the Hine's emerald dragonfly. In addition, conservation partnerships on non-Federal lands are important conservation tools for this species in Missouri that could be negatively affected by the designation of critical habitat. As such, there is no reason to believe that this exclusion would result in extinction of the species.

Private Land Management—Exclusions Under Section 4(b)(2) of the Act

We are excluding all private land in Missouri under section 4(b)(2) of the Act based on the cooperative conservation partnership with private landowners in Missouri. Missouri units 2 (in part), 4, 6, 8 (in part), 9, 10, 11 (in part), 12, 13, 15, 19, and 20 are under private ownership.

The Nature Conservancy manages Grasshopper Hollow (in Unit 11) in accordance with the Grasshopper Hollow Management Plan (The Nature Conservancy 2006, p. 1–4) to maintain fen habitat. The plan includes management goals that specifically address the Hine's emerald dragonfly and its habitat: (1) Sustain the high quality fen complex, with a full suite of fen biota; (2) Restore the fen system in suitable drained fields at the north end of Doe Run lands; and (3) Ensure the long term viability of healthy populations of the Hine's emerald dragonfly.

Threats to the species identified on private land are feral hogs, habitat fragmentation, road construction and maintenance, ecological succession, all terrain vehicles, beaver dams, utility maintenance, application of herbicides, and change in ownership. All threats listed above for private property in Missouri are addressed in the Missouri Department of Conservation's state-wide recovery plan for the Hine's emerald dragonfly (Missouri Department of Conservation 2007f, 1–33pp) and through close coordination between personnel with the MDC's PLS Division or Regional Natural History biologists and private landowners. Additionally, MDC personnel work closely and proactively with the National Resources Conservation Service (NRCS) and the Service's Partners for Fish and Wildlife Program to initiate management and maintenance actions on fens occupied by Hine's emerald dragonflies that benefit the species and alleviate potential threats. The Missouri Department of Conservation (2007d, 1–2pp) has developed BMPs for the Hine's emerald dragonfly, which further displays the agencies dedication to conserving the species and its habitat on both State and private land. These BMPs and close coordination with MDC's Recovery Leader for Hine's emerald dragonflies have resulted in the implementation of various activities on private property to benefit the species or minimize potential threats. Current and ongoing conservation actions on private lands include the following: Developing private land partner property plans; providing landowners with technical support through ongoing site visits; providing grazing and forage harvesting recommendations to minimize potential fen damage; excluding heavy equipment from fen habitat; placing signs on fen habitat alerting land owners to the sensitivity of this natural community; providing public land owners with public outreach regarding the life history requirements of Hine's emerald dragonflies and the sensitivity of its unique habitat; providing recommendations on the control of beavers, which are harmful to delicate fen habitat; providing education on the need and correct use of prescribed fire; excluding livestock from fens and other wetland types; restoring fens and wetlands by restoring hydrology or controlling invasive species and woody brush invasion; applying appropriate nutrient and pest management on adjacent agricultural fields to reduce runoff; implementing practices that control erosion and prevent sediment delivery to wetlands; and when applicable, facilitating the transfer of property from private to public ownership. Although implementing Hine's emerald dragonfly BMPs on private land is voluntary, the best way we have found to ensure effective conservation on private lands is through such voluntary actions. Private landowners are generally more receptive to voluntary conservation actions on their lands than they are to regulated actions or perceived regulation. The MDC has successfully conducted conservation actions on many private land parcels and has dedicated numerous staff hours to these actions (Table 7).

TABLE 7.—SUMMARY OF PRIVATE LAND INITIATIVES AND AVERAGE ANNUAL EXPENDITURE FOR HINE'S EMERALD DRAGONFLY CONSERVATION MEASURES CONDUCTED BY MDC STAFF ON PRIVATE LANDS (SINCE 2005)

Conservation action	Average annual expenditure since 2005 (in MDC staff hours)
Landowner technical support in the form of in-field consultation, correspondence, and other communications. Includes operations that effect private land fens that are known Hine's emerald dragonfly sites or potential sites.	250 hours.
Farm plan development and fen restoration planning for private landowners. Includes the development of planning documents for private landowners that have Ozark fens.	75 hours.
Grazing system and forage harvesting recommendations to private landowners. Many Missouri fens are located in pastures or hay meadows. Maintaining stocking rates at suitable levels benefits Ozark fens and limits pressures associated with woody encroachment.	50 hours.
Technical support to landowners directly related to beaver control within Ozark fen communities.	25 hours.
Technical assistance to landowners regarding fencing options to exclude cattle or combat possible ATV incursions.	25 hours.
Coordination with utility companies applying herbicides or operating mowing equipment on rights-of-way that cross private lands—activities that have the potential to damage fen communities and Hine's emerald dragonfly habitats.	50 hours.
Fen restoration demonstration projects including woody encroachment clearing and herbicide application; often in direct coordination with private land partners.	50 hours plus herbicide and application expenses of $2500.00.
Demonstration exotics control including herbicide application and integrated pest management strategy development. Willow encroachment, reed canary grass control, and multi-flora rose control within fens on private lands. Several private land fens have characteristic infestations of undesirable species; MDC staff have applied herbicides to problem exotic invasive plant species to ensure fen habitats are suitable for Hine's emerald dragonfly.	25 hours.
Coordination with private landowners to ensure Hine's emerald dragonfly habitat is not impacted by pasture renovation activities; includes delineation of habitat areas with private land partners.	15 hours (There have only been a few opportunities for this action).
Signage placement on private land fens. Signage is placed on some fens when requested by private landowners or to engender support and understanding for fen restoration projects.	15 hours.
Installation of firelines, in cooperation with private landowners, on burn units that include fen communities.	15 hours.
Coordination with landowners interested in selling property with Ozark fens and wetland habitats that have the potential to support Hine's emerald dragonfly. Includes close communications with landowners; interagency coordination and technical assistance; coordination with surveyors, real estate lawyers, and biologists.	40 hours.
Presentation and outreach events directed to landowners with Hine's emerald dragonfly populations or Ozark fen natural communities.	40 hours.
Media contacts (radio, television, printed media) and coordination directly related to Hine's emerald dragonfly recovery.	80 hours.
Coordination with conservation agents, often regarding private land fens that may be threatened by ATV activities.	40 hours.
Patrols and enforcement operations	50 hours.

Effective measures will continue to be incorporated to minimize threats from feral hogs and beavers by implementing MDC's state-wide recovery plan for the Hine's emerald dragonfly (Missouri Department of Conservation 2007f, 1–3pp) and by providing technical assistance and implementation assistance to private landowners through coordination with MDC's PLS Division or Regional Natural History biologists, the NRCS, and the Service's Partners for Fish and Wildlife Program. Utility maintenance (Units 8 and 14) and herbicide application to maintain power line rights-of-way (Unit 8) were identified as potential threats at two units. Implementing the actions outlined in Missouri Department of Conservation's state-wide recovery plan for the Hine's emerald dragonfly and ongoing coordination among the MDC's PLS Division, MDC's Hine's emerald dragonfly recovery coordinator, and the appropriate utility maintenance company and its contractors will continue to minimize potential threats (Missouri Department of Conservation 2007f, 1–3pp). The potential change in ownership on private land in Missouri from cooperative landowners to ones who may not want to manage their land to benefit the species is a concern on some private lands. This issue will continue to be addressed by close coordination between new landowners and MDC's PLS Division or their Hine's emerald dragonfly recovery coordinator. The landowner's access to grants and technical assistance from multiple landowner incentive programs administered through the MDC, NRCS, and the Service's Partners for Fish and Wildlife Program will remain a main focus of outreach to potential new private property owners. Unit 14 is under private ownership but is a designated State Natural Area (Missouri Natural Areas Committee 2007). An updated plan developed for the area ensures that the integrity of the fen is maintained (Missouri Natural Areas Committee 2007).

Personnel from MDC are currently working in cooperation with private landowners that have important fen habitat on their lands that support Hine's emerald dragonflies. This direct work with private landowners allows for effective maintenance and

enhancement of Hine's emerald dragonfly habitat in the state. MDC is also working toward establishing new landowner relationships and cooperative management programs that will provide important contributions to Hine's emerald dragonfly recovery. Because of the close coordination and excellent working partnership of all parties listed above, we believe that threats to Hine's emerald dragonfly and its habitat on private property in Missouri are minimized. The conservation measures as outlined above provide greater benefit to the Hine's emerald dragonfly than would designating critical habitat on private lands in Missouri. Thus the relative benefits of designation of these lands are diminished and limited.

(1) Benefits of Designation.

The primary effect of designating any particular area as critical habitat is the requirement for Federal agencies to consult with us under section 7 of the Act to ensure actions they carry out, authorize, or fund do not destroy or adversely modify designated critical habitat. Absent critical habitat designation, Federal agencies remain obligated under section 7 to consult with us on actions that may affect a federally listed species to ensure such actions do not jeopardize the species' continued existence.

Designation of critical habitat may also provide educational benefits by informing land managers of areas essential to the conservation of the Hine's emerald dragonfly. In the case of Missouri, private conservation groups have already demonstrated their knowledge and understanding of essential habitat for the species through active recovery efforts and consultation. The Missouri public, particularly landowners with Hine's emerald dragonfly habitat on their lands, is also well informed about the Hine's emerald dragonfly.

Furthermore, the benefits of including several of the privately owned areas in Missouri in designated critical habitat would have been minimal because the land managers/landowners are currently implementing conservation actions for the Hine's emerald dragonfly and its habitat that are beyond those that could be required if critical habitat were designated.

(2) Benefits of Exclusion.

We view the continued cooperative conservation partnerships with private landowners to be essential for the conservation of the Hine's emerald dragonfly in Missouri. The designation of critical habitat on private lands in Missouri would harm ongoing and future partnerships that have been or may be developed on those lands. Many private landowners in Missouri view critical habitat negatively and believe that such designation would impact their ability to manage their land. This is despite many attempts at public outreach and education to the contrary. Based on past experiences in Missouri, designation of critical habitat would likely hamper the conservation actions that have been initiated for the Hine's emerald dragonfly on private land through various landowner incentive programs. The MDC has a longstanding history of working with private landowners in Missouri, especially regarding the conservation of federally listed species. Of the 26 units being excluded in the State, 12 (46 percent) are on private land. The MDC has worked closely with the NRCS to implement various landowner incentive programs that are available through the Farm Bill.

To further facilitate the implementation of these and other landowner incentive programs on the ground, the MDC created the PLS Division and established 49 staff positions throughout the State. The PLS Division works with multiple landowners within the range of the Hine's emerald dragonfly in Missouri to undertake various conservation actions to maintain and/or enhance fen habitat. The MDC has also worked closely with the Service's Partners for Fish and Wildlife Program to implement various management actions on private lands. Close coordination between the two agencies for actions that could benefit the species on private land will continue. The designation of critical habitat for the Hine's emerald dragonfly on private land in Missouri would significantly hinder the ability to implement those landowner incentive programs with multiple landowners, which would negate conservation benefits already initiated for the species or those planned in the future.

The Hine's emerald dragonfly, along with other federally listed species, is such a contentious issue in Missouri that the species is viewed negatively by many private landowners. Multiple private landowners have been contacted by MDC personnel to obtain permission to survey the species on their property. In some cases, access has been denied because of negative perceptions associated with the presence of federally listed species on private land and the perception that all fens currently occupied by the Hine's emerald dragonfly would be designated as critical habitat (Bob Gillespie, MDC, pers. comm. June 2005).

Although access to survey some private land has been denied, several landowners have conducted various management actions to benefit the Hine's emerald dragonfly, especially in Reynolds County where the largest amount of currently occupied habitat on privately owned land occurs. The designation of critical habitat on such sites would have dissolved developing partnerships and prevented the initiation of additional conservation actions. Additionally, it is likely that the designation of critical habitat on private land in Missouri would have ended the cooperation associated with conservation actions already underway (Missouri Department of Conservation, in litt. 2007).

Based on potential habitat identified by examining the Service's National Wetland Inventory maps, there are other areas with suitable Hine's emerald dragonfly habitat where the species may be found. Many of these sites occur on private land. Pending further research on currently occupied sites, especially related to population dynamics and the role Missouri populations may play in achieving the recovery objectives outlined in the Service's Recovery Plan (U.S. Fish and Wildlife Service 2001, pp. 31–32), the likely discovery of additional sites could provide significant contributions towards the range-wide recovery of the species. Thus, continued or additional denial of access to private property could hamper the recovery of the species.

(3) Benefits of Exclusion Outweigh the Benefits of Inclusion.

We find that the benefits of designating critical habitat for the Hine's emerald dragonfly in Missouri are small in comparison to the benefits of exclusion. Exclusion will enhance the partnership efforts with private conservation groups and private landowners focused on conservation of the species in the State, and secure conservation benefits for the species beyond those that could be required under a critical habitat designation.

The benefits of designating critical habitat on private lands in Missouri are minor compared to the much greater benefits derived from exclusion, including the maintenance of existing, established partnerships and encouragement of additional conservation partnerships in the future. It is our strong belief that benefits gained through extra outreach efforts associated with critical habitat and additional section 7 requirements (in the limited situations where there is a Federal nexus), are negated by the loss of current and future conservation partnerships, especially given that

access to private property and the possible discovery of additional sites in Missouri could help facilitate recovery of the species.

(4) The Exclusions Will Not Result in Extinction of the Species.

We believe that excluding the Missouri units in private ownership (units 2 (in part), 4, 6, 8 (in part), 9, 10, 11 (in part), 12, 13, 15, 19, and 20) from critical habitat would not result in the extinction of Hine's emerald dragonfly because current conservation efforts under The Nature Conservancy's Management Plan for Grasshopper Hollow adequately protect essential Hine's emerald dragonfly habitat and provide appropriate management to maintain and enhance the PCEs for the Hine's emerald dragonfly. In addition, conservation partnerships on non-Federal lands are important conservation tools for this species in Missouri that could be negatively affected by the designation of critical habitat in Missouri, where there is an established negative sentiment toward federal regulation for endangered species by some private landowners. As such, there is no reason to believe that this exclusion would result in extinction of the species.

Our economic analysis indicates an overall low cost resulting from the designation. Therefore, we have found no areas for which the economic benefits of exclusion outweigh the benefits of designation, and so have not excluded any areas from this designation of critical habitat for the Hine's emerald dragonfly based on economic impacts. In addition, we anticipate no impact to national security, Tribal lands, or HCPs from this critical habitat designation, and have not excluded any lands based on those factors.

Economic Analysis

Section 4(b)(2) of the Act requires us to designate critical habitat on the basis of the best scientific information available and to consider the economic and other relevant impacts of designating a particular area as critical habitat. We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of specifying such areas as critical habitat. We cannot exclude such areas from critical habitat when such exclusion will result in the extinction of the species concerned. Following the publication of the proposed critical habitat designation, we conducted an economic analysis to estimate the potential economic effect of the designation. The draft analysis was made available for public review on March 20, 2007. We accepted comments on the draft analysis until April 3, 2007.

The primary purpose of the economic analysis is to estimate the potential economic impacts associated with the designation of Hine's emerald dragonfly critical habitat. This information is intended to assist the Secretary in making decisions about whether the benefits of excluding particular areas from the designation outweigh the benefits of including those areas in the designation. This economic analysis considers the economic efficiency effects that may result from the designation, including habitat protections that may be co-extensive with the listing of the species. It also addresses distribution of impacts, including an assessment of the potential effects on small entities and the energy industry. This information can be used by the Secretary to assess whether the effects of the designation might unduly burden a particular group or economic sector.

This analysis focuses on the direct and indirect costs of the rule. However, economic impacts to land use activities can exist in the absence of critical habitat. These impacts may result from, for example, local zoning laws, State and natural resource laws, and enforceable management plans and best management practices applied by other State and Federal agencies. Economic impacts that result from these types of protections are not included in the analysis as they are considered to be part of the regulatory and policy baseline.

The draft economic analysis forecasts the costs associated with conservation activities for the Hine's emerald dragonfly would range from $16.8 million to $46.7 million in undiscounted dollars over the next 20 years. In discounted terms, potential economic costs are estimated to be $13.3 to $34.5 million (using a 3 percent discount rate) and $10.5 to $25.2 million (using a 7 percent discount rate). In annualized terms, potential costs are expected to range from $0.8 to $2.3 million annually (annualized at 3 percent) and $0.9 to $2.4 million annually (annualized at 7 percent). The Service did not exclude any areas based on economics.

A copy of the economic analysis with supporting documents is included in our administrative record and may be obtained by contacting the Field Supervisor, Chicago, Illinois Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**) or by downloading from the Internet at *http://www.fws.gov/midwest/Endangered.*

Required Determinations

Regulatory Planning and Review

In accordance with Executive Order 12866, this document is a significant rule because it may raise legal and policy issues. Based on our draft economic analysis, potential post-designation (2007–2026) costs are estimated to range from $16.8 to $46.6 million in undiscounted 2006 dollars. In discounted terms, potential economic costs are estimated to be $13.3 to $34.5 million (using a 3 percent discount rate) and $10.5 to $25.2 million (using a 7 percent discount rate). In annualized terms, potential costs are expected to range from $0.8 to $2.3 million annually (3 percent) and $0.9 to $2.4 million annually (at 7 percent). Therefore, we do not believe that the designation of critical habitat for the Hine's emerald dragonfly would result in an annual effect on the economy of $100 million or more or affect the economy in a material way. Due to the timeline for publication in the **Federal Register**, the Office of Management and Budget (OMB) has not formally reviewed the rule or accompanying draft economic analysis.

Further, Executive Order 12866 directs Federal Agencies promulgating regulations to evaluate regulatory alternatives (Office of Management and Budget, Circular A–4, September 17, 2003). Pursuant to Circular A–4, once it has been determined that the Federal regulatory action is appropriate, the agency will need to consider alternative regulatory approaches. Because the determination of critical habitat is a statutory requirement under the ACT, we must then evaluate alternative regulatory approaches, where feasible, when promulgating a designation of critical habitat.

In developing our designations of critical habitat, we consider economic impacts, impacts to national security, and other relevant impacts pursuant to section 4(b)(2) of the Act. Based on the discretion allowable under this provision, we may exclude any particular area from the designation of critical habitat providing that the benefits of such exclusion outweigh the benefits of specifying the area as critical habitat and that such exclusion would not result in the extinction of the species. As such, we believe that the evaluation of the inclusion or exclusion of particular areas, or combination thereof, in a designation constitutes our regulatory alternative analysis.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq., as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. Based upon our draft economic analysis of the designation, we provide our analysis for determining whether the designation of critical habitat for the Hine's emerald dragonfly would result in a significant economic impact on a substantial number of small entities. This determination is subject to revision based on comments received as part of the final rulemaking. According to the Small Business Administration (SBA), small entities include small organizations, such as independent nonprofit organizations, and small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents, as well as small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term significant economic impact is meant to apply to a typical small business firm's business operations.

To determine if the Hine's emerald dragonfly critical habitat designation would affect a substantial number of small entities, we considered the number of small entities affected within particular types of economic activities (such as residential and commercial development). We considered each industry or category individually to determine if certification is appropriate. In estimating the numbers of small entities potentially affected, we also considered whether their activities have any Federal involvement; some kinds of activities are unlikely to have any Federal involvement and so will not be affected by the designation of critical habitat. Designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies; non-Federal activities are not affected.

Federal agencies must consult with us if their activities may affect designated critical habitat. Consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into the existing consultation process.

In our draft economic analysis, we evaluated the potential economic effects on small business entities resulting from conservation actions related to the listing of the Hine's emerald dragonfly and designation of its critical habitat. This analysis estimated prospective economic impacts due to the implementation of Hine's emerald dragonfly conservation efforts in six categories: development activities, water use, utility and infrastructure maintenance, road and railway use, species management and habitat protection activities, and recreation. The following is a summary of information contained in the draft economic analysis:

(a) Development Activities

According to the draft economic analysis, the forecast cost of Hine's emerald dragonfly development-related losses ranges from $13.0 to $22.6 million (undiscounted) over 20 years, or $10.1 to 15.9 million assuming a 3 percent discount rate and $8.0 to $11.2 assuming a 7 percent discount rate. The costs consist of the following: (1) Losses in residential land value in Wisconsin and Michigan due to potential limitations on residential development; (2) impacts to Material Services Corporation (MSC) quarrying operations in Illinois; and (3) dragonfly conservation efforts associated with the construction of the Interstate 355 Extension. Given the small average size and value of private land parcels in Wisconsin and Michigan, the non-institutional landowners (those for which land value losses were computed; institutionally owned properties do not have assessed property values) are most likely individuals, who are not considered small entities by the SBA. MSC has 800 employees in Illinois and Indiana, and was recently purchased by Hanson, PLC, which has more than 27,000 employees worldwide. The SBA Small Business Standard for Crushed and Broken Limestone Mining and Quarrying industry sector is 500 employees. Therefore, MSC is not considered a small entity. The conservation-related costs associated with the construction of the Interstate 355 Extension are borne by the Illinois Tollway Authority. The Illinois Tollway Authority does not meet the definition of a small entity. As a result of this information, we have determined that the designation of critical habitat for the Hine's emerald dragonfly is not anticipated to have a significant effect on a substantial number of small development businesses.

(b) Water Use

According to the draft economic analysis, the forecast cost of Hine's emerald dragonfly water use-related losses range from $46,000 to $7.0 million (undiscounted) over 20 years, or $33,000 to $5.4 million assuming a 3 percent discount rate and $21,000 to $4.0 million assuming a 7 percent discount rate. Public water systems may incur costs associated with drilling deep water aquifer wells. The USEPA Agency has defined small entity water systems as those that serve 10,000 or fewer people. None of the municipalities that could be required to construct deep aquifer wells as a result of conservation efforts for the Hine's emerald dragonfly has populations below 10,000. As a result of this information, we have determined that the designation of critical habitat for the Hine's emerald dragonfly is not anticipated to have a substantial effect on a substantial number of small municipalities.

(c) Utility and Infrastructure Maintenance

According to the draft economic analysis, the forecast cost of Hine's emerald dragonfly utility and infrastructure maintenance-related losses is estimated to be $1.5 million (undiscounted) over 20 years, or $1.3 million assuming a 3 percent discount rate and $1.1 million assuming a 7 percent discount rate. The costs are associated with necessary utility and infrastructure maintenance using dragonfly-sensitive procedures. Within the designated critical habitat units, Commonwealth Edison is responsible for electrical line maintenance, county road authorities for road maintenance, and Midwest Generation for railroad track maintenance in Illinois Units 1 and 2. Neither company is considered a small entity. As a result of this information, we have determined that the designation of critical habitat for the

Hine's emerald dragonfly is not anticipated to have a significant effect on a substantial number of small entities.

(d) Road and Railway Use

According to the draft economic analysis, the forecast cost of Hine's emerald dragonfly road and railway use-related losses range from $1.7 to $15.0 million (undiscounted) over 20 years, or $1.5 to $11.7 million assuming a 3 percent discount rate and $1.3 to $8.8 million assuming a 7 percent discount rate. The costs are associated with necessary railway upgrades for dragonfly conservation. Midwest Generation is responsible for railroad track improvements in Illinois. Neither Midwest Generation nor the individual travelers who would be affected by slower road speeds are considered small entities. As a result of this information, we have determined that the designation of critical habitat for the Hine's emerald dragonfly is not anticipated to have a significant effect on a substantial number of small entities.

(e) Species Management and Habitat Protection Activities

According to the draft economic analysis, the forecast cost of Hine's emerald dragonfly species management and habitat protection-related losses is estimated at $886,000 (undiscounted) over 20 years, or $710,000 assuming a 3 percent discount rate and $563,000 assuming a 7 percent discount rate. The costs primarily consist of species monitoring, maintenance of habitat, invasive species and feral hog control, and beaver dam mitigation. Species management and habitat protection costs will be borne by The Nature Conservancy (Wisconsin chapter), The Ridges Sanctuary, the Service, the U.S. Forest Service, the MIDNR, and the MDC. None of those entities meets the definition of a small entity. As a result of this information, we have determined that the designation of critical habitat for the Hine's emerald dragonfly is not anticipated to have a significant effect on a substantial number of small entities.

(f) Recreation

According to the draft economic analysis, the forecast cost of Hine's emerald dragonfly recreation-related losses are estimated at $19,000. Recreational off-road vehicles and equestrian activities have the potential to alter Hine's emerald dragonfly habitat and extirpate populations. The costs are associated with mitigating the effects of those recreational activities. Those costs will be borne by the MIDNR, MDC, the U.S. Forest Service, and various county police departments. None of those entities meets the definition of a small entity. As a result of this information, we have determined that the designation of critical habitat for the Hine's emerald dragonfly is not anticipated to have a significant effect on a substantial number of small entities.

Based on the previous, sector-by-sector analysis, we have determined that this critical habitat designation would not result in a significant economic impact on a substantial number of small entities.

Executive Order 13211

On May 18, 2001, the President issued Executive Order (E.O.) 13211 on regulations that significantly affect energy supply, distribution, and use. E.O. 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This final rule is considered a significant regulatory action under E.O. 12866 due to potential novel legal and policy issues, but it is not expected to significantly affect energy supplies, distribution, or use. Appendix A of the draft economic analysis provides a discussion and analysis of this determination. The Midwest Generation facilities that rely on the transportation of coal through Illinois Units 1 and 2 generate 1,960 megawatts of electricity. The dragonfly conservation measures advocated by the Service, however, are not intended to alter the operation of these facilities. Rather, the recommended conservation activities focus on improving maintenance and railway upgrades. Thus, no energy-related impacts associated with Hine's emerald dragonfly conservation activities within critical habitat units are expected. As such, the designation of critical habitat is not expected to significantly affect energy supplies, distribution, or use and a Statement of Energy Effects is not required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501), the Service makes the following findings:

(a) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments,'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance; or (ii) a duty arising from participation in a voluntary Federal program.'' The designation of critical habitat does not impose a legally binding duty on non-Federal government entities or private parties. Under the ACT, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. Non-Federal entities that receive Federal funding, assistance, permits, or otherwise require approval or authorization from a Federal agency for an action may be indirectly impacted by the designation of critical habitat. However, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply; nor would critical habitat shift the costs of the large entitlement programs listed above on to State governments.

(b) As discussed in the draft economic analysis of the designation of critical habitat for the Hine's emerald dragonfly, the impacts on nonprofits and small governments are expected to be

negligible. It is likely that small governments involved with development and infrastructure projects will be interested parties or involved with projects involving section 7 consultations for the Hine's emerald dragonfly within their jurisdictional areas. Any costs associated with this activity are likely to represent a small portion of a local government's budget. Consequently, we do not believe that the designation of critical habitat for the Hine's emerald dragonfly will significantly or uniquely affect these small governmental entities. As such, a Small Government Agency Plan is not required.

Takings

In accordance with E.O. 12630 (''Government Actions and Interference with Constitutionally Protected Private Property Rights''), we have analyzed the potential takings implications of designating critical habitat for the Hine's emerald dragonfly in a Takings Implications Assessment (TIA). The TIA concludes that the designation of critical habitat for this species does not pose significant takings implications for lands within or affected by the designation.

Federalism

In accordance with Executive Order 13132, the rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with DOI and Department of Commerce policy, we requested information from, and coordinated development of, this final critical habitat designation with appropriate State resource agencies in Illinois, Michigan, and Wisconsin. The designation of critical habitat in areas currently occupied by the Hine's emerald dragonfly may impose nominal additional regulatory restrictions to those currently in place and, therefore, may have little incremental impact on State and local governments and their activities. The designation may have some benefit to these governments in that the areas that contain the features essential to the conservation of the species are more clearly defined, and the PCEs of the habitat necessary to the conservation of the species are specifically identified. While making this definition and identification does not alter where and what federally sponsored activities may occur, it may assist these local governments in long-range planning (rather than waiting for case-by-case section 7 consultations to occur).

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are designating critical habitat in accordance with the provisions of the Endangered Species Act. This final rule uses standard property descriptions and identifies the PCEs within the designated areas to assist the public in understanding the habitat needs of the Hine's emerald dragonfly.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act. This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the Tenth Circuit, we do not need to prepare environmental analyses as defined by the NEPA in connection with designating critical habitat under the Endangered Species Act of 1973, as amended. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This assertion was upheld in the courts of the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. Ore. 1995), cert. denied 116 S. Ct. 698 (1996).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and the Department of Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. We have determined that there are no tribal lands occupied at the time of listing that contain the features essential for the conservation of the species and no tribal lands that are unoccupied areas that are essential for the conservation of the Hine's emerald dragonfly. Therefore, critical habitat for the Hine's emerald dragonfly has not been designated on Tribal lands.

References Cited

A complete list of all references cited in this rulemaking is available upon request from the Field Supervisor, Chicago Illinois Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT** section).

Author(s)

The primary author of this package is the Chicago, Illinois, Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

■ Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

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

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

■ 2. In § 17.11(h), the List of Endangered and Threatened Wildlife, revise the entry for ''Dragonfly, Hine's emerald'' under ''INSECTS'' to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*	*	
INSECTS							
*	*	*	*	*	*	*	
Dragonfly, Hine's emerald.	*Somatochlora hineana*	U.S.A. (AL, IL, IN, MI, MO, OH, and WI).	NA	E	573	17.95(i)	NA
*	*	*	*	*	*	*	

■ 3. In § 17.95(i), add an entry for ''Hine's emerald dragonfly (*Somatochlora hineana*),'' in the same alphabetical order in which this species appears in the table at 50 CFR 17.11(h), to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(i) Insects.

* * * * *

Hine's emerald dragonfly (*Somatochlora hineana*)

(1) Critical habitat units are depicted for Cook, DuPage and Will Counties, Illinois; Alpena, Mackinac, and Presque Isle Counties, Michigan; and Door and Ozaukee Counties, Wisconsin, on the maps below.

(2) The PCEs of critical habitat for the Hine's emerald dragonfly are:

(i) For egg deposition and larval growth and development:

(A) Organic soils (histosols, or with organic surface horizon) overlying calcareous substrate (predominantly dolomite and limestone bedrock);

(B) Calcareous water from intermittent seeps and springs and associated shallow, small, slow flowing streamlet channels, rivulets, and/or sheet flow within fens;

(C) Emergent herbaceous and woody vegetation for emergence facilitation and refugia;

(D) Occupied burrows maintained by crayfish for refugia; and

(E) Prey base of aquatic macroinvertebrates, including mayflies, aquatic isopods, caddisflies, midge larvae, and aquatic worms.

(ii) For adult foraging, reproduction, dispersal, and refugia necessary for roosting, resting and predator avoidance (especially during the vulnerable teneral stage):

(A) Natural plant communities near the breeding/larval habitat which may include fen, marsh, sedge meadow, dolomite prairie, and the fringe (up to 328 ft (100m)) of bordering shrubby and forested areas with open corridors for movement and dispersal; and

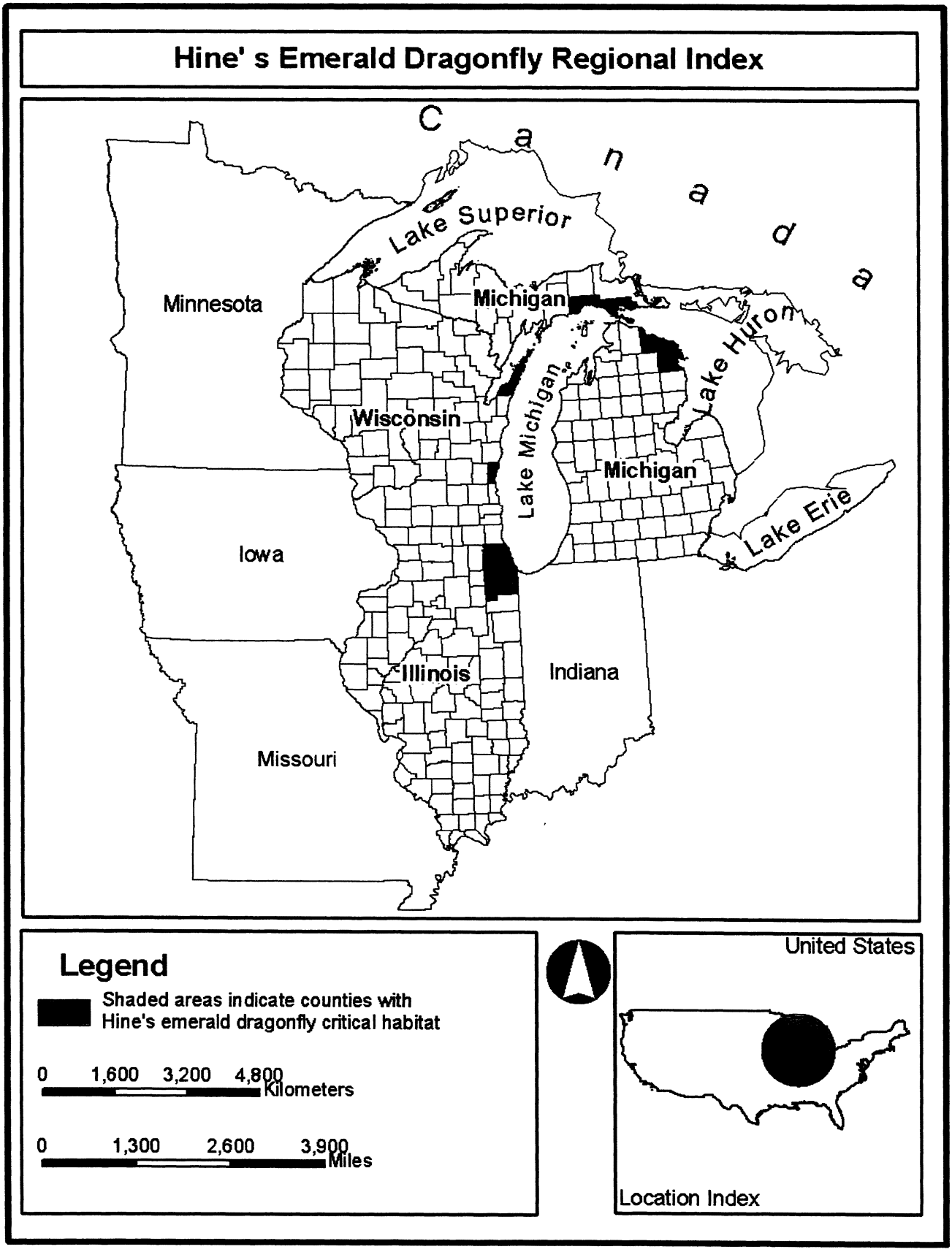
(B) Prey base of small, flying insect species (e.g., dipterans).

(3) Critical habitat does not include human-made structures existing on the effective date of this rule and not containing one or more of the PCEs, such as buildings, lawns, old fields, hay meadows, fallow crop fields, manicured lawns, pastures, piers and docks, aqueducts, airports, and roads, and the land on which such structures are located. We define ''old field'' here as cleared areas that were formerly forested and may have been used as crop or pasture land that currently support a mixture of native and non-native herbs and low shrubs. ''Fallow field'' is defined as a formerly plowed field that has been left unseeded for a season or more and is presently uncultivated. In addition, critical habitat does not include open-water areas (i.e., areas beyond the zone of emergent vegetation) of lakes and ponds.

(4) *Critical habitat map units.* Data layers defining map units were created on a base of USGS 7.5′ quadrangles, and critical habitat units were then mapped using Geographical Information Systems, Universal Transverse Mercator (UTM) coordinates. Critical habitat units are described using the public land survey system (township (T), range (R) and section (Sec.)).

(5) Note: Index map of critical habitat units (Index map) follows:

BILLING CODE 4310–55–P


Hine' s Emerald Dragonfly Regional Index
Canada
Lake Superior
Minnesota
Michigan
Lake Huron
Wisconsin
Lake Michigan
Michigan
Lake Erie
Iowa
Illinois
Indiana
Missouri
Legend
Shaded areas indicate counties with Hine's emerald dragonfly critical habitat
0 1,600 3,200 4,800 Kilometers
0 1,300 2,600 3,900 Miles
United States
Location Index

(6) Illinois Units 1 through 7, Cook, DuPage, and Will Counties, Illinois.

(i) Illinois Unit 1: Will County. Located in T36N, R10E, Sec. 22, Sec. 27, SE¼ NE¼ Sec. 28, NE¼ SE¼ Sec. 28, NW¼ NW¼ Sec. 34 of the Joliet 7.5′ USGS topographic quadrangle. Land south of Illinois State Route 7, east of Illinois State Route 53, and west of the Des Plaines River.

(ii) Illinois Unit 2: Will County. Located in T36N, R10E, Sec. 3, NW¼ E½ Sec. 10, E½ Sec. 15 of the Romeoville and Joliet 7.5′ USGS topographic quadrangles. Land east of Illinois State Route 53, and west of the Des Plaines River.

(iii) Illinois Unit 3: Will County. Located in T37N, R10E, SW¼ Sec. 26, NW¼ SE¼ Sec. 26, E½ Sec. 34, W½ NW¼ Sec. 35 of the Romeoville 7.5′ USGS topographic quadrangle. Land west and north of the Des Plaines River and north of East Romeoville Road.

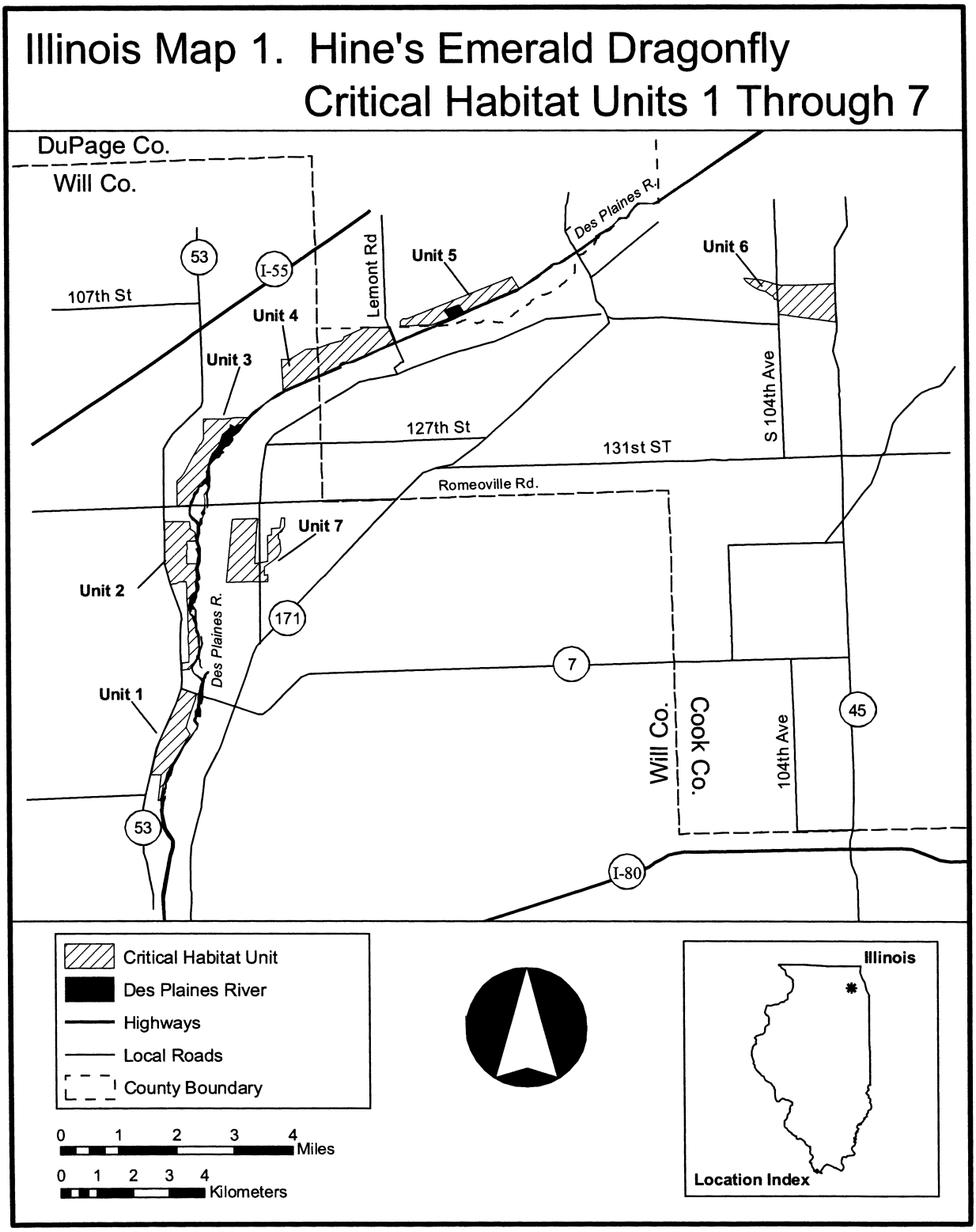
(iv) Illinois Unit 4: Will and Cook Counties. Located in T37N, R10E, S½ NE¼ Sec. 24, W½ SW¼ Sec. 24, SE¼ Sec. 24 and T37N, R11E, SW¼ SW¼ Sec. 17, Sec. 19, NW¼ Sec. 20 of the Romeoville 7.5′ USGS topographic quadrangle. Land to the south of Bluff Road, west of Lemont Road, and north of the Des Plaines River.

(v) Illinois Unit 5: DuPage County. Located in T37N, R11E, NW¼ Sec. 15, NW¼ SW¼ Sec. 15, S½ NE¼ Sec. 16, SW¼ Sec. 16, N½ SE¼ Sec. 16, SE¼ Sec. 17 of the Sag Bridge 7.5′ USGS topographic quadrangle. Land to the north of the Des Plaines River.

(vi) Illinois Unit 6: Cook County. Located in T37N, R12E, S½ Sec. 16, S½ NE¼ Sec. 17, N½ SE¼ Sec. 17, N½ Sec. 21 of the Sag Bridge and Palos Park 7.5′ USGS topographic quadrangles. Land to the north of the Calumet Sag Channel, south of 107th Street, and east of U.S. Route 45.

(vii) Illinois Unit 7: Will County. Located in T36N, R10E, W½ Sec. 1, Sec. 2, N½ Sec. 11 of the Romeoville and Joliet 7.5′; USGS topographic quadrangles. Land east of the Illinois and Michigan Canal.

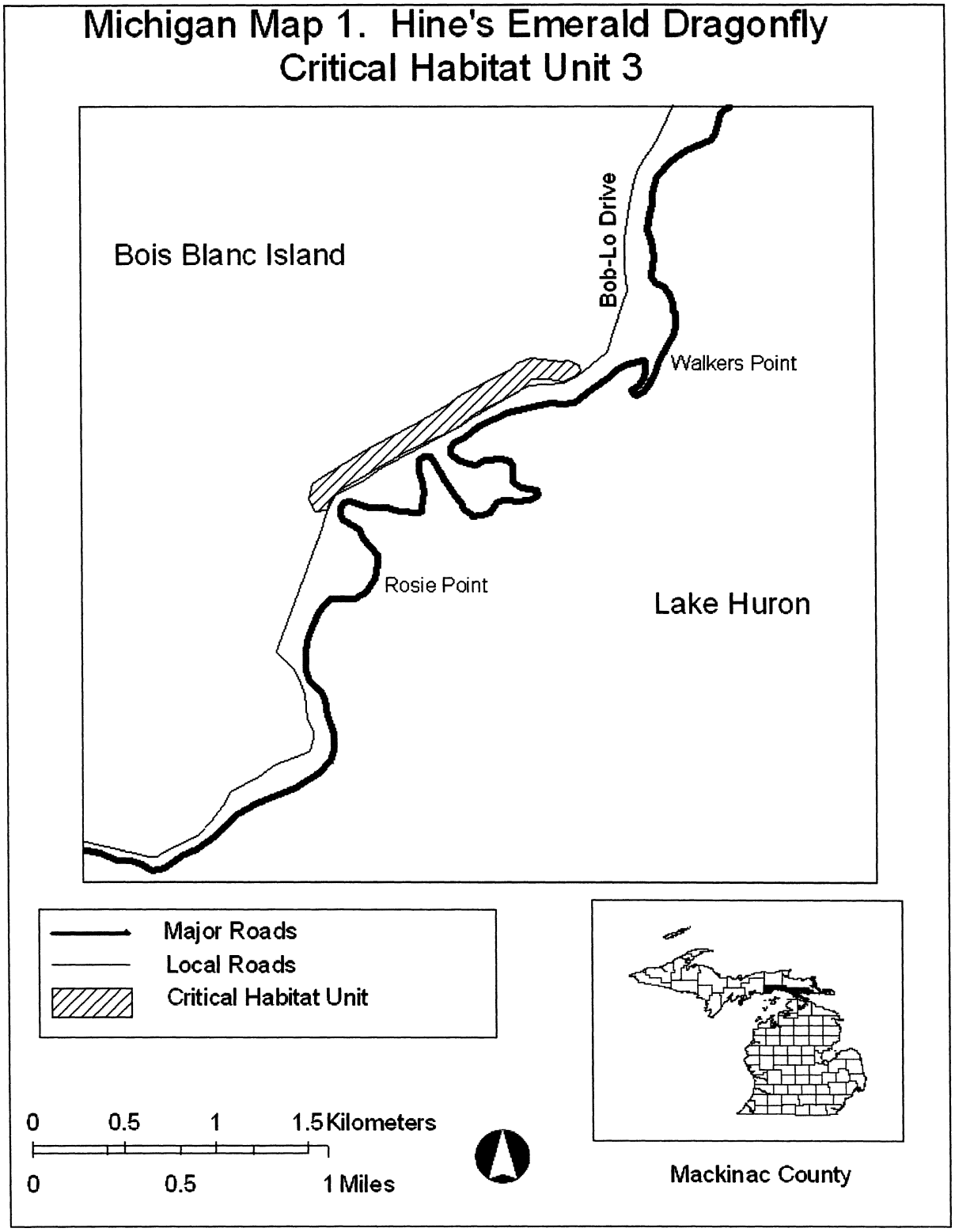
(viii) Note: Map of Illinois critical habitat Units 1 through 7 (Illinois Map 1) follows:



(7) Michigan Unit 3, Mackinac County, Michigan.

(i) Michigan Unit 3: Mackinac County. Located on the east end of Bois Blanc Island. Bois Blanc Island has not adopted an addressing system using the public land survey system. The unit is located in Government Lots 25 and 26 of the Cheboygan and McRae Bay 7.5′; USGS topographic quadrangles. The unit extends from approximately Walker's Point south to Rosie Point on the west side of Bob-Lo Drive. It extends from the road approximately 328 ft (100 m) to the west.

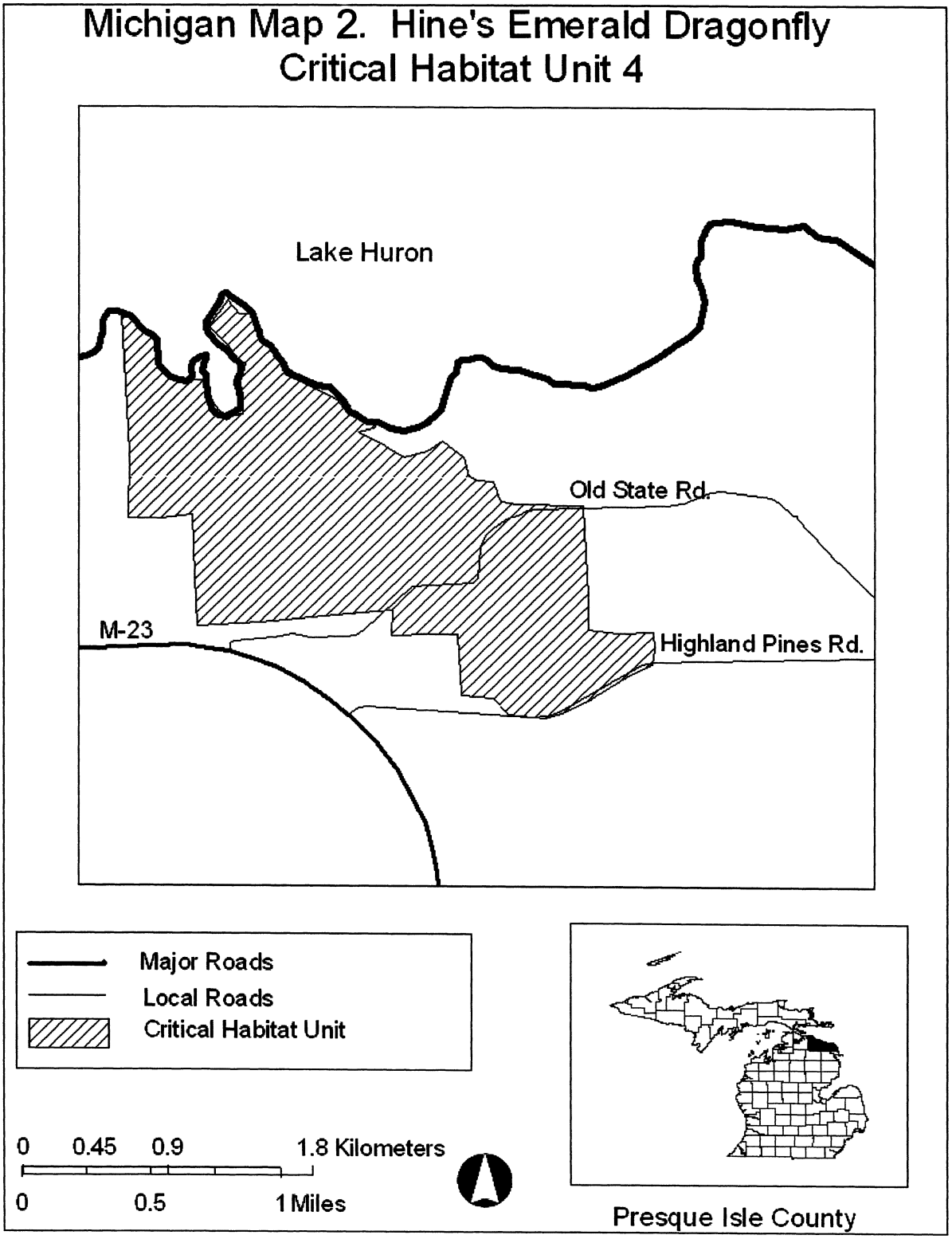
(ii) Note: Map of Michigan critical habitat Unit 3 (Michigan Map 1) follows:



(8) Michigan Unit 4, Presque Isle County, Michigan.

(i) Michigan Unit 4: Presque Isle County. Located approximately 12 miles southeast of the village of Rogers City. The unit contains all of T34N, R7E, SW¼ SW¼ Sec. 14, SW¼ NW¼ Sec. 15, NE¼ SW¼ Sec. 15, NW¼ SE¼ Sec. 15, NW¼ SW¼ Sec. 15, SE¼ SE¼ Sec. 15, NW¼ NE¼ Sec. 16, NE¼ NW¼ Sec. 16, SE¼ NE¼ Sec. 16, and NW¼ NW¼ Sec. 23. It also contains portions of T34N, R7E, all ¼ sections in Secs. 15, all ¼ sections in Sec. 16, SE¼ and SW¼ Sec. 9, SW¼ Sec. 10, SW¼ Sec. 14, NE¼ Sec. 22, NW¼ and NE¼ Sec. 23 of the Thompson's Harbor 7.5′ USGS topographic quadrangle. The northern boundary of the unit is Lake Huron and the southern boundary is north of M–23.

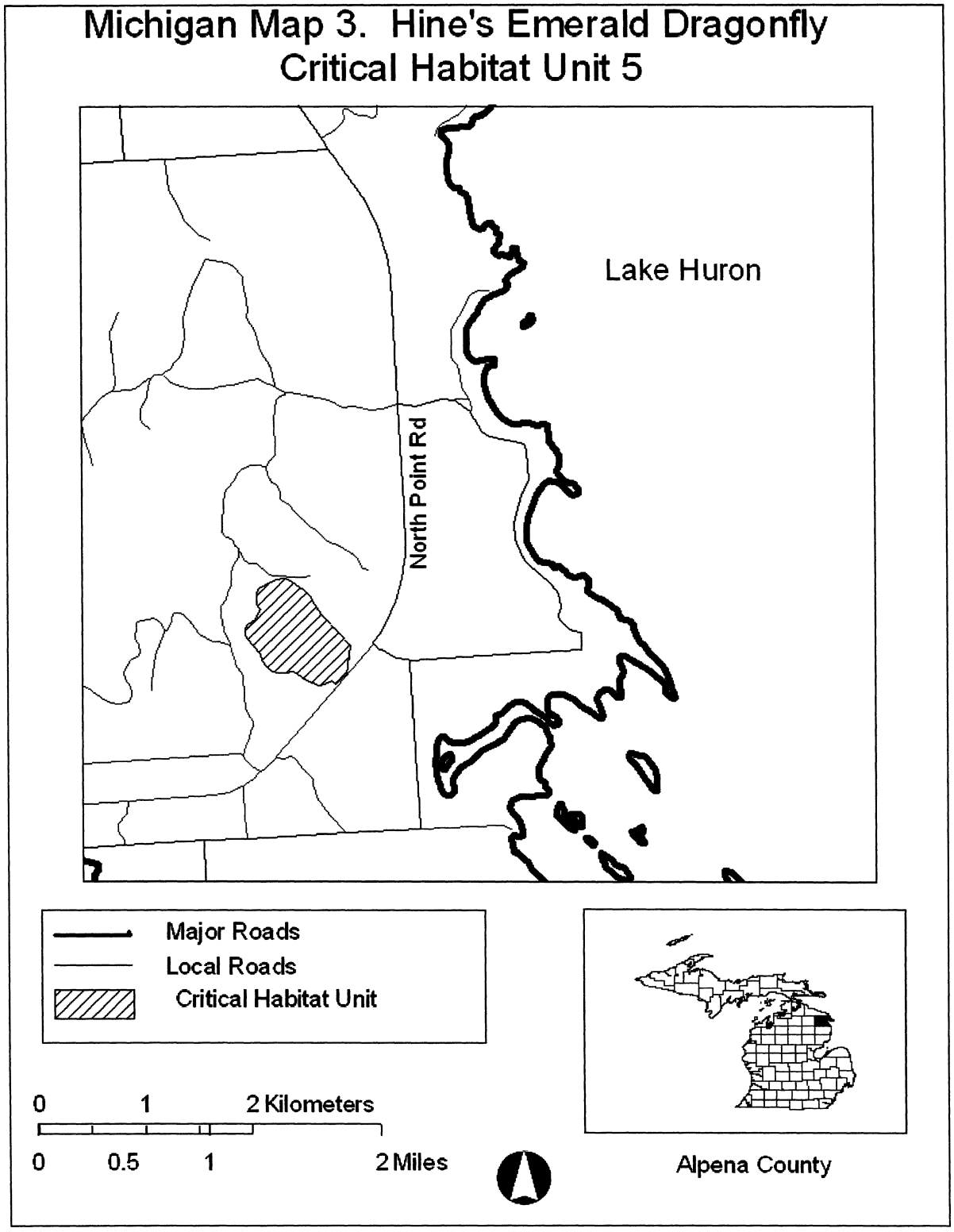
(ii) Note: Map of Michigan critical habitat Unit 4 (Michigan Map 2) follows:



(9) Michigan Unit 5, Alpena County, Michigan.

(i) Michigan Unit 5: Alpena County. Located approximately 9 miles northeast of the village of Alpena. The unit contains all of T31N, R9E, SE¼ SW¼ Sec. 9. It also contains portions of T31N, R9E, NW¼ SW¼ Sec. 9, NE¼ SW¼ Sec. 9, SW¼ SW¼ Sec. 9, SW¼ SE¼ Sec. 9; and portions of T31N, R9E, NE¼ NW¼ Sec. 16, NW¼ NE¼ Sec. 16, NW¼ NW¼ Sec. 16 of the 7.5′ USGS topographic quadrangle North Point 7.5′ USGS topographic quadrangle. North Point Road is east of the area.

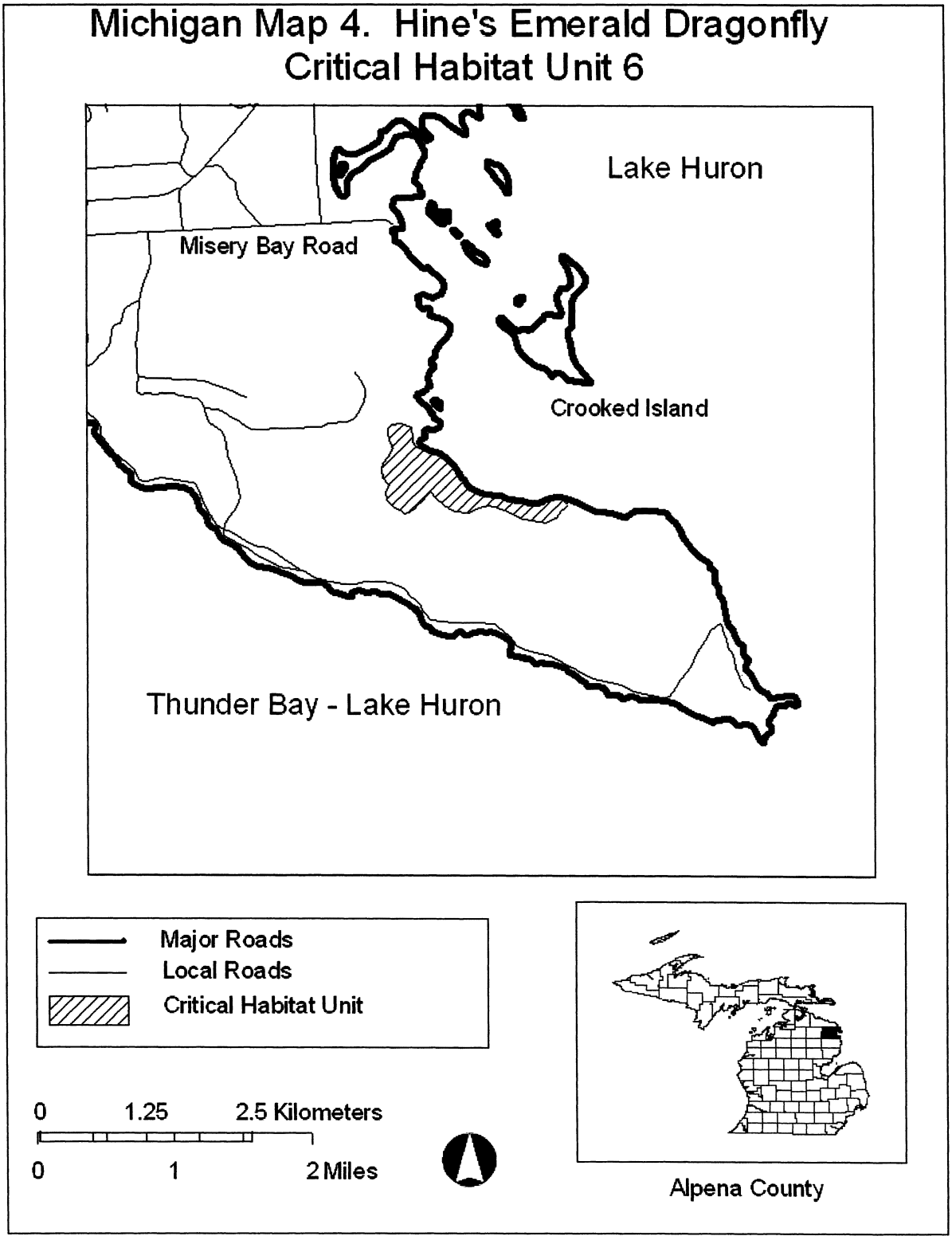
(ii) Note: Map of Michigan critical habitat Unit 5 (Michigan Map 3) follows:



(10) Michigan Unit 6, Alpena County, Michigan.

(i) Michigan Unit 6: Alpena County. Located approximately 5 miles east of the village of Alpena. The unit contains all of T31N, R9E, SW¼ SE¼ Sec. 27. It also contains portions of T31N, R9E, NW¼ SE¼ Sec. 27, NE¼ SW¼ Sec. 27, SE¼ SW¼ Sec. 27, SE¼ SE¼ Sec. 27; portions of T31N, R9E, NE¼ NW¼ Sec. 34, NW¼ NE¼ Sec. 34, NE¼ NE¼ Sec. 34; and portions of T31N, R9E, NW¼ NW¼ Sec. 35, NE¼ NW¼, NW¼ NE¼ Sec. 35 of the North Point 7.5′ USGS topographic quadrangle. Lake Huron is the east boundary of the unit.

(ii) Note: Map of Michigan critical habitat Unit 6 (Michigan Map 4) follows:



(11) Wisconsin Unit 1, Door County, Wisconsin.

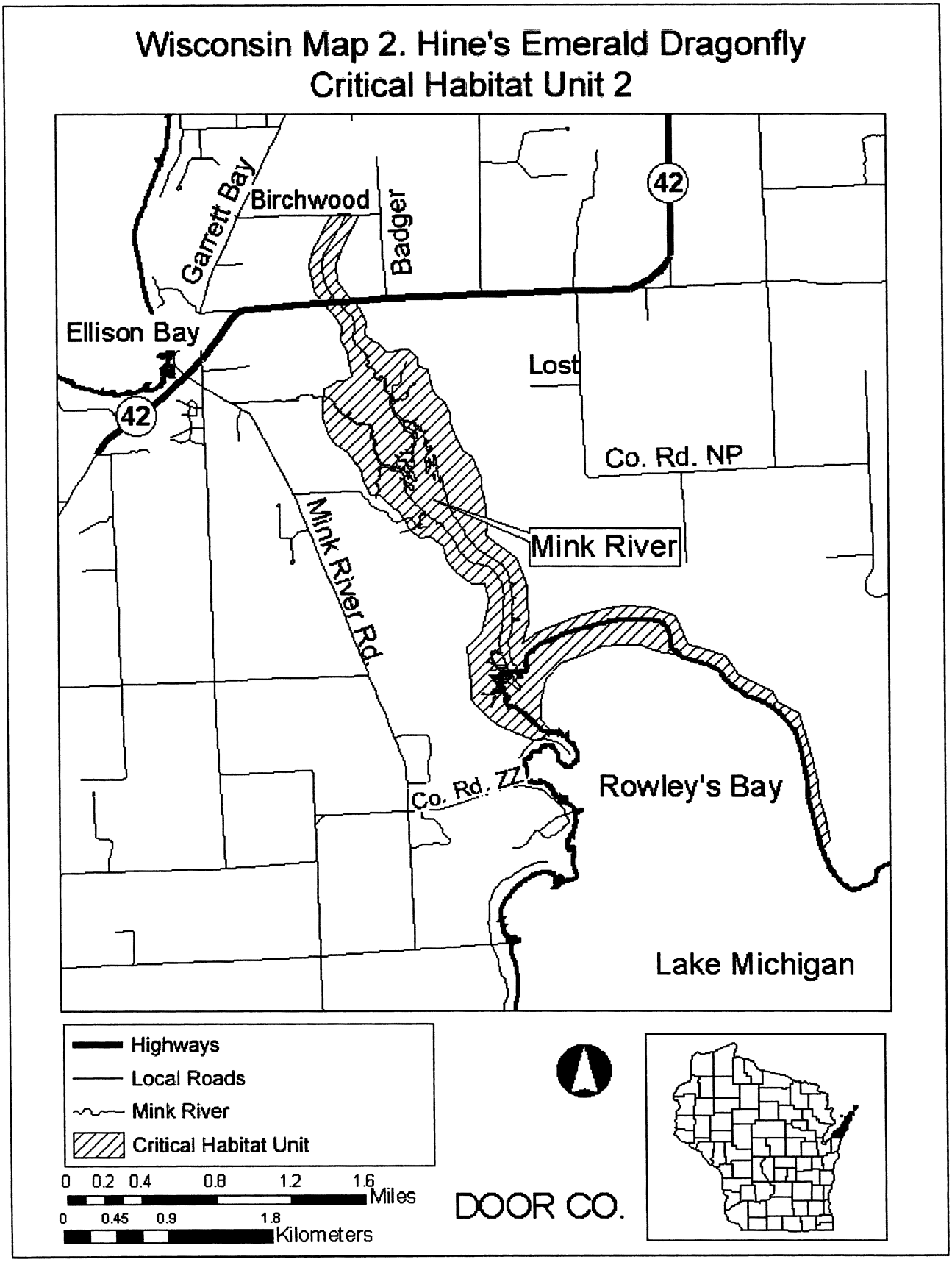
(i) Wisconsin Unit 1: Washington Island, Door County. Located in T33N, R30E, W½ and NE¼ Sec. 4, SE¼ Sec. 5 of Washington Island SE and Washington Island NE 7.5′ USGS topographic quadrangles. Lands included are located adjacent to and west of Wickman Road, south of Town Line Road, East of Deer Lane and East Side Roads, north of Lake View Road and include Big Marsh and Little Marsh.

(ii) Note: Map of Wisconsin critical habitat Unit 1 (Wisconsin Map 1) follows:

(12) Wisconsin Unit 2, Door County, Wisconsin.

(i) Wisconsin Unit 2: Door County. Located in T32N, R28E, SE¼ Sec. 11, NW¼ Sec. 13, NE¼ Sec. 14 of the Ellison Bay 7.5′ USGS topographic quadrangle, and in T32N, R28E, W½ Sec. 13, E½ Sec. 14, NE¼ Sec. 23, portions of each ¼ of Sec. 24, N½ Sec. 25, and T32N, R29E, S½ Sec. 19, W½ Sec. 29, NE¼ Sec. 30 of Sister Bay 7.5′ USGS topographic quadrangle. Lands included are located east of the Village of Ellison Bay, south of Garrett Bay Road and Mink River Roads, North of County Road ZZ, west of Badger Road, County Road NP and Juice Mill Road, and includes the Mink River.

(ii) Note: Map of Wisconsin critical habitat Unit 2 (Wisconsin Map 2) follows:


Wisconsin Map 2. Hine's Emerald Dragonfly
Critical Habitat Unit 2
Garrett Bay
Birchwood
Badger
42
Ellison Bay
42
Lost
Co. Rd. NP
Mink River
Mink River Rd.
Co. Rd. ZZ
Rowley's Bay
Lake Michigan
Highways
Local Roads
Mink River
Critical Habitat Unit
0 0.2 0.4 0.8 1.2 1.6
Miles
0 0.45 0.9 1.8
Kilometers
DOOR CO.

(13) Wisconsin Units 3 through 7, Door County, Wisconsin.

(i) Wisconsin Unit 3: Door County. Located in T31N R28E, S½ S10, NE¼ S15 of Sister Bay 7.5′ USGS topographic quadrangle. Lands included are located south of County Road ZZ, north of North Bay (Lake Michigan), west of North Bay Road, east of Old Stage Road and about two miles east of the Village of Sister Bay and include a portion of Three-Springs Creek.

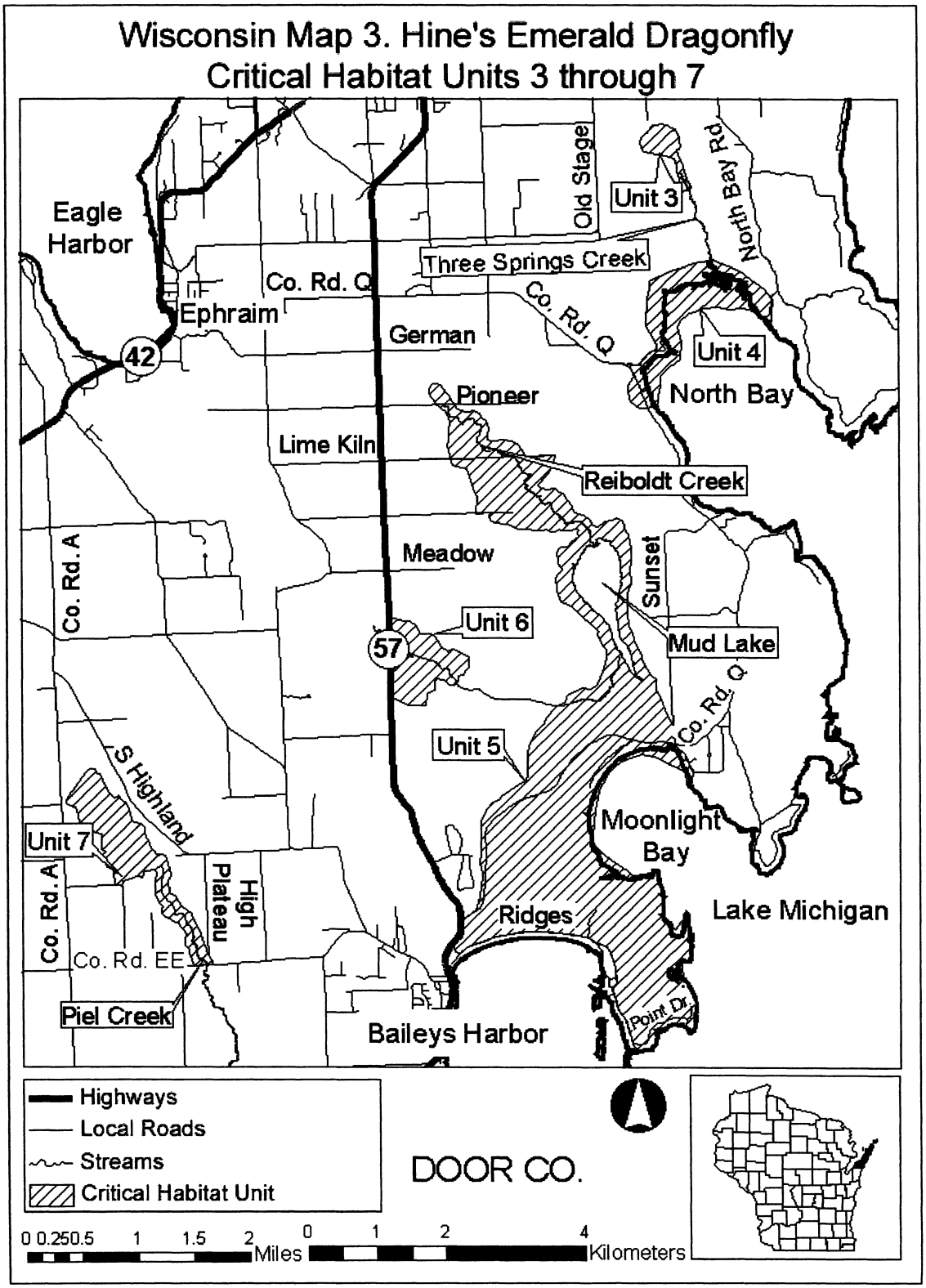
(ii) Wisconsin Unit 4: Door County. Located in T31N, R28E, SW¼ and S½ Sec. 15, portions of each ¼ of Sec. 22, and N½ of Sec. 23 of the Sister Bay 7.5′ USGS topographic quadrangle. Lands are located along the north and northwest sides of North Bay (Lake Michigan).

(iii) Wisconsin Unit 5: Door County. Located in T31N, R28E, S½ Sec. 20, E½ Sec. 29, NW¼ and S½ Sec. 28, N½ and SE¼ Sec. 33, and W½ Sec. 34. It also is located in T30N, R28E, W½ Sec. 3, E½ and SW¼ Sec. 4, SE¼ Sec. 8, Sec. 9, N½ Sec. 10, W½ and SE¼ Sec.15, Sec. 16, and Sec. 17 of the Baileys Harbor East, and Sister Bay 7.5′ USGS topographic quadrangles. Lands located south of German Road, east of State Highway 57, west of North Bay Drive, Sunset Drive and Moonlight Bay (Lake Michigan), north of Ridges Road and Point Drive and include Mud Lake and Reiboldt Creek.

(iv) Wisconsin Unit 6: Door County. Located in T30N, R28E, portions of each ¼ of Sec. 5 of the Baileys Harbor East 7.5′ USGS topographic quadrangle and Baileys Harbor West 7.5′ USGS topographic quadrangle. Lands are located about 2¼ miles north of the Town of Baileys Harbor, east of State Highway 57, south of Meadow Road and are associated with an unnamed stream.

(v) Wisconsin Unit 7: Door County. Located in T30N, R27E, Sec. 11, SW¼ Sec. 13, and N½ and SE ¼ Sec. 14 of the Baileys Harbor West 7.5′ USGS topographic quadrangle. Lands are located north of County Road EE, east of County Road A and west of South Highland and High Plateau Roads, about two miles northeast of Town of Baileys Harbor and are associated with the headwaters of Piel Creek.

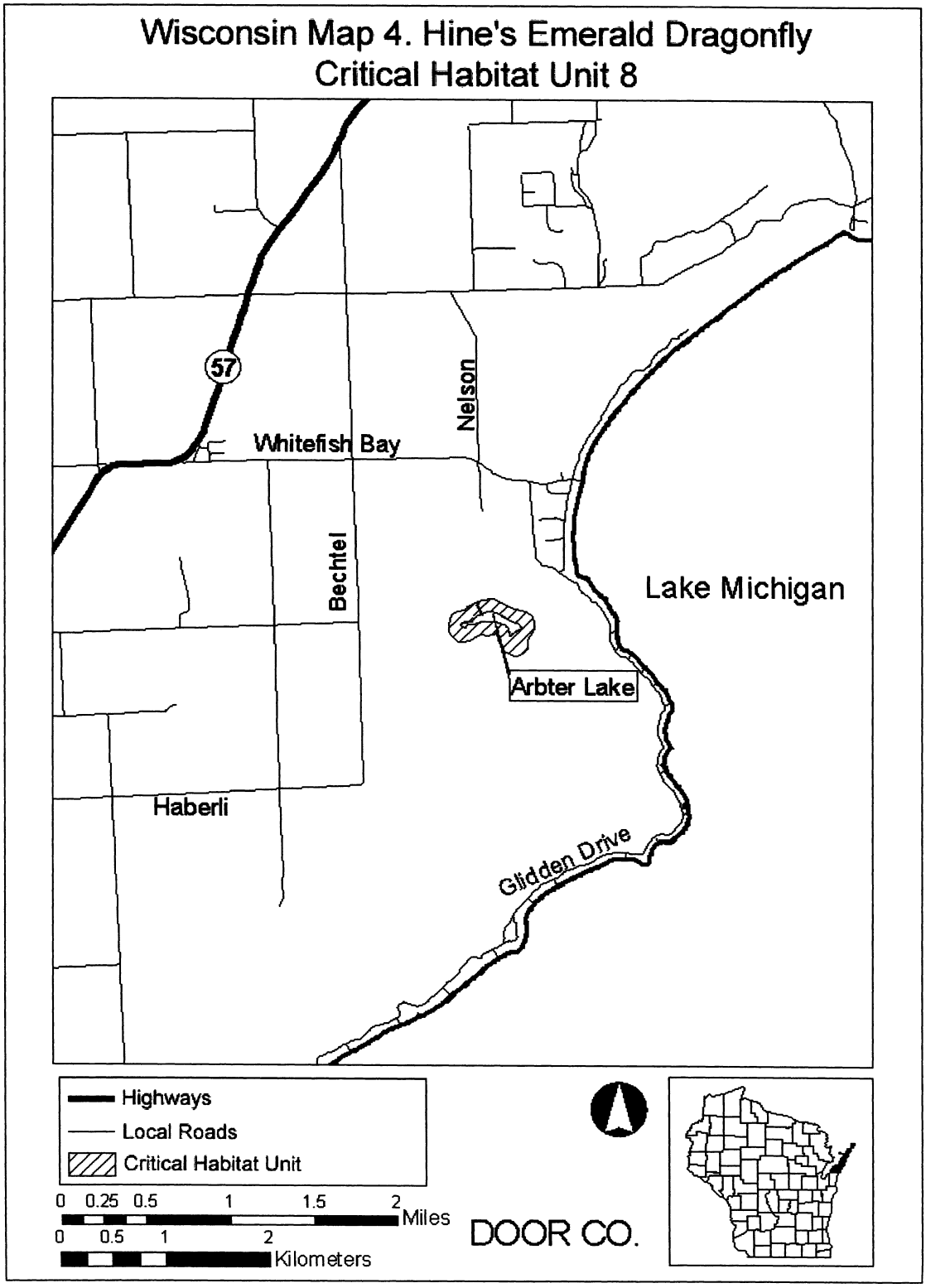
(vi) Note: Map of Wisconsin critical habitat Units 3 through 7 (Wisconsin Map 3) follows:



(14) Wisconsin Unit 8, Door County, Wisconsin.

(i) Wisconsin Unit 8: Door County. Located in T28N, R27E, S½ Sec. 16, N½ Sec. 21 of the Jacksonport 7.5′ USGS topographic quadrangle. Lands are located east of Bechtel Road, South of Whitefish Bay Road, west of Glidden Drive and include Arbter Lake.

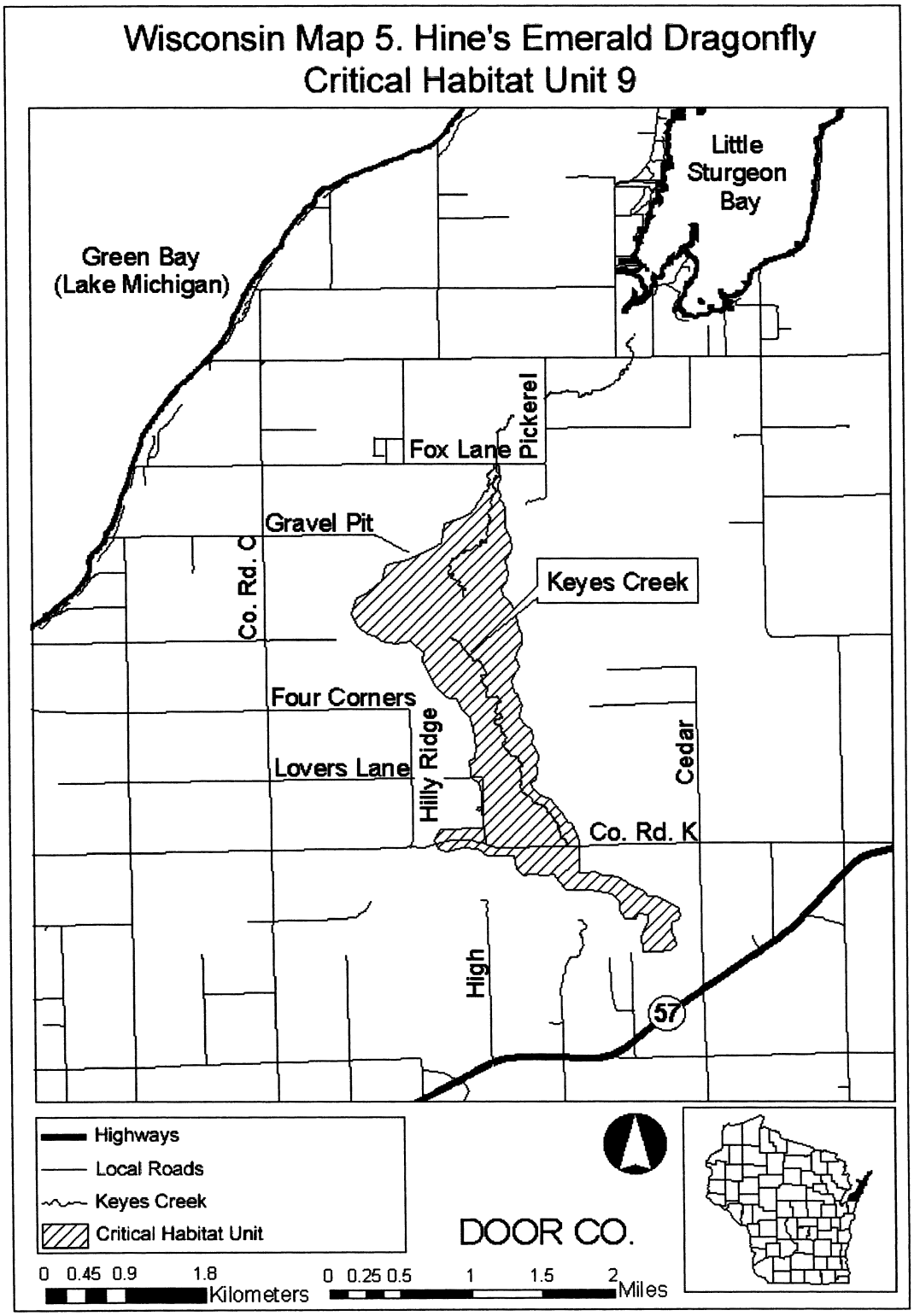
(ii) Note: Map of Wisconsin critical habitat Unit 8 (Wisconsin Map 4) follows:



(15) Wisconsin Unit 9, Door County, Wisconsin.

(i) Wisconsin Unit 9: Door County, Wisconsin. Located in T27N, R24E, SE¼ Sec.16, E½ Sec. 20, portions of each ¼ of Secs. 21, 28 and 33, NW¼ and S½ Sec. 34. Also located in T26N, R24E, NW¼ Sec. 3 of the Little Sturgeon 7.5′ USGS topographic quadrangle. Lands are located west of Pickeral Road and Cedar Lane, north of State Highway 57, east of Hilly Ridge Road and County Road C, south of Fox Lane Road, about 1.5 miles southwest of Little Sturgeon Bay (Lake Michigan) and include portions of Keyes Creek and associated wetlands.

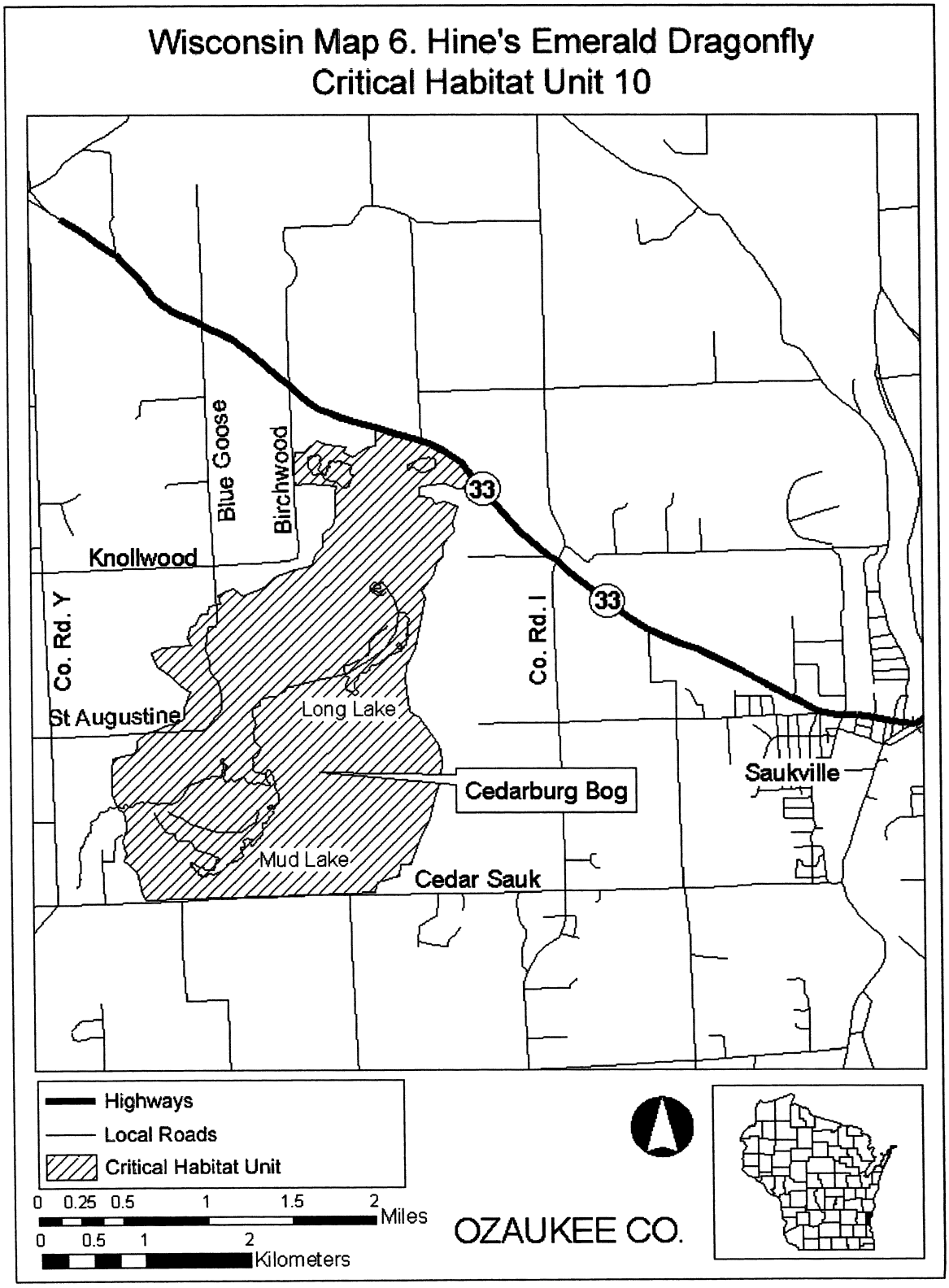
(ii) Note: Map of Wisconsin critical habitat Unit 9 (Wisconsin Map 5) follows:



(16) Wisconsin Unit 10, Ozaukee County, Wisconsin.

(i) Wisconsin Unit 10: Ozaukee County. Located in T11N, R21E, E½ of Sec. 20, portions of each ¼ of Sec. 21, W½ Sec. 28, Sec. 29, E½ Sec. 30, E½ and portions of NW¼ and SW¼ Sec. 31, Sec. 32, and W½ Sec. 33 of the Cedarburg, Five Corners, Newburg, and Port Washington West 7.5′ USGS topographic quadrangles. Lands are located south of State Highway 33, east of County Road Y and Birchwood Road, north of Cedar Sauk Road about 2 miles west of Saukville, and includes the majority of Cedarburg Bog.

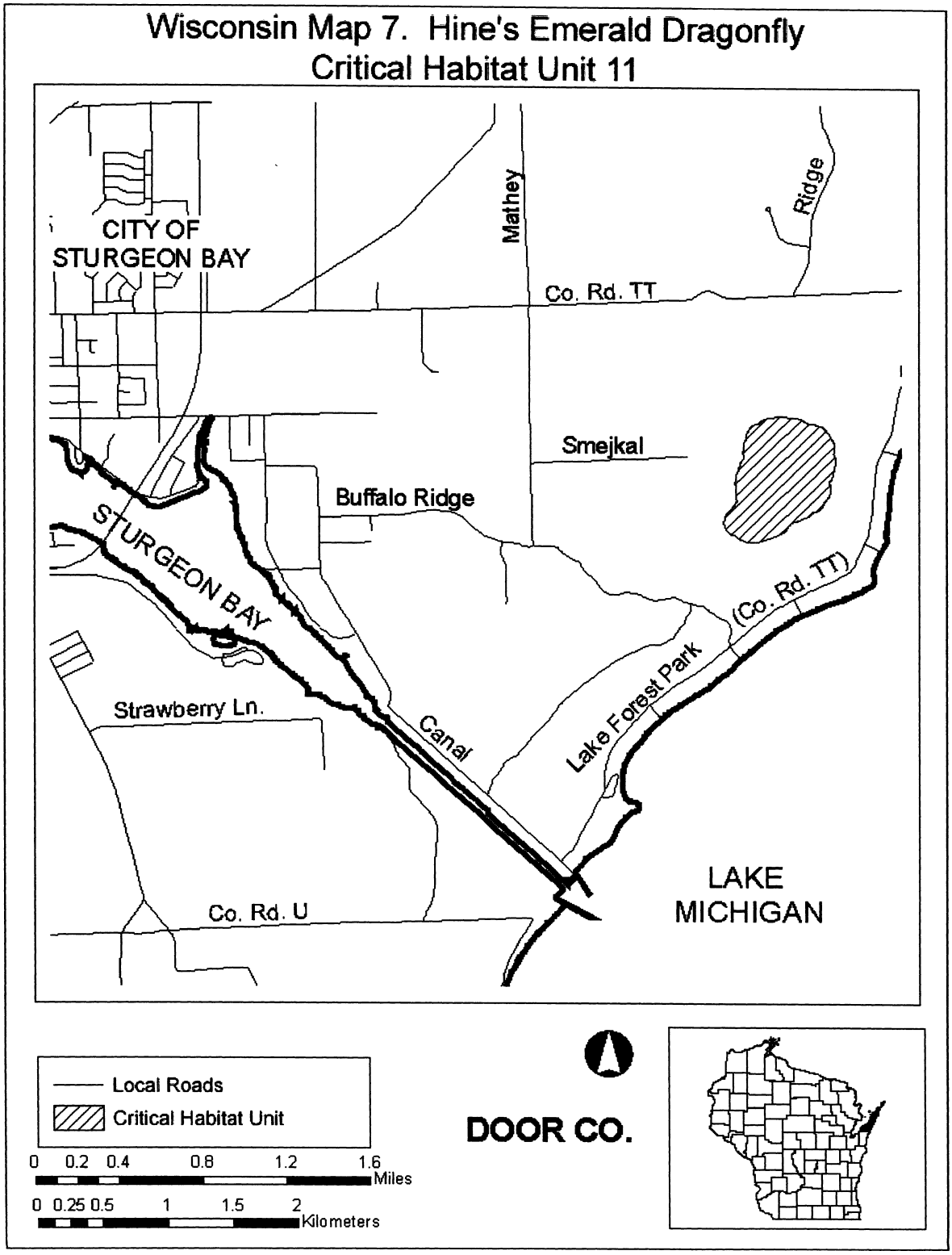
(ii) Note: Map of Wisconsin critical habitat Unit 10 (Wisconsin Map 6) follows:



(17) Wisconsin Unit 11, Door County, Wisconsin.

(i) Wisconsin Unit 11: Door County. Located in T27N, R26E, SE¼ Sec. 11, Sec. 12, NW¼ Sec. 13, and NE¼ Sec. 14 of the Sturgeon Bay East 7.5′ USGS topographic quadrangle. Lands are located south of County Road TT, east of Mathey Road, north of Buffalo Ridge Trail, west of Lake Forest Park Road (also County Road TT), about 1½ miles west of the City of Sturgeon Bay, and include portions of Kellner's Fen.

(ii) Note: Map of Wisconsin critical habitat Unit 11 (Wisconsin Map 7) follows:



* * * * *

Dated: August 20, 2007.

Todd Willens,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 07–4194 Filed 9–4–07; 8:45 am]

BILLING CODE 4310–55–C

Federal Register

Wednesday,
September 5, 2007

Part IV

The President

Proclamation 8170—National Preparedness Month, 2007

Proclamation 8171—National Employer Support of the Guard and Reserve Week, 2007

Federal Register
Vol. 72, No. 171
Wednesday, September 5, 2007

Presidential Documents

Title 3—

The President

Proclamation 8170 of August 30, 2007

National Preparedness Month, 2007

By the President of the United States of America

A Proclamation

National Preparedness Month is an opportunity to raise awareness about the importance of emergency preparedness and to encourage all Americans to better prepare their homes and communities for emergencies.

Protecting America's homeland and citizens is the shared responsibility of the entire Nation. Individuals can prepare themselves and their families for emergencies by taking simple steps such as organizing an emergency supply kit, making a personal preparedness plan, becoming informed about different threats, and getting involved in preparing their community. These activities create a culture of preparedness and can help save lives.

My Administration continues to improve our Nation's ability to prepare for emergencies. The Department of Homeland Security is working with other Federal, State, and local government organizations, as well as the private sector, to prevent, respond to, and recover from all types of emergencies. Together, Americans can significantly enhance the level of national preparedness to further safeguard our communities and secure our homeland.

This month is also an opportunity to pay tribute to America's first responders who put themselves at risk for the safety of their fellow citizens. These brave police officers, firefighters, and emergency service personnel exemplify the compassion and commitment that help strengthen our country. We will be forever grateful for their service and sacrifice.

During National Preparedness Month, I encourage all Americans to get involved in their community's preparedness efforts. Citizens may visit ready.gov and citizencorps.gov to learn more about emergency preparedness and ways to take action.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim September 2007 as National Preparedness Month. I call upon the people of the United States to recognize the importance of preparing for potential emergencies and to observe this month by participating in appropriate events, activities, and preparedness programs.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of August, in the year of our Lord two thousand seven, and of the Independence of the United States of America the two hundred and thirty-second.

[FR Doc. 07–4371
Filed 9–4–07; 8:45 am]
Billing code 3195–01–P

Presidential Documents

Proclamation 8171 of August 30, 2007

National Employer Support of the Guard and Reserve Week, 2007

By the President of the United States of America

A Proclamation

During National Employer Support of the Guard and Reserve Week, we recognize the vital contributions of the brave men and women who serve our great Nation, and we pay tribute to the employers who support them.

The courageous men and women of the National Guard and Reserve are fighting a new and unprecedented war, having answered the call to defend our freedom and way of life. At home, the National Guard is working to protect our borders, and provide vital aid and assistance in times of crisis and natural disasters. The dedicated service of those who wear the uniform reflects the best of America, and all Americans are proud to stand behind the men and women of the National Guard and Reserve.

Our Nation also appreciates the sacrifice of employers across our country who support the important mission of our National Guard and Reserve personnel. Employers across America demonstrate their patriotism by providing time off, pay, health-care benefits, and job security to their Guard and Reserve employees, helping them prepare for their return to families and to civilian life. The commitment of our Nation's employers is a vital and integral part of the success of our Armed Forces.

During National Employer Support of the Guard and Reserve Week, we offer our country's deepest gratitude to the dedicated men and women of the National Guard and Reserve and to the employers who support them in their important service to our Nation.

NOW, THEREFORE, I, GEORGE W. BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim September 9 through September 15, 2007, as National Employer Support of the Guard and Reserve Week. I encourage all Americans to join me in expressing our thanks to members of our National Guard and Reserve and their civilian employers for their patriotism and sacrifices on behalf of our Nation. I also call upon State and local officials, private organizations, businesses, and all military commanders to observe this week with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of August, in the year of our Lord two thousand seven, and of the Independence of the United States of America the two hundred and thirty-second.

[FR Doc. 07–4372
Filed 9–4–07; 8:45 am]
Billing code 3195–01–P

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FEDERAL REGISTER PAGES AND DATE, SEPTEMBER

CFR PARTS AFFECTED DURING SEPTEMBER

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

REMINDERS

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.

RULES GOING INTO EFFECT SEPTEMBER 5, 2007

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COMMERCE DEPARTMENT

Industry and Security Bureau

Export Administration regulations; legal authority citations updates; published 9-5-07

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:

West Coast States and Western Pacific fisheries—

Highly migratory species; published 8-6-07

ENVIRONMENTAL PROTECTION AGENCY

Air quality implementation plans; approval and promulgation; various States:

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HOMELAND SECURITY DEPARTMENT

Coast Guard

Drawbridge operations:

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New York; correction; published 9-5-07

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Federal Aviation Administration

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Bombardier; published 8-21-07

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Prunes (fresh) grown in Washington and Oregon; comments due by 9-11-07; published 7-13-07 [FR E7-13583]

AGRICULTURE DEPARTMENT

Animal and Plant Health Inspection Service

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Genetically engineered organisms and products:

Introductions of plants genetically engineered to encode compounds for industrial use; permit requirements; comments due by 9-11-07; published 7-17-07 [FR 07-03474]

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Louisiana; comments due by 9-14-07; published 8-15-07 [FR E7-16044]

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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 "PLUS" (Public Laws

Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

H.R. 2863/P.L. 110–75

To authorize the Coquille Indian Tribe of the State of Oregon to convey land and interests in land owned by the Tribe. (Aug. 13, 2007; 121 Stat. 724)

H.R. 2952/P.L. 110–76

To authorize the Saginaw Chippewa Tribe of Indians of the State of Michigan to convey land and interests in lands owned by the Tribe. (Aug. 13, 2007; 121 Stat. 725)

H.R. 3006/P.L. 110–77

To improve the use of a grant of a parcel of land to the State of Idaho for use as an agricultural college, and for other purposes. (Aug. 13, 2007; 121 Stat. 726)

S. 375/P.L. 110–78

To waive application of the Indian Self-Determination and Education Assistance Act to a specific parcel of real property transferred by the United States to 2 Indian tribes in the State of Oregon, and for other purposes. (Aug. 13, 2007; 121 Stat. 727)

S. 975/P.L. 110–79

Granting the consent and approval of the Congress to an interstate forest fire protection compact. (Aug. 13, 2007; 121 Stat. 730)

S. 1716/P.L. 110–80

To amend the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, to strike a requirement relating to forage producers. (Aug. 13, 2007; 121 Stat. 734)

Last List August 13, 2007

CORRECTION

In the last **List of Public Laws** printed in the *Federal Register* on August 13, 2007, H.R. 2025, Public Law 110-65, and H.R. 2078, Public Law 110-67, were printed incorrectly. They should read as follows:

H.R. 2025/P.L. 110–65

To designate the facility of the United States Postal Service located at 11033 South State Street in Chicago, Illinois, as the ''Willye B. White Post Office Building''. (Aug. 9, 2007; 121 Stat. 568)

H.R. 2078/P.L. 110–67

To designate the facility of the United States Postal Service located at 14536 State Route 136 in Cherry Fork, Ohio, as the ''Staff Sergeant Omer T. 'O.T.' Hawkins Post Office''. (Aug. 9, 2007; 121 Stat. 570)

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