12–8–06 Friday
Vol. 71 No. 236 Dec. 8, 2006

Pages 71037–71462

Federal Register

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.archives.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge as one of the databases on GPO Access, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** *www.gpoaccess.gov/nara,* available through GPO Access, is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward.

For more information about GPO Access, contact the GPO Access User Support Team, call toll free 1-888-293-6498; DC area 202-512-1530; fax at 202-512-1262; or via e-mail at *gpoaccess@gpo.gov.* The Support Team is available between 7:00 a.m. and 9:00 p.m. Eastern Time, Monday–Friday, except official holidays.

The annual subscription price for the **Federal Register** paper edition is $749 plus postage, or $808, plus postage, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $165, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 71 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Printing Office, Washington DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Paper or fiche	**202–741–6005**
Assistance with Federal agency subscriptions	**202–741–6005**

FEDERAL REGISTER WORKSHOP

THE FEDERAL REGISTER: WHAT IT IS AND HOW TO USE IT

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, December 12, 2006
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

Printed on recycled paper.

Contents

Federal Register

Vol. 71, No. 236

Friday, December 8, 2006

Administration on Aging
See Aging Administration

Aging Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71172–71173

Agriculture Department
See Food and Nutrition Service
See Forest Service
See Grain Inspection, Packers and Stockyards Administration
See Rural Business-Cooperative Service

Army Department
See Engineers Corps
RULES
Environmental quality:
Installation; off-road vehicles use on army land; removed, 71051–71052
Supplies and equipment:
Biological Defense Safety Program, Technical Safety Requirements; removed, 71051
NOTICES
Meetings:
U.S. Military Academy, Board of Visitors, 71142

Blind or Severely Disabled, Committee for Purchase From People Who Are
See Committee for Purchase From People Who Are Blind or Severely Disabled

Census Bureau
NOTICES
Surveys, determinations, etc.:
Manufacturing area; annual, 71131–71132

Centers for Disease Control and Prevention
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71173–71174
Committees; establishment, renewal, termination, etc.:
HIV and STD Prevention and Treatment Advisory Committee, 71174
Energy Employees Occupational Illness Compensation Program Act of 2000:
Special Exposure Cohort; employee class designations—
Hanford Nuclear Reservation, Richland, WA, 71174
Los Alamos National Laboratory, Los Alamos, NM, 71174–71175
Oak Ridge Institute of Nuclear Studies Cancer Research Hospital, Oak Ridge, TN, 71174
Oak Ridge Thermal Diffusion Plant (S-50), Oak Ridge, TN, 71175
Meetings:
Immunization Practices Advisory Committee, 71175–71176

Centers for Medicare & Medicaid Services
See Inspector General Office, Health and Human Services Department
RULES
Medicare:
Physician fee schedule (CY 2007); payment policies and relative value units
Correction, 71062–71072
Medicare and Medicaid:
Hospital participation conditions; patients' rights, 71378–71428
Programs of All-inclusive Care for Elderly; program revisions, 71244–71337
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71176–71180

Coast Guard
NOTICES
Environmental statements; availability, etc.:
National security cutters; homeporting; Alameda, CA, 71182–71183
Reports and guidance documents; availability, etc.:
Voyage data recorders installation on passenger vessels; information request, 71184–71185

Commerce Department
See Census Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71130–71131

Committee for Purchase From People Who Are Blind or Severely Disabled
NOTICES
Procurement list; additions and deletions, 71129–71130

Committee for the Implementation of Textile Agreements
NOTICES
Cotton, wool, and man-made-textiles:
Ukraine, 71142

Defense Acquisition Regulations System
RULES
Acquisition regulations:
Combating trafficking in persons, 71072

Defense Department
See Army Department
See Defense Acquisition Regulations System
See Engineers Corps
See Navy Department

Education Department
PROPOSED RULES
Postsecondary education:
Academic Competitiveness Grant and National Science and Mathematics Access to Retain Talent Grant Programs; grant and loan programs amendments, 71117–71119
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71145–71147

Employee Benefits Security Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71190–71191

Employment and Training Administration
NOTICES
Adjustment assistance; applications, determinations, etc.:
American Wood Dryers Inc., 71191
Bendix Commercial Vehicle Systems (C.V.S.) LLC, 71192
Hipwell Manufacturing Co., 71192
International Truck And Engine, 71192
Liberty Throwing Co., Inc., 71192
Moll Industries, 71193
NewPage - Luke Maryland Coated Paper Mill, 71193–71194
Water Pik, Inc., 71194
West Tennessee Machining, et al., 71194–71196
Xyron Inc., 71196
Federal Unemployment Tax Act; credit reduction avoidance approvals, disapprovals, etc.:
Missouri employers, 71196

Energy Department
See Energy Efficiency and Renewable Energy Office
See Federal Energy Regulatory Commission

Energy Efficiency and Renewable Energy Office
RULES
Energy conservation:
Consumer products and commercial and industrial equipment—
Technical amendment to energy conservation standards, 71340–71375

Engineers Corps
NOTICES
Environmental statements; availability, etc.:
Rancho Cordova, CA; mixed use development, 71142–71143

Environmental Protection Agency
RULES
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Cyproconazole, 71052–71058
Solid wastes:
State municipal solid waste landfill permit programs—
Nebraska; correction, 71241
Toxic substances:
Coke oven light oil (coal); testing requirements; revocation, 71058–71062
NOTICES
Environmental statements; availability, etc.:
Agency comment availability, 71164
Agency weekly receipts, 71164–71165
Meetings:
Scientific Counselors Board, 71165–71166
Superfund; response and remedial actions, proposed settlements, etc.:
Constitution Road Drum Site, GA, 71166
Jehl Cooperage Site, TN, 71166–71167
Pittsburgh Metal and Equipment Site, PA, 71167

Executive Office of the President
See Presidential Documents

Federal Aviation Administration
PROPOSED RULES
Airworthiness directives:
Airbus, 71101–71106
Boeing, 71099–71101
Empresa Brasileira de Aeronautica S.A. (EMBRAER), 71096–71099
NOTICES
Advisory circulars; availability, etc.:
Aircraft Certification Service advisory circulars, policy documents, and technical standard orders, 71236

Federal Election Commission
PROPOSED RULES
Compliance procedures:
Administrative fines challenges, 71093–71096
Campaign finance violations; self-reporting submissions, 71090–71093
Enforcement matters; policy statement, 71084–71087
Probable cause hearings; pilot program, 71088–71090

Federal Energy Regulatory Commission
NOTICES
Electric rate and corporate regulation combined filings, 71153–71155
Environmental statements; notice of intent:
Downeast LNG, Inc., 71156–71157
Quoddy Bay LNG, L.L.C., 71157–71158
Southern Star Central Gas Pipeline, Inc., 71159–71160
Hydroelectric applications, 71160–71164
Applications, hearings, determinations, etc.:
Caithness Long Island, LLC, 71147
Duke Energy Marshall, LLC, 71148
Duke Energy Murray, LLC, 71148
Duke Energy Sandersville, L.L.C., 71148–71149
Duke Energy Southaven, L.L.C., 71149
Eason, Carl R., 71149–71150
Endeavor Power Partners, LLC, 71150
Great Lakes Energy LLC, 71150–71151
High Desert Power Project, LLC, 71151
House, Wade C., et al., 71151
Mac Trading, Inc., 71151–71152
Questar Pipeline Co., 71152–71153
Texas Eastern Transmission, LP, 71153

Federal Motor Carrier Safety Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71236–71237

Federal Railroad Administration
NOTICES
Exemption petitions, etc.:
BNSF Railway and Norfolk Southern Railway, 71237–71238

Federal Reserve System
NOTICES
Banks and bank holding companies:
Change in bank control, 71167–71168
Formations, acquisitions, and mergers, 71168

Fish and Wildlife Service
NOTICES
Environmental statements; availability, etc.:
St. Marks National Wildlife Refuge, FL; comprehensive conservation plan, 71185

Food and Drug Administration
RULES
Animal drugs, feeds, and related products:
Lincomycin and spectinomycin powder, 71038
Oxytetracycline powder, 71038–71039

Food and Nutrition Service
PROPOSED RULES
Food Stamp Program:
Disqualified recipient reporting and computer matching requirements, 71075–71084

Forest Service
NOTICES
Environmental statements; notice of intent:
Malheur National Forest, OR, 71120–71122

Geological Survey
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71186

Grain Inspection, Packers and Stockyards Administration
NOTICES
Agency designation actions:
Various States, 71122–71124

Health and Human Services Department
See Aging Administration
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See Inspector General Office, Health and Human Services Department
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71168–71169
Reports and guidance documents; availability, etc.:
Engagement of Institutions in Human Subjects Research, 71169–71172
Scientific misconduct findings; administrative actions:
McMaster, Nicholas, 71172

Homeland Security Department
See Coast Guard
NOTICES
Privacy Act; systems of records, 71182

Housing and Urban Development Department
NOTICES
Homeless assistance; excess and surplus Federal properties, 71185

Inspector General Office, Health and Human Services Department

NOTICES
Privacy Act; systems of records, 71180–71182

Interior Department
See Fish and Wildlife Service
See Geological Survey
See Land Management Bureau
See National Indian Gaming Commission
See National Park Service
See Reclamation Bureau
See Surface Mining Reclamation and Enforcement Office

Internal Revenue Service
RULES
Income taxes:
Business electronic filing; guidance, 71040–71045
Railroad track maintenance credit
Correction, 71039–71040, 71045–71047
PROPOSED RULES
Income taxes:
Annuity contracts; property exchanges
Correction, 71241
Controlled foreign corporations and other property; exclusion from gross income of previously taxed earnings and profits
Correction, 71116–71117

International Trade Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71132–71134
Export trade certificates of review, 71134–71135

International Trade Commission
PROPOSED RULES
Adjudicative procedures; proposed amendments of rules for investigations and proceedings, 71113–71115

Justice Department
RULES
National Environmental Policy Act; implementation:
Procedures and council on regulations to ensure compliance, 71047–71051

Labor Department
See Employee Benefits Security Administration
See Employment and Training Administration
See Mine Safety and Health Administration
NOTICES
Reports and guidance documents; availability, etc.:
Labor Department Freedom of Information Act improvement plan; comment request and public forum, 71189–71190

Land Management Bureau
NOTICES
Coal leases, exploration licenses, etc.:
Colorado, 71186–71187
Meetings:
Pinedale Anticline Working Group, 71187
Royalty management:
Stripper Well Royalty Reduction Program; royalty rate reductions; benefits termination, 71187

Mine Safety and Health Administration
RULES
Coal mine safety and health:
Underground mines—
Emergency evacuations; emergency temporary standard, 71430–71455

National Aeronautics and Space Administration
RULES
Federal Acquisition Regulation (FAR):
Supplemental administrative changes, 71072–71073

National Highway Traffic Safety Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71238–71240

National Indian Gaming Commission
PROPOSED RULES
Classification standards:
Electronic or electromechanical facsimile; games similar to bingo; and electronic, computer, or other technologic aids to Class II games; definitions, 71115

National Nanotechnology Coordination Office
NOTICES
Meetings, 71196–71197

National Oceanic and Atmospheric Administration
RULES
Fishery conservation and management:
Northeastern United States fisheries—
Atlantic herring, 71073–71074
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71135–71136
Endangered and threatened species permit applications, 71136–71142

National Park Service
NOTICES
Environmental statements; availability, etc.:
Benefits-sharing draft environmental impact statement, 71187–71188
Native American human remains, funerary objects; inventory, repatriation, etc.:
Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA, 70982-70983 [**Editorial Note:** This document was inadvertently dropped from the **Federal Register** Table of Contents, December 7, 2006.]

Navy Department
NOTICES
Environmental statements; notice of intent:
Virginia Capes Range Complex, VA and NC, 71143–71145

Nuclear Regulatory Commission
NOTICES
Environmental statements; availability, etc.:
BWX Technologies, Inc., 71198
Applications, hearings, determinations, etc.:
Carolina Power & Light Co., 71197

Presidential Documents
EXECUTIVE ORDERS
Metro-North Railroad and certain labor organizations; establishment of emergency board to investigate labor disputes (EO 13417), 71457–71461

Railroad Retirement Board
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71198–71199

Reclamation Bureau
NOTICES
Environmental statements; availability, etc.:
South Delta Improvement Program, CA, 71188–71189

Rural Business-Cooperative Service
NOTICES
Grants and cooperative agreements; availability, etc.:
Rural Business Opportunity Program, 71124–71127
Rural Economic Development Loan and Grant Program (FY 2007), 71127–71129

Securities and Exchange Commission
RULES
Organization, functions, and authority delegations:
Chief Administrative Law Judge, 71037
PROPOSED RULES
Securities:
Municipal securities disclosure; amendments, 71109–71113
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71199–71200
Public Company Accounting Oversight Board:
Budget and annual accounting support fee, 71200–71201
Self-regulatory organizations; proposed rule changes:
American Stock Exchange LLC, 71201–71206
Depository Trust Co., 71206–71208
NASDAQ Stock Market LLC, 71208–71213
National Association of Securities Dealers, Inc., 71213–71215
New York Stock Exchange LLC, 71215–71230

State Department
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71230–71231

Surface Mining Reclamation and Enforcement Office
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 71189

Surface Transportation Board
NOTICES
Railroad operation, acquisition, construction, etc.:
Stillwater Central Railroad, 71240
Railroad services abandonment:
Union Pacific Railroad Co., 71240

Textile Agreements Implementation Committee
See Committee for the Implementation of Textile Agreements

Transportation Department
See Federal Aviation Administration
See Federal Motor Carrier Safety Administration
See Federal Railroad Administration
See National Highway Traffic Safety Administration
See Surface Transportation Board
PROPOSED RULES
Air carrier control:
Fitness review policies; certain proposed amendments withdrawn, 71106–71109
NOTICES
Grants and cooperative agreements; availability, etc.:
Congestion Initiative Urban Partnership Agreement, 71231–71236

Treasury Department
See Internal Revenue Service

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 71244–71337

Part III
Energy Department, Energy Efficiency and Renewable Energy Office, 71340–71375

Part IV
Health and Human Services Department, Centers for Medicare & Medicaid Services, 71378–71428

Part V
Labor Department, Mine Safety and Health Administration, 71430–71455

Part VI
Executive Office of the President, Presidential Documents, 71457–71461

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

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.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Executive Orders:

13417.....71459

7 CFR

Proposed Rules:

272.....71075
273.....71075

10 CFR

430.....71340
431.....71340

11 CFR

Proposed Rules:

104.....71084
111 (3 documents) 71088, 71090, 71093

14 CFR

Proposed Rules:

39 (4 documents) 71096, 71099, 71101, 71103
399.....71106

17 CFR

200.....71037

Proposed Rules:

240.....71109

19 CFR

Proposed Rules:

210.....71113

21 CFR

520 (2 documents) 71038

25 CFR

Proposed Rules:

502.....71115
546.....71115
547.....71115

26 CFR

1 (3 documents) 71039, 71040, 71045
301.....71040
602 (3 documents) 71039, 71040, 71045

Proposed Rules:

1 (2 documents) 71116, 71241

28 CFR

61.....71047

30 CFR

3.....71430
48.....71430
50.....71430
75.....71430

32 CFR

626.....71051
627.....71051
656.....71051

34 CFR

Proposed Rules:

674.....71117
682.....71117
685.....71117

40 CFR

180.....71052
239.....71241
258.....71241
799.....71058

42 CFR

405.....71062
410.....71062
411.....71062
414.....71062
415.....71062
424.....71062
460.....71244
462.....71244
466.....71244
473.....71244
476.....71244
482.....71378

48 CFR

212.....71072
222.....71072
252.....71072
1802.....71072
1805.....71072
1819.....71072
1825.....71072
1827.....71072
1828.....71072
1852.....71072

50 CFR

648.....71073

Rules and Regulations

Federal Register
Vol. 71, No. 236
Friday, December 8, 2006

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

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

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 200

[Release No. 34–54867]

Delegation of Authority to Chief Administrative Law Judge

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') is amending its rules to delegate authority to the Chief Administrative Law Judge to issue orders to discontinue administrative proceedings as to a particular respondent who has died or cannot be found, or because of a mistake in the identity of a respondent named in the order for proceedings. The delegation is intended to conserve Commission resources, as well as expedite disposition of administrative proceedings.

EFFECTIVE DATE: January 8, 2007.

FOR FURTHER INFORMATION CONTACT: Geoffrey D. Kruczek, Office of Administrative Law Judges, (202) 551–6030, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–2557.

SUPPLEMENTARY INFORMATION: The Commission today is amending its rules governing the delegation of authority to the Chief Administrative Law Judge. The Commission's Office of the General Counsel has delegated authority to grant motions of staff counsel to discontinue administrative proceedings as to a particular respondent who has died or cannot be found, or because of a mistake in the identity of a respondent named in the order for proceedings.[1] The Commission has determined to extend this delegation to the Chief Administrative Law Judge.[2] The Commission believes that this delegation will conserve Commission and staff resources, as well as expedite the disposition of staff motions prompted by these circumstances. Nevertheless, the staff may submit motions to the Commission for consideration, as it deems appropriate. The amendment also deletes reference to the Public Utility Holding Company Act of 1935, which has been repealed.

Administrative Law Matters

The Commission finds, in accordance with section 553(b)(A) of the Administrative Procedure Act, 5 U.S.C. 553(b)(A), that this amendment relates solely to agency organization, procedure or practice. Accordingly, notice and opportunity for public comment are unnecessary. Because notice and comment are not required for this final rule, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act.[3] Because the rule relates to ''agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties,'' it is not subject to the Small Business Regulatory Enforcement Fairness Act.[4]

Section 23(a)(2) of the Securities Exchange Act of 1934 requires the Commission, in adopting rules under such Act, to consider the anticompetitive effects of any rules it adopts. The Commission does not believe this rule will have any impact on competition because it imposes no new burden on respondents in administrative proceedings, and is intended to expedite disposition of those proceedings. The rule does not contain any collection of information requirements as defined by the Paperwork Reduction Act of 1995, as amended.[5] The rule will not impose any costs on the public.

Statutory Basis and Text of Amendment

This amendment to the Commission's delegations is being adopted pursuant to statutory authority granted to the Commission, including section 3 of the Sarbanes-Oxley Act of 2002, 15 U.S.C. 7202; section 19 of the Securities Act of 1933, 15 U.S.C. 77s; sections 4A, 19, and 23 of the Securities Exchange Act of 1934, 15 U.S.C. 78d–1, 78s, 78w; section 319 of the Trust Indenture Act of 1939, 15 U.S.C. 77sss; sections 38 and 40 of the Investment Company Act of 1940, 15 U.S.C. 80a–37 and 80a–39; and section 211 of the Investment Advisers Act of 1940, 15 U.S.C. 80b–11.

List of Subjects in 17 CFR Part 200

Authority delegations (Government agencies).

Text of Adopted Rule

■ For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

■ 1. The authority citation for part 200, subpart A, continues to read as follows:

Authority: 15 U.S.C. 77s, 77o, 77sss, 78d, 78d–1, 78d–2, 78w, 78*ll*(d), 78mm, 80a–37, 80b–11, and 7202, unless otherwise noted.

■ 2. Section 200.30–10 is amended by:

■ a. Removing ''the Public Utility Holding Company Act of 1935, 15 U.S.C. 79a *et seq.*,'' in the introductory text to paragraph (a);

■ b. Removing the period at the end of paragraph (a)(7) and in its place adding a semicolon; and

■ c. Adding paragraph (a)(8).

The addition reads as follows:

§ 200.30–10 Delegation of authority to Chief Administrative Law Judge.

* * * * *

(a) * * *

(8) To grant motions of staff counsel to discontinue administrative proceedings as to a particular respondent who has died or cannot be found, or because of a mistake in the identity of a respondent named in the order for proceedings.

* * * * *

Dated: December 4, 2006.

By the Commission.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E6–20884 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

[1] 17 CFR 200.30–14(g)(1)(vi).

[2] 17 CFR 200.30–10.

[3] *See* 5 U.S.C. 603.

[4] *See* 5 U.S.C. 804(3)(C).

[5] *See* 44 U.S.C. 3501 *et seq.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lincomycin and Spectinomycin Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Agri Laboratories, Ltd. The ANADA provides for the oral use of lincomycin and spectinomycin soluble powder to create a solution administered in the drinking water of chickens as an aid in the control of airsacculitis.

DATES: This rule is effective December 8, 2006.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed ANADA 200–407 that provides for use of Lincomycin-Spectinomycin (lincomycin hydrochloride and spectinomycin dihydrochloride pentahydrate) Water Soluble Powder to create a solution administered in the drinking water of chickens as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *M. gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin. Agri Laboratories, Ltd.'s Lincomycin-Spectinomycin Water Soluble Powder is approved as a generic copy of L–S 50 Water Soluble Powder, sponsored by Pharmacia & Upjohn Co., a Division of Pfizer, Inc., under NADA 046–109. The ANADA is approved as of November 9, 2006, and the regulations are amended in 21 CFR 520.1265 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. In § 520.1265, revise the section heading and paragraph (b)(2) to read as follows:

§ 520.1265 Lincomycin and spectinomycin powder.

* * * * *

(b) * * *

(2) Nos. 057561, 059130, and 061623 for use of product described in paragraph (a)(2) of this section.

* * * * *

Dated: November 28, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6–20929 Filed 12–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by IVX Animal Health, Inc. The supplemental ANADA revises labeling of generic oxytetracycline soluble powder with the current scientific names of the causative bacteria of foulbrood of honeybees.

DATES: This rule is effective December 8, 2006.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200–247 that provides for the use of Oxytetracycline HCl Soluble Powder-343 in several species. The supplement revises labeling of generic oxytetracycline soluble powder with the current scientific names of the causative bacteria of foulbrood of honeybees. The supplemental ANADA is approved as of November 9, 2006, and the regulations are amended in 21 CFR 520.1660d to reflect the approval and a current format.

Approval of this supplemental ANADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. In § 520.1660d, revise paragraph (d)(2)(ii) to read as follows:

§ 520.1660d Oxytetracycline powder.

* * * * *

(d) * * *

(2) * * *

(ii) *Indications for use.* For control of American foulbrood caused by *Paenibacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline.

* * * * *

Dated: November 22, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. E6–20928 Filed 12–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9286]

RIN 1545–BE91

Railroad Track Maintenance Credit; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document corrects temporary regulations (TD 9286) that were published in the **Federal Register** on Friday, September 8, 2006 (71 FR 53009) providing rules for claiming the railroad track maintenance credit under section 45G of the Internal Revenue Code for qualified railroad track maintenance expenditures paid or incurred by a Class II railroad or Class III railroad and other eligible taxpayers during the taxable year.

DATES: This correction is effective September 8, 2006.

FOR FURTHER INFORMATION CONTACT: Winston H. Douglas, (202) 622–3110 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations (TD 9286) that is the subject of this document is under section 45G of the Internal Revenue Code.

Need for Correction

As published, the temporary regulations (TD 9286) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Correction of Publication

■ Accordingly, 26 CFR parts 1 and 602 are corrected by making the following correcting amendments:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.45G–0T is amended by removing the entry for § 1.45G–1T(e) and (e)(2) and redesignating the entries for § 1.45G–1T(e)(1) and § 1.45G–1T(e)(1)(i), (ii) and (iii) as the entries for (e), (e)(1), (e)(2) and (e)(3) respectively.

■ **Par. 3.** Section 1.45G–1T is amended by:

■ 1. Removing paragraph (e)(2);

■ 2. Redesignating paragraphs (e)(1)(i), (e)(1)(ii), and (e)(1)(iii) as paragraphs (e)(1), (e)(2), and (e)(3), respectively;

■ 3. Revising paragraph (a), sixth sentence, paragraph (b)(9), paragraph (d)(6) *Example 2.*(ii), last sentence, paragraph headings (e), (e)(1), (e)(2) and (e)(3), paragraph (e)(2), second and fifth sentences, paragraph (e)(3), first sentence, *Example 1.*(*i*), third sentence, *Example 1.*(*iii*), second sentence, *Example 2.*(*iii*), fourth sentence, and paragraph (g)(3). The revisions read as follows:

§ 1.45G–1T Railroad track maintenance credit (temporary).

(a) * * * Paragraph (e) of this section contains rules for adjusting basis for the amount of the RTMC claimed by an eligible taxpayer. * * *

(b) * * *

(9) Except as provided in paragraph (e)(2) of this section, *railroad track* is property described in STB property accounts 8 (ties), 9 (rails and other track material), and 11 (ballast) in 49 CFR part 1201, subpart A.

* * * * *

(d) * * *

(6) * * *

Example 2. * * *

(ii) * * * Because O's tentative amount of RTMC does not exceed O's credit limitation amount for the taxable year ending March 31, 2007, O may claim a RMTC for the taxable year ending March 31, 2007, in the amount of $75,000.

* * * * *

(e) *Adjustments to basis*—* * *

(1) *In general.* * * *

(2) *Basis adjustment made to railroad track.* * * * For purposes of section 45G(e)(3) and this paragraph (e)(2), the adjusted basis of any railroad track with respect to which the eligible taxpayer claims the RTMC is limited to the amount of QRTME, if any, that is required to be capitalized into the qualifying railroad structure or an intangible asset. * * * If all or some of the QRTME paid or incurred by an eligible taxpayer during the taxable year is capitalized under section 263(a) to more than one asset, whether tangible or intangible (for example, railroad track and bridges), the reduction to the basis of these assets under this paragraph (e)(2) is allocated among each of the assets subject to the reduction in proportion to the unadjusted basis of each asset at the time the QRTME is paid or incurred during that taxable year.

(3) *Examples.* The application of this paragraph (e) is illustrated by the following examples. * * *

Example 1. * * *

(*i*) * * * X uses the track maintenance allowance method for track structure expenditures (for further guidance, see Rev. Proc. 2002–65 (2002–2 CB 700) and § 601.601(d)(2)(ii)(*b*) of this chapter). * * *

(*iii*) * * * In accordance with paragraph (e)(2) of this section, X reduces the capitalized amount of $250,000 by the RTMC of $500,000 claimed by X for 2006, but not below zero. * * *

Example 2. * * *

(*iii*) * * * In accordance with paragraph (e)(2) of this section, Z reduces the capitalized amount of $1 million by the RTMC of $500,000 claimed by Z for 2006. * * *

* * * * *

(g) * * *

(3) *Special rules for 2005 returns.* If a taxpayer's Federal income tax return for a taxable year beginning after December 31, 2004, and ending before September 7, 2006, is filed before October 10, 2006, and the taxpayer is not filing an amended Federal income tax return for that taxable year pursuant to paragraph (g)(2) of this section before the taxpayer's next filed original Federal income tax return, see paragraphs (d)(4)(iv) and (f)(7) of this section for the statements that must be attached to the taxpayer's next filed original Federal income tax return.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 4.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 5.** In § 602.101, paragraph (b) is amended by revising the following entry in to the table to read as follows:

§ 602.101 OMB control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.45G–1T	1545–2031
* * * * *	

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. E6–20799 Filed 12–7–06; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 301 and 602

[TD 9300]

Guidance Necessary to Facilitate Business Electronic Filing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations designed to eliminate regulatory impediments to the electronic filing of certain income tax returns and other forms. These regulations affect business taxpayers who file income tax returns electronically. This document also makes conforming changes to certain current regulations.

DATES: *Effective Date:* These regulations are effective on December 8, 2006.

Applicability Date: These regulations apply with respect to taxable years beginning after December 31, 2002. The applicability of §§ 1.170A–11T, 1.556–2T, 1.565–1T, 1.936–7T, 1.1017–1T, 1.1368–1T, 1.1377–1T, 1.1502–21T(b)(3)(i) and (b)(3)(ii)(B), 1.1502–75T, 1.1503–2T, 1.6038B–1T(b)(1)(ii) and 301.7701–3T will expire on December 8, 2006.

FOR FURTHER INFORMATION CONTACT: Nathan Rosen, (202) 622–4910 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–1868. The collection of information in these final regulations is in § 1.170A–11(b)(2). The information required in § 1.170A–11(b)(2) concerning the date on which a corporation's board of directors authorizes a certain type of charitable contribution assists the IRS in determining the deductibility of such contributions. Responses to this collection of information are mandatory.

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

The estimated annual burden per respondent is .25 hours.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports, Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

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

Background

This document contains amendments to 26 CFR part 1 and 26 CFR part 301 designed to eliminate regulatory impediments to the electronic submission of tax returns and other forms filed by corporations, partnerships, other business entities, and their owners.

In 1998, Congress enacted the Internal Revenue Service Restructuring and Reform Act of 1998 (RRA 1998), Pub. L. No. 105–206 (112 Stat. 685) (1998). RRA 1998 states a Congressional policy to promote the paperless filing of Federal tax returns. Section 2001(a) of RRA 1998 set a goal for the IRS to have at least 80 percent of all Federal tax and information returns filed electronically by 2007. Section 2001(b) of RRA 1998 requires the IRS to establish a 10-year strategic plan to eliminate barriers to electronic filing.

Finalization of December 2003 Regulations Facilitating Electronic Filing

On December 19, 2003, the IRS and Treasury published in the **Federal Register** (TD 9100, 2004–1 C.B. 297 [68 FR 70701]) temporary and final regulations modifying the regulations under sections 170, 556, 565, 936, 1017, 1368, 1377, 1502, 1503, 6038B and 7701 of the Internal Revenue Code. In the same issue of the **Federal Register**, the IRS and Treasury published a notice of proposed rulemaking (REG–116664–01, 2004–1 C.B. 319 [68 FR 70747]) proposing to amend regulations under the code sections noted in the previous sentence. The temporary, final, and proposed regulations published on December 19, 2003, are collectively referred to as the December 2003 Regulations.

The December 2003 Regulations generally affect taxpayers who must file any of the following forms: Form 926, ''Return by a U.S. Transferor of Property to a Foreign Corporation''; Form 972, ''Consent of Shareholder To Include Specific Amount in Gross Income''; Form 973, ''Corporation Claim for Deduction for Consent Dividends''; Form 982, ''Reduction of Tax Attributes Due to Discharge of Indebtedness (and Section 1082 Basis Adjustment)''; Form 1120, ''U.S. Corporation Income Tax Return''; Form 1120S, ''U.S. Income Tax Return for an S Corporation''; Form 1122, ''Authorization and Consent of Subsidiary Corporation To Be Included in a Consolidated Income Tax Return''; Form 5471, ''Information Return of U.S. Persons With Respect To Certain Foreign Corporations''; Form 5712–A, ''Election and Verification of the Cost Sharing or Profit Split Method Under Section 936(h)(5)''; and Form 8832, ''Entity Classification Election.''

Prior to the changes adopted by the December 2003 Regulations, certain regulations under the code sections cited above impeded electronic filing of returns. Some of these regulations, for example, impeded electronic filing by requiring taxpayers to include third-party signatures on their tax returns or by requiring taxpayers to attach documents or statements generated by a third party. Other regulations required a taxpayer to sign an IRS form and file it as an attachment to the taxpayer's income tax return. To address certain situations in which regulations required

taxpayers to attach documents or statements to their tax returns, for example, the December 2003 Regulations allowed taxpayers to retain such items in their books and records. Taxpayers would be obligated, of course, to make the items available for inspection by the IRS.

The IRS received no comments responding to the December 2003 Regulations, and no public hearing regarding the proposed regulations was requested or held. Accordingly, the temporary and proposed regulations are adopted with no substantive change by this Treasury decision, and the corresponding temporary regulations are removed. These final regulations make certain non-substantive changes to the December 2003 Regulations as described below.

Section 556 was repealed by the American Jobs Creation Act, Pub. L. No. 108–357 (118 Stat. 1418), effective for taxable years of foreign corporations beginning after December 31, 2004, and effective for taxable years of United States shareholders with or within which such taxable years of foreign corporations end. The provision in the December 2003 Regulations eliminating an electronic filing impediment under section 556 applied to tax years ending before the repeal of section 556. Therefore, these final regulations amend section 1.556–2 of the Income Tax Regulations despite the repeal of section 556 itself.

These final regulations remove certain portions of section 1.1502–21T and place such language in sections 1.1502–21(b)(3)(i) and (b)(3)(ii)(B), so as to eliminate impediments to the electronic filing of Form 1120. Other portions of that temporary regulation, however, predate the December 2003 Regulations or relate to matters other than electronic filing, and this document does not revise those portions.

The regulations as finalized by this Treasury decision clarify that references in the following regulations to tax return due dates include extensions of such due dates: See 1.565–1(b)(3), 1.936–7(b), Q. & A. 1, 1.1368–1(f)(5)(iii) and (g)(2)(iii) and 1.1503–2(g)(2)(i) and (iv)(B)(3)*(iii).*

January 2006 Final Regulations Facilitating Electronic Filing

On January 23, 2006, the IRS and Treasury released TD 9243, (TD 9243, 2006–8 I.R.B. 475 [71 FR 4276]) (the January 2006 Final Regulations) which, among other things, removed an impediment to electronic filing of Form 926. In the December 2003 Regulations, the IRS and Treasury had previously amended both sections 1.6038B–1(b)(1)(i) and 1.6038B–1(b)(1)(ii) of the Income Tax Regulations to eliminate an impediment to electronic filing of Form 926. The January 2006 Final Regulations amended section 1.6038B–1(b)(1)(i) and removed temporary regulations section 1.6038B–1T(b)(1)(i). Therefore, because the amendment in the December 2003 Regulations to 1.6038B–1T(b)(1)(i) has already been adopted in final regulations, these final regulations amend 1.6038B–1(b)(1)(ii) and remove 1.6038B–1T(b)(1)(ii), but do not address section 1.6038B–1(b)(1)(i).

May 2006 Regulations Facilitating Electronic Filing

On May 26, 2006, the IRS and Treasury Department released TD 9264 (the May 2006 Regulations), which contained numerous temporary regulations amending or replacing final regulations. Some of these final regulations had required taxpayers to provide detailed information about a transaction. In other cases, the scope of various reporting requirements was not clear. The May 2006 Regulations simplified, clarified or, in some cases, eliminated these reporting burdens.

The May 2006 Regulations also eliminated regulatory impediments to the electronic filing of certain statements that taxpayers are required to include on or with their Federal income tax returns. In some cases, this impediment was removed by deleting the requirement that the taxpayer sign such statement. In other cases, where the taxpayer and a third party were both required to sign such statement, this impediment was removed by requiring each party to indicate on such statement that it had entered into an agreement with the other party addressing the substantive matters covered by the final regulations. Requiring such a statement from the parties in place of the dual signatures eliminates an e-file impediment, but to protect the Service's interests, the May 2006 regulations require each party to keep either the original or a copy of the underlying agreement in its records.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the collection of information in these regulations involves an insignificant expenditure of time by taxpayers, as noted above under the heading ''Paperwork Reduction Act.'' Accordingly, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the December 2003 Regulations and the December 2003 notice of proposed rulemaking were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Nathan Rosen, Office of Associate Chief Counsel (Procedure and Administration), Administrative Provisions and Judicial Practice Division.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR parts 1, 301 and 602 are amended as follows:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.170A–11 is amended by revising paragraph (b)(2) to read as follows:

§ 1.170A–11 Limitation on, and carryover of, contributions by corporations.

* * * * *

(b) * * *

(2) The election must be made at the time the return for the taxable year is filed, by reporting the contribution on the return. There shall be attached to the return when filed a written declaration stating that the resolution authorizing the contribution was adopted by the board of directors during the taxable

year. For taxable years beginning before January 1, 2003, the declaration shall be verified by a statement signed by an officer authorized to sign the return that it is made under penalties of perjury, and there shall also be attached to the return when filed a copy of the resolution of the board of directors authorizing the contribution. For taxable years beginning after December 31, 2002, the declaration must also include the date of the resolution, the declaration shall be verified by signing the return, and a copy of the resolution of the board of directors authorizing the contribution is a record that the taxpayer must retain and keep available for inspection in the manner required by § 1.6001–1(e).

* * * * *

§ 1.170A–11T [Removed]

■ **Par. 3.** Section 1.170A–11T is removed.

■ **Par. 4.** Section 1.556–2 is amended by revising paragraphs (e)(2)(vii) and (e)(3) to read as follows:

§ 1.556–2 Adjustments to taxable income.

* * * * *

(e) * * *

(2) * * *

(vii) In the case of a return for a taxable year beginning before January 1, 2003, a copy of the contract, lease, or rental agreement;

* * * * *

(3) If the statement described in § 1.556–2(e)(2) is attached to a taxpayer's income tax return for a taxable year beginning after December 31, 2002, a copy of the applicable contract, lease or rental agreement is not required to be submitted with the return, but must be retained by the taxpayer and kept available for inspection in the manner required by § 1.6001–1(e).

* * * * *

§ 1.556–2T [Removed]

■ **Par. 5.** Section 1.556–2T is removed.

■ **Par. 6** Section 1.565–1 is amended by revising paragraph (b)(3) to read as follows:

§ 1.565–1 General rule.

* * * * *

(b) * * *

(3) A consent may be filed at any time not later than the due date (including extensions) of the corporation's income tax return for the taxable year for which the dividends paid deduction is claimed. With such return, and not later than the due date (including extensions) thereof, the corporation must file Forms 972 for each consenting shareholder, and a return on Form 973 showing by classes the stock outstanding on the first and last days of the taxable year, the dividend rights of such stock, distributions made during the taxable year to shareholders, and giving all the other information required by the form. For taxable years beginning before January 1, 2003, the Form 973 filed with the corporation's income tax return shall contain or be verified by a written declaration that is made under the penalties of perjury and the Forms 972 filed with the return must be duly executed by the consenting shareholders. For taxable years beginning after December 31, 2002, the Form 973 filed with the corporation's income tax return shall be verified by signing the return and the Forms 972 filed with the return must be duly executed by the consenting shareholders or, if unsigned, must contain the same information as the duly executed originals. If the corporation submits unsigned Forms 972 with its return for a taxable year beginning after December 31, 2002, the duly executed originals are records that the corporation must retain and keep available for inspection in the manner required by § 1.6001–1(e).

* * * * *

§ 1.565–1T [Removed]

■ **Par. 7.** Section 1.565–1T is removed.

■ **Par. 8.** Section 1.936–7 is amended by revising paragraph (b), Q. & A. 1, to read as follows:

§ 1.936–7 Manner of making election under section 936(h)(5); special election for export sales; revocation of election under section 936(a).

* * * * *

(b) *Manner of making election.*

Q. 1: How does a possessions corporation make an election to use the cost sharing method or profit split method?

A. 1: A possessions corporation makes an election to use the cost sharing or profit split method by filing Form 5712–A (''Election and Verification of the Cost Sharing or Profit Split Method Under Section 936(h)(5)'') and attaching it to its tax return. Form 5712–A must be filed on or before the due date (including extensions) of the tax return of the possessions corporation for its first taxable year beginning after December 31, 1982. The electing corporation must set forth on the form the name and the taxpayer identification number or address of all members of the affiliated group (including foreign affiliates not required to file a U.S. tax return). All members of the affiliated group must consent to the election. For elections filed with respect to taxable years beginning before January 1, 2003, an authorized officer of the electing corporation must sign the statement of election and must declare that he has received a signed statement of consent from an authorized officer, director, or other appropriate official of each member of the affiliated group. Elections filed for taxable years beginning after December 31, 2002, must incorporate a declaration by the electing corporation that it has received a signed consent from an authorized officer, director, or other appropriate official of each member of the affiliated group and will be verified by signing the return. The election is not valid for a taxable year unless all affiliates consent. A failure to obtain an affiliate's written consent will not invalidate the election out if the possessions corporation made a good faith effort to obtain all the necessary consents or the failure to obtain the missing consent was inadvertent. Subsequently created or acquired affiliates are bound by the election. If an election out is revoked under section 936(h)(5)(F)(iii), a new election out with respect to that product area cannot be made without the consent of the Commissioner. The possessions corporation shall file an amended Form 5712–A with its timely filed (including extensions) income tax return to reflect any changes in the names or number of the members of the affiliated group for any taxable year after the first taxable year to which the election out applies. By consenting to the election out, all affiliates agree to provide information necessary to compute the cost sharing payment under the cost sharing method or combined taxable income under the profit split method, and failure to provide such information shall be treated as a request to revoke the election out under section 936(h)(5)(F)(iii).

* * * * *

§ 1.936–7T [Removed]

■ **Par. 9.** Section 1.936–7T is removed.

■ **Par. 10.** Section 1.1017–1 is amended by revising paragraph (g)(2)(iii)(B) to read as follows:

§ 1.1017–1 Basis reductions following a discharge of indebtedness.

* * * * *

(g) * * *

(2) * * *

(iii) * * *

(B) *Taxpayer's requirement.* For taxable years beginning before January 1, 2003, statements described in § 1.1017–1(g)(2)(iii)(A) must be attached to a taxpayer's timely filed (including extensions) Federal income tax return

for the taxable year in which the taxpayer has COD income that is excluded from gross income under section 108(a). For taxable years beginning after December 31, 2002, taxpayers must retain the statements and keep them available for inspection in the manner required by § 1.6001–1(e), but are not required to attach the statements to their returns.

* * * * *

§ 1.1017–1T [Removed]

■ **Par. 11.** Section 1.1017–1T is removed.

■ **Par. 12.** Section 1.1368–1 is amended by revising paragraphs (f)(5)(iii) and (g)(2)(iii) to read as follows:

§ 1.1368–1 Distributions by S corporations.

* * * * *

(f) * * *

(5) * * *

(iii) *Corporate statement regarding elections.* A corporation makes an election for a taxable year under § 1.1368–1(f) by attaching a statement to a timely filed (including extensions) original or amended return required to be filed under section 6037 for that taxable year. In the statement, the corporation must identify the election it is making under § 1.1368–1(f) and must state that each shareholder consents to the election. In the case of elections for taxable years beginning before January 1, 2003, an officer of the corporation must sign under penalties of perjury the statement on behalf of the corporation. In the case of elections for taxable years beginning after December 31, 2002, the statement described in this paragraph (f)(5)(iii) shall be verified by signing the return. A statement of election to make a deemed dividend under § 1.1368–1(f) must include the amount of the deemed dividend that is distributed to each shareholder.

* * * * *

(g) * * *

(2) * * *

(iii) *Time and manner of making election.* A corporation makes an election under § 1.1368–1(g)(2)(i) for a taxable year by attaching a statement to a timely filed (including extensions) original or amended return required to be filed under section 6037 for a taxable year (without regard to the election under § 1.1368–1(g)(2)(i)). In the statement, the corporation must state that it is electing for the taxable year under § 1.1368–1(g)(2)(i) to treat the taxable year as if it consisted of separate taxable years. The corporation also must set forth facts in the statement relating to the qualifying disposition (*e.g.*, sale, gift, stock issuance, or redemption), and state that each shareholder who held stock in the corporation during the taxable year (without regard to the election under § 1.1368–1(g)(2)(i)) consents to this election. For purposes of this election, a shareholder of the corporation for the taxable year is a shareholder as described in section 1362(a)(2). A single election statement may be filed for all elections made under § 1.1368–1(g)(2)(i) for the taxable year. An election made under § 1.1368–1(g)(2)(i) is irrevocable. In the case of elections for taxable years beginning before January 1, 2003, the statement through which a corporation makes an election under § 1.1368–1(g)(2)(i) must be signed by an officer of the corporation under penalties of perjury. In the case of elections for taxable years beginning after December 31, 2002, the statement described in the preceding sentence shall be verified by signing the return.

* * * * *

§ 1.1368–1T [Removed]

■ **Par. 13.** Section 1.1368–1T is removed.

■ **Par. 14.** Section 1.1377–1 is amended by revising paragraph (b)(5)(i)(C) to read as follows:

§ 1.1377–1 Pro rata share.

* * * * *

(b) * * *

(5) * * *

(i) * * *

(C) The signature on behalf of the S corporation of an authorized officer of the corporation under penalties of perjury, except that for taxable years beginning after December 31, 2002, the election statement described in § 1.1377–1(b)(5)(i) of this section shall be verified, and the requirement of this paragraph (b)(5)(i)(C) is satisfied, by the signature on the Form 1120S filed by the S corporation.

* * * * *

§ 1.1377–1T [Removed]

■ **Par. 15.** Section 1.1377–1T is removed.

■ **Par. 16.** Section 1.1502–21 is amended by revising paragraphs (b)(3)(i) and (b)(3)(ii)(B) to read as follows:

§ 1.1502–21 Net operating losses.

* * * * *

(b) * * *

(3) *Special rules*—(i) *Election to relinquish carryback.* A group may make an irrevocable election under section 172(b)(3) to relinquish the entire carryback period with respect to a CNOL for any consolidated return year. Except as provided in § 1.1502–21(b)(3)(ii)(B), the election may not be made separately for any member (whether or not it remains a member), and must be made in a separate statement entitled ''THIS IS AN ELECTION UNDER § 1.1502–21(b)(3)(i) TO WAIVE THE ENTIRE CARRYBACK PERIOD PURSUANT TO SECTION 172(b)(3) FOR THE [insert consolidated return year] CNOLs OF THE CONSOLIDATED GROUP OF WHICH [insert name and employer identification number of common parent] IS THE COMMON PARENT.'' The statement must be filed with the group's income tax return for the consolidated return year in which the loss arises. If the consolidated return year in which the loss arises begins before January 1, 2003, the statement making the election must be signed by the common parent. If the consolidated return year in which the loss arises begins after December 31, 2002, the election may be made in an unsigned statement.

(ii) * * *

(B) *Acquisition of member from another consolidated group.* If one or more members of a consolidated group becomes a member of another consolidated group, the acquiring group may make an irrevocable election to relinquish, with respect to all consolidated net operating losses attributable to the member, the portion of the carryback period for which the corporation was a member of another group, provided that any other corporation joining the acquiring group that was affiliated with the member immediately before it joined the acquiring group is also included in the waiver. This election is not a yearly election and applies to all losses that would otherwise be subject to a carryback to a former group under section 172. The election must be made in a separate statement entitled ''THIS IS AN ELECTION UNDER § 1.1502–21(b)(3)(ii)(B)(*2*) TO WAIVE THE PRE-[insert first taxable year for which the member (or members) was not a member of another group] CARRYBACK PERIOD FOR THE CNOLs attributable to [insert names and employer identification number of members].'' The statement must be filed with the acquiring consolidated group's original income tax return for the year the corporation (or corporations) became a member. If the year in which the corporation (or corporations) became a member begins before January 1, 2003, the statement must be signed by the common parent and each of the members to which it applies. If the year in which the corporation (or corporations) became a member begins after December 31, 2002,

the election may be made in an unsigned statement.

* * * * *

■ **Par. 17.** Section 1.1502–21T is amended by revising paragraphs (a) through (b)(3)(ii)(B) to read as follows:

§ 1.1502–21T Net operating losses (temporary).

(a) through (b)(3)(ii)(B) [Reserved]. For further guidance, see § 1.1502–21(a) through (b)(3)(ii)(B).

* * * * *

■ **Par. 18.** Section 1.1502–75 is amended by revising paragraph (h)(2) to read as follows:

§ 1.1502–75 Filing of consolidated returns.

* * * * *

(h) * * *

(2) *Filing of Form 1122 for first year.* If, under the provisions of paragraph (a)(1) of this section, a group wishes to file a consolidated return for a taxable year, then a Form 1122 (''Authorization and Consent of Subsidiary Corporation To Be Included in a Consolidated Income Tax Return'') must be executed by each subsidiary. For taxable years beginning before January 1, 2003, the executed Forms 1122 must be attached to the consolidated return for the taxable year. For taxable years beginning after December 31, 2002, the group must attach either executed Forms 1122 or unsigned copies of the completed Forms 1122 to the consolidated return. If the group submits unsigned Forms 1122 with its return, it must retain the signed originals in its records in the manner required by § 1.6001–1(e). Form 1122 is not required for a taxable year if a consolidated return was filed (or was required to be filed) by the group for the immediately preceding taxable year.

* * * * *

§ 1.1502–75T [Removed]

■ **Par. 19.** Section 1.1502–75T is removed.

■ **Par. 20.** Section 1.1503–2 is amended by revising paragraphs (g)(2)(i), (g)(2)(iv)(B)(*3*)(*iii*) and (g)(2)(vi)(B) to read as follows:

§ 1.1503–2 Dual consolidated loss.

* * * * *

(g) * * *

(2) * * *

(i) *In general.* Paragraph (b) of this section shall not apply to a dual consolidated loss if the consolidated group, unaffiliated dual resident corporation, or unaffiliated domestic owner elects to be bound by the provisions of this paragraph (g)(2). In order to elect relief under this paragraph (g)(2), the consolidated group, unaffiliated dual resident corporation, or unaffiliated domestic owner must attach to its timely filed (including extensions) U.S. income tax return for the taxable year in which the dual consolidated loss is incurred an agreement described in paragraph (g)(2)(i)(A) of this section. The agreement must be signed under penalties of perjury by the person who signs the return. For taxable years beginning after December 31, 2002, the agreement attached to the income tax return of the consolidated group, unaffiliated dual resident corporation or unaffiliated domestic owner pursuant to the preceding sentence may be an unsigned copy. If an unsigned copy is attached to the return, the consolidated group, unaffiliated dual resident corporation, or unaffiliated domestic owner must retain the original in its records in the manner specified by § 1.6001–1(e). The agreement must include the following items, in paragraphs labeled to correspond with the items set forth in paragraph (g)(2)(i)(A) through (F) of this section.

(A) A statement that the document submitted is an election and an agreement under the provisions of paragraph (g)(2) of this section.

(B) The name, address, identifying number, and place and date of incorporation of the dual resident corporation, and the country or countries that tax the dual resident corporation on its worldwide income or on a residence basis, or, in the case of a separate unit, identification of the separate unit, including the name under which it conducts business, its principal activity, and the country in which its principal place of business is located.

(C) An agreement by the consolidated group, unaffiliated dual resident corporation, or unaffiliated domestic owner to comply with all of the provisions of § 1.1503–2(g)(2)(iii)-(vii).

(D) A statement of the amount of the dual consolidated loss covered by the agreement.

(E) A certification that no portion of the dual resident corporation's or separate unit's losses, expenses, or deductions taken into account in computing the dual consolidated loss has been, or will be, used to offset the income of any other person under the income tax laws of a foreign country.

(F) A certification that arrangements have been made to ensure that no portion of the dual consolidated loss will be used to offset the income of another person under the laws of a foreign country and that the consolidated group, unaffiliated dual resident corporation, or unaffiliated domestic owner will be informed of any such foreign use of any portion of the dual consolidated loss.

* * * * *

(iv) * * *

(B) * * *

(*3*) * * *

(*iii*) The unaffiliated domestic corporation or new consolidated group must file, with its timely filed (including extensions) income tax return for the taxable year in which the event described in paragraph (g)(2)(iv)(B)(*1*) or (*2*) of this section occurs, an agreement described in paragraph (g)(2)(i) of this section (new (g)(2)(i) agreement), whereby it assumes the same obligations with respect to the dual consolidated loss as the corporation or consolidated group that filed the original (g)(2)(i) agreement with respect to that loss. The new (g)(2)(i) agreement must be signed under penalties of perjury by the person who signs the return and must include a reference to this paragraph (g)(2)(iv)(B)(*3*)(*iii*). For taxable years beginning after December 31, 2002, the agreement attached to the return pursuant to the preceding sentence may be an unsigned copy. If an unsigned copy is attached to the return, the corporation or consolidated group must retain the original in its records in the manner specified by § 1.6001–1(e).

* * * * *

(vi) * * *

(B) *Annual certification.* Except as provided in § 1.1503–2(g)(2)(vi)(C), until and unless Form 1120 or the Schedules thereto contain questions pertaining to dual consolidated losses, the consolidated group, unaffiliated dual resident corporation, or unaffiliated domestic owner must file with its income tax return for each of the 15 taxable years following the taxable year in which the dual consolidated loss is incurred a certification that the losses, expenses, or deductions that make up the dual consolidated loss have not been used to offset the income of another person under the tax laws of a foreign country. For taxable years beginning before January 1, 2003, the annual certification must be signed under penalties of perjury by a person authorized to sign the agreement described in § 1.1503–2(g)(2)(i). For taxable years beginning after December 31, 2002, the certification is verified by signing the return with which the certification is filed. The certification for a taxable year must identify the dual consolidated loss to which it pertains by setting forth the taxpayer's year in which the loss was incurred and the amount of such loss. In addition, the certification must warrant that

arrangements have been made to ensure that the loss will not be used to offset the income of another person under the laws of a foreign country and that the taxpayer will be informed of any such foreign use of any portion of the loss. If dual consolidated losses of more than one taxable year are subject to the rules of this paragraph (g)(2)(vi)(B), the certifications for those years may be combined in a single document but each dual consolidated loss must be separately identified.

* * * * *

§ 1.1503–2T [Removed]

■ **Par. 21.** Section 1.1503–2T is removed.

■ **Par. 22.** Section 1.6038B–1 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 1.6038B–1 Reporting of certain transfers to foreign corporations.

* * * * *

(b) * * *

(1) * * *

(ii) *Reporting by corporate transferor.* For transfers by corporations in taxable years beginning before January 1, 2003, Form 926 must be signed by an authorized officer of the corporation if the transferor is not a member of an affiliated group under section 1504(a)(1) that files a consolidated Federal income tax return and by an authorized officer of the common parent corporation if the transferor is a member of such an affiliated group. For transfers by corporations in taxable years beginning after December 31, 2002, Form 926 shall be verified by signing the income tax return to which the form is attached.

* * * * *

■ **Par. 23.** Section 1.6038B–1T is amended by revising paragraphs (a) through (b)(3) to read as follows:

§ 1.6038B–1T Reporting of certain transactions to foreign corporations (Temporary).

(a) through (b)(3) [Reserved]. For further guidance, see § 1.6038B–1(a) through (b)(3).

* * * * *

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 24.** The authority citation for part 301 continues to read, in part, as follows:

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

■ **Par. 25.** Section 301.7701–3 is amended by revising paragraph (c)(1)(ii) to read as follows:

§ 301.7701–3 Classification of certain business entities.

* * * * *

(c) * * * (1) * * *

(ii) *Further notification of elections.* An eligible entity required to file a Federal tax or information return for the taxable year for which an election is made under § 301.7701–3(c)(1)(i) must attach a copy of its Form 8832 to its Federal tax or information return for that year. If the entity is not required to file a return for that year, a copy of its Form 8832 (''Entity Classification Election'') must be attached to the Federal income tax or information return of any direct or indirect owner of the entity for the taxable year of the owner that includes the date on which the election was effective. An indirect owner of the entity does not have to attach a copy of the Form 8832 to its return if an entity in which it has an interest is already filing a copy of the Form 8832 with its return. If an entity, or one of its direct or indirect owners, fails to attach a copy of a Form 8832 to its return as directed in this section, an otherwise valid election under § 301.7701–3(c)(1)(i) will not be invalidated, but the non-filing party may be subject to penalties, including any applicable penalties if the Federal tax or information returns are inconsistent with the entity's election under § 301.7701–3(c)(1)(i). In the case of returns for taxable years beginning after December 31, 2002, the copy of Form 8832 attached to a return pursuant to this paragraph (c)(1)(ii) is not required to be a signed copy.

* * * * *

§ 301.7701–3T [Removed]

■ **Par. 26.** Section 301.7701–3T is removed.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 27.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 28.** In § 602.101, paragraph (b) is amended by removing the entry for ''1.170A–11T'' and revising the entry for ''1.170A–11'' to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.170A–11	1545–0123 1545–0074 1545–1868

CFR part or section where identified and described	Current OMB control No.
* * * * *	

Linda Kroening,

Deputy Commissioner for Services and Enforcement.

Approved: December 1, 2006.

Eric Solomon,

Acting Deputy Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. E6–20734 Filed 12–7–06; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9286]

RIN 1545–BE91

Railroad Track Maintenance Credit; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to temporary regulations.

SUMMARY: This document contains corrections to temporary regulations (TD 9286) that were published in the **Federal Register** on Friday, September 8, 2006 (71 FR 53009) providing rules for claiming the railroad track maintenance credit under section 45G of the Internal Revenue Code for qualified railroad track maintenance expenditures paid or incurred by a Class II railroad or Class III railroad and other eligible taxpayers during the taxable year.

DATES: This correction is effective September 8, 2006.

FOR FURTHER INFORMATION CONTACT: Winston H. Douglas, (202) 622–3110 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The correction notice that is the subject of this document is under section 45G of the Internal Revenue Code.

Need for Correction

As published, temporary regulations (TD 9286) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the temporary regulations (TD 9286), which was the subject of FR Doc. E6–14858, is corrected as follows:

1. On page 53010, column 1, in the preamble, under the paragraph heading ''*General Overview*'', first and second lines from the bottom of the second paragraph, the language ''assigned to such person by such a railroad.'' is corrected to read ''assigned to such person by a Class II railroad or a Class III railroad.''.

2. On page 53010, column 2, in the preamble, under the paragraph heading ''*Scope*'', first paragraph of the column, last line of the paragraph, the language ''of controlled groups under section 45G.'' is corrected to read ''of controlled groups under section 45G with respect to the RTMC.''.

3. On page 53010, column 2, in the preamble, under the paragraph heading ''*Eligible Taxpayer*'', fourth line of the first paragraph, the language ''defined in the temporary regulations as:'' is corrected to read ''defined as:''.

4. On page 53010, column 2, in the preamble, under the paragraph heading ''*Eligible Taxpayer*'', third line from the bottom of the first paragraph, the language ''railroad track assigned to the person for'' is corrected to read ''railroad track assigned to the taxpayer for''.

5. On page 53010, column 2, in the preamble, under the paragraph heading ''*Eligible Taxpayer*'', second through the sixth line from the bottom of the second paragraph, the language ''Price Index)). 49 CFR part 1201, subpart A, § 1–1(a). In general, Class III railroads have annual carrier operating revenues of $20 million or less after applying the railroad revenue deflator formula. 49'' is corrected to read ''Price Index)). See 49 CFR part 1201, subpart A, § 1–1(a). In general, Class III railroads have annual carrier operating revenues of $20 million or less after applying the railroad revenue deflator formula. See 49''.

6. On page 53010, column 3, in the preamble, under the paragraph heading ''*Eligible Taxpayer*'', second paragraph of the column, tenth to seventeenth lines, the language ''services are the transport of freight by rail, the loading and unloading of freight transported by rail, locomotive leasing or rental, and maintenance of a railroad's right-of-way (including vegetation control). Examples of services that are not railroad-related services are general business services,'' is corrected to read ''services include the transport of freight by rail, the loading and unloading of freight transported by rail, locomotive leasing or rental, and maintenance of a railroad's right-of-way (including vegetation control). Examples of services that are not railroad-related services include general business services,''.

7. On page 53011, column 1, in the preamble, under the paragraph heading ''*Determination of QRTME Paid or Incurred*'', second paragraph, third and fourth lines, the language ''to a taxpayer using an accrual method of accounting. In this case, paid or'' is corrected to read ''to taxpayers using an accrual method of accounting. For such taxpayers, paid or''.

8. On page 53011, column 1, in the preamble, under the paragraph heading ''*Determination of QRTME Paid or Incurred*'', second paragraph, fifteenth to twentieth lines, the language ''any such expenditures. The temporary regulations provide that reimbursements may consist of amounts paid either directly or indirectly to the taxpayer. Examples of indirect reimbursements are discounted freight shipping rates,'' is corrected to read ''any expenditures that would otherwise qualify as QRTME. The temporary regulations provide that reimbursements may consist of amounts paid either directly or indirectly to the taxpayer. Examples of indirect reimbursements include discounted freight shipping rates,''.

9. On page 53011, column 1, in the preamble, under the paragraph heading ''*Determination of QRTME Paid or Incurred*'', third paragraph, first line, the language ''If an eligible taxpayer (assignee) pays'' is corrected to read ''The IRS and Treasury believe that the statute is intended to allow suppliers and shippers to claim the credit for providing the funding for the QRTME performed on railroad track owned by, or leased to, a Class II railroad or Class III railroad. However, the suppliers and shippers may not have the necessary expertise to perform the repairs and improvements. The IRS and Treasury believe that these eligible taxpayers should be able to claim the credit for providing the funding to the extent that the Class II railroads and Class III railroads use such funding to perform the repairs and improvements to the track. Therefore, if an eligible taxpayer (assignee) pays''.

10. On page 53011, column 1, in the preamble, under the paragraph heading ''*Determination of QRTME Paid or Incurred*'', third paragraph, fifth line from the bottom of the column, the language ''paragraph, this QRTME would be'' is corrected to read ''paragraph, QRTME would be''.

11. On page 53011, column 2, in the preamble, under the paragraph heading ''*Assignment of Railroad Track Miles*'', first paragraph, first through fifth lines, the language ''For purposes of section 45G, the temporary regulations provide that an assignment of a mile of railroad track is not a legal transfer of title, but merely a designation. This designation must be'' is corrected to read ''The temporary regulations provide that an assignment of a mile of railroad track is not a legal transfer of title, but merely a designation made solely for purposes of section 45G. This designation must be''.

12. On page 53011, column 2, in the preamble, under the paragraph heading ''*Assignment of Railroad Track Miles*'', second paragraph, fifth line, the language ''track. Thus, if a Class II railroad or Class'' is corrected to read ''track. If a Class II railroad or Class''.

13. On page 53011, column 2, in the preamble, under the paragraph heading ''*Assignment of Railroad Track Miles*'', fourth paragraph, second line, the language ''that a taxpayer must file Form 8900,'' is corrected to read ''that a taxpayer file Form 8900,''.

14. On page 53011, column 3, in the preamble, last paragraph of the column, first line, the language ''The temporary regulations also'' is corrected to read ''The temporary regulations''.

15. On page 53012, column 1, in the preamble, first paragraph of the column, first line, the language ''assignment is properly reported.'' is corrected to read ''assignment is reported.''.

16. On page 53012, column 1, in the preamble, under the paragraph heading ''*Special Rules*'', first paragraph, second through fourth lines from the bottom of the paragraph, the language ''structure (railroad track, roadbed, bridges, and related track structures) and intangible assets to which the'' is corrected to read ''structure and intangible assets to which the''.

17. On page 53012, column 1, in the preamble, under the paragraph heading ''*Special Rules*'', second paragraph, sixth line, the language ''of the RTMC allowable. This reduction'' is corrected to read ''of the RTMC allowable. The basis reduction''.

18. On page 53012, column 1, in the preamble, under the paragraph heading ''*Special Rules*'', third paragraph, first line, the language ''The temporary regulations also'' is corrected to read ''The temporary regulations do not''.

19. On page 53012, column 2, in the preamble, under the paragraph heading ''*Special Rules*'', first paragraph of the column, fourth line to the last of the paragraph, the language ''legislative history does not refer to, any exception to this rule. Accordingly, pursuant to section 61 and the regulations under section 61, the owner of the tangible assets (for example, railroad track and roadbed) with respect to which the QRTME is paid or incurred by another

person that does not have a depreciable interest in those assets has gross income in the amount of that QRTME. However, the application of section 61 to QRTME paid or incurred with respect to eligible railroad track that is leased by a Class II railroad or Class III railroad raises a question as to under what circumstances the owner or lessee should recognize gross income with respect to QRTME. The IRS and Treasury Department request comments on this issue.'' is replaced to read ''legislative history does not refer to, any exception to this rule for an owner of tangible assets (for example, railroad track and roadbed) for the value of the repairs or improvements to such assets with respect to which QRTME is paid or incurred by another person that does not have a depreciable interest in such assets.''

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. E6–20740 Filed 12–7–06; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 61

[Docket No. USMS 101]

RIN 1105–AB13

Supplement to Justice Department Procedures and Council on Environmental Quality Regulations To Ensure Compliance With the National Environmental Policy Act

AGENCY: United States Marshals Service, Justice.

ACTION: Final rule.

SUMMARY: This rule adds Appendix E to part 61 of the Department of Justice's regulations to ensure better compliance with the National Environmental Policy Act (NEPA) of 1969. The rule supplements existing Department procedures and regulations of the Council on Environmental Quality and only pertains to internal procedures of the United States Marshals Service (USMS).

EFFECTIVE DATE: This rule is effective January 8, 2007.

FOR FURTHER INFORMATION CONTACT: Joseph Band, Office of Chief Counsel, United States Marshals Service, Washington, DC 20002; Telephone (202) 307–9722.

SUPPLEMENTARY INFORMATION:

Background

The USMS published a notice of proposed rulemaking on this subject on January 10, 2006 (71 FR 3248). The USMS received no comments before the comment period closed on March 21, 2006. Accordingly, this document finalizes the proposed rule without change.

Need for This Rule

This rule is needed so that the USMS can comply more fully with NEPA. Under NEPA, Federal agencies are required to implement internal procedures to ensure proper environmental consideration of proposed agency actions. The internal procedures promote the protection of the environment by minimizing the use of natural resources and by improving planning and decision-making processes to avoid excess pollution and environmental degradation.

Overview of the Rule's Standards

In complying with and implementing NEPA, the USMS shall make efforts to produce clear and concise NEPA documents and increase administrative efficiency.

All NEPA documents, specifically Environmental Assessments (EAs) and Environmental Impact Statements (EISs), shall be analytical, clear, and concise. The documents shall focus on significant issues and shall be presented in plain language and in the standard format outlined in Appendix E. In order to reduce paperwork, EISs shall be limited to approximately 150 pages, or in unusually complex matters, 300 pages. To avoid duplicative work, NEPA documents shall, whenever possible, be prepared jointly with State and local governments and shall adopt, incorporate by reference, or combine, existing USMS and other agencies' analyses, documentation, and/or other environmental reports.

The USMS shall make every effort to prevent and reduce delay. The USMS will follow the procedures outlined in the CEQ regulations including, (1) Integrating the NEPA process in the early stages of planning to ensure that decisions reflect environmental values, and to head off potential conflicts and/or delays, (2) emphasizing inter-agency cooperation before the environmental analysis and documentation is prepared, (3) ensuring the swift and fair resolution of any dispute by designating a lead agency for any inter-agency projects, (4) employing the scoping process to distinguish the significant issues requiring consideration in the NEPA analysis, (5) setting deadlines for the NEPA process as appropriate for individual proposed actions, (6) initiating the NEPA analysis as early as possible to coincide with the agency's presentation of a proposal by another party, and (7) using accelerated procedures as described in the CEQ regulations for legislative proposals.

Implementation of Changes

Through this rule, the USMS is revising its guidance, establishing policy, and assigning responsibilities for implementing the requirements of Section 102(2) of NEPA (42 U.S.C. 4321, *et seq.*), Executive Order 11514 of March 5, 1970, titled ''Protection and Enhancement of Environmental Quality,'' and regulations of the CEQ (40 CFR parts 1500–1508).

This rule is intended to (1) Enhance the USMS' ability to comply with NEPA, related legal authorities, and Executive Orders, (2) allow non-significant program actions to be exempt from the requirement to prepare an EA or EIS, (3) focus NEPA analysis upon major Federal actions significantly affecting the quality of the environment, (4) ensure public involvement in decision-making regarding environmental impact on local communities, and (5) reflect changes in the current USMS organizational structure. Development of these revised regulations was orchestrated by USMS headquarters and district office personnel who represent the USMS' collective technical and managerial expertise in environmental quality and NEPA compliance. In addition to revising part 61 by adding Appendix E, the USMS will provide guidance materials to district offices.

These changes affect USMS internal procedures. The USMS consulted with the CEQ during the development of this rule.

Regulatory Certifications

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'' § 1 (b), Principles of Regulation. The Department of Justice has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, § 3(f), Regulatory Planning and Review; and, accordingly, this rule has not been reviewed by the Office of Management and Budget. This rule provides environmental benefits by ensuring the USMS compliance with NEPA to improve planning and avoid excess pollution and environmental degradation. Further, this rule affects

USMS internal procedures. Whatever costs that may result from this rule should be outweighed by the reduction in delay and excessive paperwork from the improved procedures.

Executive Order 13132

This regulation only affects the internal procedures of the USMS and, accordingly, will not have substantial direct effects on the States, relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Regulatory Flexibility Act

The Director of the USMS, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and approved it, certifying that it will not have a significant economic impact on a substantial number of small entities because this regulation only affects the internal procedures of the USMS.

Unfunded Mandates Reform Act of 1995

This rule will not result in an expenditure of $100,000,000 or more in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, nor will it significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more, a major increase in costs or prices, significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Environmental Impact

This rule supplements CEQ regulations and provides guidance to USMS employees regarding procedural requirements for NEPA analysis and documentation activities. In accordance with NEPA, the rule implements procedures that establish specific criteria, and identification, for three classes of actions: Those that require preparation of an environmental impact statement, those that require preparation of an environmental assessment, and those that are categorically excluded from further NEPA review (40 CFR 1507.3(b)). However, these procedures only provide internal guidance to assist USMS employees and do not serve to make the final determination of what level of NEPA analysis is required for any particular proposed action. The CEQ does not require agencies to prepare a NEPA analysis or document before establishing such procedures. *See Heartwood, Inc.* v. *U.S. Forest Service*, 73 F. Supp. 2d 962, 972–73 (S.D. Ill. 1999), *aff'd*, 230 F.3d 947, 954–55 (7th Cir. 2000) (holding that establishing categorical exclusions does not require NEPA analysis and documentation). The requirements for establishing agency NEPA procedures are set forth at 40 CFR 1505.1 and 1507.3. The USMS consulted with the CEQ during the development of these categorical exclusions and provided an opportunity for public review.

List of Subjects in 28 CFR Part 61

Environmental protection, Environmental impact statements.

■ Accordingly, for the reasons set forth in the preamble, part 61 of chapter I of Title 28 of the Code of Federal Regulations is amended to read as follows:

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

Authority: 28 U.S.C. 509; 5 U.S.C. 301; Executive Order 11911.

■ 2. Appendix E to part 61 is added to read as follows:

Appendix E to Part 61—United States Marshals Service Procedures Relating to the Implementation of the National Environmental Policy Act

1. Authority

These procedures are issued pursuant to the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321, *et seq.*, regulations of the Council on Environmental Quality (CEQ), 40 CFR part 1500, *et seq.*, regulations of the Department of Justice (DOJ), 28 CFR part 61, *et seq.*, the Environmental Quality Improvement Act of 1970, as amended, 42 U.S.C. 4371, *et seq.*, Section 309 of the Clean Air Act, as amended, 42 U.S.C. 7609, and Executive Order 11514, ''Protection and Enhancement of Environmental Quality,'' March 5, 1970, as amended by Executive Order 11991, May 24, 1977.

2. Purpose

These provisions supplement existing DOJ and CEQ regulations and outline internal USMS procedures to ensure compliance with NEPA. Through these provisions, the USMS shall promote the environment by minimizing the use of natural resources, and by improving planning and decision-making processes to avoid excess pollution and environmental degradation.

The USMS' Environmental Assessments (EAs) and Environmental Impact Statements (EISs) shall be as concise as possible and EISs should be limited to approximately 150 pages in normal circumstances or 300 pages for proposals of unusual scope or complexity. The USMS shall, whenever possible, jointly prepare documents with State and local governments and, when appropriate, avoid duplicative work by adopting, or incorporating by reference, existing USMS and other agencies' analyses and documentation.

In developing an EA or EIS, the USMS shall comply with CEQ regulations, observing that EAs and EISs should (1) Be analytic, rather than encyclopedic, (2) be written in plain language, (3) follow a clear, standard format in accordance with CEQ regulations, (4) follow a scoping process to distinguish the significant issues from the insignificant issues, (5) include a brief summary, (6) emphasize the more useful sections of the document, such as the discussions of alternatives and their environmental consequences, while minimizing the discussion of less useful background information, (7) scrutinize existing NEPA documentation for relevant analyses of programs, policies, or other proposals that guide future action to eliminate repetition, (8) where appropriate, incorporate material by reference, with citations and brief descriptions, to avoid excessive length, and (9) integrate NEPA requirements with other environmental review and consultation requirements mandated by law, Executive Order, Department of Justice policy, or USMS policy. When preparing an EA or EIS, the USMS shall request comments to be as specific as possible.

To ensure compliance with NEPA, the USMS shall make efforts to prevent and reduce delay. The USMS will follow the procedures outlined in the CEQ regulations including, (1) Integrating the NEPA process in the early stages of planning to ensure that decisions reflect environmental values, and to head off potential conflicts and/or delays, (2) emphasizing inter-agency cooperation before the environmental analysis and documentation is prepared, (3) ensuring the swift and fair resolution of any dispute over the designation of the lead agency, (4) employing the scoping process to distinguish the significant issues requiring consideration in the NEPA analysis, (5) setting deadlines for the NEPA process as appropriate for individual proposed actions, (6) initiating the NEPA analysis as early as possible to coincide with the agency's consideration of a proposal by another party, and (7) using accelerated procedures, as described in the CEQ regulations, for legislative proposals.

3. Agency Description

The USMS is a Federal law enforcement agency. The agency performs numerous law enforcement activities, including judicial security, warrant investigations, witness protection, custody of individuals arrested by Federal agencies, prisoner transportation, management of seized assets, and other law enforcement missions.

4. Typical Classes of USMS Actions

(a) The general types of proposed actions and projects that the USMS undertakes are as follows:

(1) Operational concepts and programs, including logistics procurement, personnel assignment, real property and facility management, and environmental programs,

(2) Transfers or disposal of equipment or property,

(3) Leases or entitlement for use, including donation or exchange,

(4) Federal contracts, actions, or agreements for detentions services. A detention facility may be a facility (A) owned and/or operated by a contractor, or (B) owned and/or operated by a State or local government, and

(5) General law enforcement activities that are exempt from NEPA analysis under CEQ regulation 40 CFR 1508.18 that involve bringing judicial, administrative, civil, or criminal enforcement actions.

(b) Scope of Analysis.

(1) Some USMS projects, contracts, and agreements may propose a USMS action that is one component of a larger project involving a private action or an action by a local or State government. The USMS' NEPA analysis and document (*e.g.*, the EA or EIS) should address the impact of the specific USMS activity and those portions of the entire project over which the USMS has sufficient control and responsibility to warrant Federal review.

(2) The USMS has control and responsibility for portions of a project beyond the limits of USMS jurisdiction where the environmental consequences of the larger project are essentially products of USMS specific action. This control turns an otherwise non-federal project into a Federal action.

(3) Sufficient control and responsibility for a facility is a site-specific determination based on the extent to which an entire project will be within the agency's jurisdiction and on other factors that determine the extent of Federal control and responsibility. For example, for construction of a facility, other factors would include, but not be limited to, the length of the contract for construction or use of the facility, the extent of government control and funding in the construction or use of the facility, whether the facility is being built solely for Federal requirements, the extent to which the costs of construction or use will be paid with Federal funds, the extent to which the facility will be used for non-Federal purposes, and whether the project should proceed without USMS action.

(4) Some USMS projects, contracts, and agreements may propose a USMS action that is one component of a larger project involving actions by other Federal agencies. Federal control and responsibility determines whether the total Federal involvement of the USMS and other Federal agencies is sufficient to grant legal control over additional portions of the project. NEPA review would be extended to an entire project when the environmental consequences of the additional portions of the project are essentially products of Federal financing, assistance, direction, regulation, or approval. The USMS shall contact the other Federal agencies involved in the action to determine their respective roles (*i.e.*, whether to be a lead or cooperating agency).

(5) Once the scope of analysis has been defined, the NEPA analysis for an action should include direct, indirect, and cumulative impacts of all Federal proposals within the purview of NEPA. Whenever practicable, the USMS can incorporate by reference, and rely upon, the environmental analyses and reviews of other Federal, tribal, State, and local agencies.

5. Environmental Impact Statement (EIS)

(a) An EIS is a document required of Federal agencies for proposals significantly affecting the quality of the human environment. EIS describes the positive and negative effects of the proposed action and any reasonable alternatives. A Notice of Intent (NOI) will be published in the **Federal Register** as soon a practicable after a decision to prepare an EIS is made and before the scoping process is initiated. An EIS shall describe how alternatives considered in it, and the decisions based on it, will or will not achieve the goals of NEPA to prevent damage to the environment and promote human health. Additionally, an EIS shall describe how the USMS will comply with relevant environmental laws and policies. The format and content of an EIS are set out at 40 CFR part 1502. The USMS may prepare an EIS without prior preparation of an EA.

(b) A Record of Decision (ROD) will be prepared at the time a decision is made regarding a proposal that is analyzed and documented in an EIS. The ROD will state the decision, discuss the alternatives considered, and state whether all alternative practicable means to avoid or minimize environmental harms have been adopted, or if not, why they were not adopted. Where applicable, the ROD will also describe and adopt a monitoring and enforcement program for any mitigation.

(c) Actions that normally require preparing an EIS include:

(1) USMS actions that are likely to have a significant environmental impact on the human environment, or

(2) Construction of a major facility on a previously undisturbed site.

6. Environmental Assessment (EA)

(a) An EA is a concise public document that is prepared for actions that do not normally require preparation of an EIS, but do not meet the requirements of a Categorical Exclusion (CE). An EA serves to briefly provide sufficient evidence and analysis for determining whether to prepare an EIS or a Finding of No Significant Impact (FONSI), aid in complying with NEPA when an EIS is not necessary, and facilitate preparation of an EIS when one is required. The EA results in either a determination that a proposed action may have a significant impact on the human environment, and therefore, requires further study in an EIS, or the issuance of a FONSI. The contents of an EA are described at 40 CFR 1508.9.

(b) A FONSI will include the EA or a summary of the EA. The FONSI will be prepared and made available to the public through means described in paragraph 9 of this Appendix, including publication in local newspapers and in the **Federal Register** for matters of national concern. The FONSI will be available for review and comment for 30 days prior to signature and the initiation of the action, unless special circumstances warrant reducing the public comment period to 15 days. Implementing the action can proceed after consideration of public comments and the decision-maker signs the FONSI.

(c) Actions that normally require preparation of an EA include:

(1) Proposals to conduct an expansion of an existing facility,

(2) Awarding a contract or entering into an agreement for new construction at a previously developed site, or an expansion of an existing facility, or

(3) Projects or other proposed actions that are activities described in categorical exclusions, but do not qualify for a categorical exclusion because they involve extraordinary circumstances.

7. Categorical Exclusions (CE)

(a) CEs are certain categories of activities determined not to have individual or cumulative significant effects on the human environment, and absent extraordinary circumstances, are excluded from preparation of an EA, or EIS, under NEPA. Using CEs for such activities reduces unnecessary paperwork and delay. Such activities are not excluded from compliance with other applicable local, State, or Federal environmental laws.

(b) Extraordinary circumstances must be considered before relying upon a CE to determine whether the proposed action may have a significant environmental effect. Any of the following circumstances preclude the use of a CE:

(1) The project may have effects on the quality of the environment that are likely to be highly controversial;

(2) The scope or size of the project is greater than normally experienced for a particular action described in subsection (c) below;

(3) There is potential for degradation, even if slight, of already-existing poor environmental conditions;

(4) A degrading influence, activity, or effect is initiated in an area not already significantly modified from its natural condition;

(5) There is a potential for adverse effects on areas of critical environmental concern or other protected resources including, but not limited to, threatened or endangered species or their habitats, significant archaeological materials, prime or unique agricultural lands, wetlands, coastal zones, sole source aquifers, 100-year-old flood plains, places listed,

proposed, or eligible for listing on the National Register of Historic Places, natural landmarks listed, proposed, or eligible for listing on the National Registry of Natural Landmarks, Wilderness Areas or wilderness study areas, or Wild and Scenic River areas; or

(6) Possible significant direct, indirect, or cumulative environmental impacts exist.

(c) Actions that normally qualify for a CE include:

(1) Minor renovations or repairs within an existing facility, unless the project would adversely affect a structure listed in the National Register of Historic Places or is eligible for listing in the register,

(2) Facility expansion, or construction of a limited addition to an existing structure, or facility, and new construction or reconstruction of a small facility on a previously developed site. The exclusion applies only if:

(i) The structure and proposed use comply with local planning and zoning and any applicable State or Federal requirements; and

(ii) The site and the scale of construction are consistent with those of existing adjacent or nearby buildings.

(3) Security upgrades of existing facility grounds and perimeter fences, not including such upgrades as adding lethal fences or major increases in height or lighting of a perimeter fence in a residential area or other area sensitive to the visual impacts resulting from height or lighting changes,

(4) Federal contracts or agreements for detentions services, including actions such as procuring guards for detention services or leasing bed space (which may include operational costs) from an existing facility operated by a State or a local government or a private correctional corporation,

(5) General administrative activities that involve a limited commitment of resources, such as personnel actions or policy related to personnel issues, organizational changes, procurement of office supplies and systems, and commitment or reallocation of funds for previously reviewed and approved programs or activities,

(6) Change in contractor or Federal operators at an existing contractor-operated correctional or detention facility,

(7) Transferring, leasing, maintaining, acquiring, or disposing of interests in land where there is no change in the current scope and intensity of land use, including management and disposal of seized assets pursuant to Federal laws,

(8) Transferring, leasing, maintaining, acquiring, or disposing of equipment, personal property, or vessels that do not increase the current scope and intensity of USMS activities, including management and disposal of seized assets pursuant to Federal forfeiture laws,

(9) Routine procurement of goods and services to support operations and infrastructure that are conducted in accordance with Department of Justice energy efficiency policies and applicable Executive Orders, such as E.O. 13148,

(10) Routine transportation of prisoners or detainees between facilities and flying activities in compliance with Federal Aviation Administration Regulations, only applicable where the activity is in accordance with normal flight patterns and elevations for the facility and where the flight patterns/elevations have been addressed in an installation master plan or other planning document that has been the subject of a NEPA review, and

(11) Lease extensions, renewals, or succeeding leases where there is no change in the intensity of the facility's use.

8. Responsibilities

(a) The Director of the USMS, in conjunction with the Senior Environmental Advisor, possesses authority over the USMS NEPA compliance.

(b) The Senior Environmental Advisor's duties include:

(1) Advising the Director or other USMS decisionmakers on USMS NEPA procedures and compliance,

(2) Supervising the Environmental Coordinator,

(3) Acting as NEPA liaison to CEQ for the Director and other USMS decisionmakers on important decisions outside the authority of the Environmental Coordinator,

(4) Consulting with CEQ regarding alternative NEPA procedures requiring the preparation of an EIS in emergency situations, and

(5) Consulting with CEQ and officials of other Federal agencies to settle agency disputes over the NEPA process, including designating lead and cooperating agencies.

(c) The USMS Environmental Coordinator will act as the agency's NEPA contact, and will be responsible for:

(1) Ensuring that adequate EAs and EISs are prepared at the earliest possible time, ensuring that decisions are made in accordance with the general policies and purposes of NEPA, verifying information provided by applicants, evaluating environmental effects; assuring that, when appropriate, EAs and EISs contain documentation from independent parties with expertise in particular environmental matters, taking responsibility for the scope and content of EAs prepared by applicants, and returning EAs and EISs that are found to be inadequate,

(2) Ensuring that the USMS conducts an independent evaluation, and where appropriate, prepares a FONSI, a NOI, and/or a ROD,

(3) Coordinating the efforts for preparation of an EIS consistent with the requirements of the CEQ regulations at 40 CFR part 1500–1508,

(4) Cooperating and coordinating planning efforts with other Federal agencies, and

(5) Providing for agency training on environmental matters.

(d) The agency shall ensure compliance with NEPA for cases where actions are planned by private applicants or other non-Federal entities before Federal involvement. The USMS, through the Environmental Coordinator shall:

(1) Identify types of actions initiated by private parties, State and local agencies and other non-Federal entities for which agency involvement is reasonably foreseeable,

(2) Provide (A) full public notice that agency advice on such matters is available, (B) detailed written publications containing that advice, and (C) early consultation in cases where agency involvement is reasonably foreseeable, and

(3) Consult early with appropriate Indian tribes, State and local agencies, and interested private persons and organizations on those projects in which the USMS involvement is reasonably foreseeable.

(e) To assist in ensuring that all Federal agencies' decisions are made in accordance with the general policies and purposes of NEPA, the USMS, through the Environmental Coordinator shall:

(1) Comment within the specified time period on other Federal agencies' EISs, where the USMS has jurisdiction by law regarding a project, and make such comments as specific as possible with regard to adequacy of the document, the merits of the alternatives, or both,

(2) Where the USMS is the lead agency on a project, coordinate with other Federal agencies and supervise the development of and retain responsibility for the EIS,

(3) Where the USMS is a cooperating agency on a project, cooperate with any other Federal agency acting as lead agency through information sharing and staff support,

(4) Independently evaluate, provide guidance on, and take responsibility for scope and contents of NEPA analyses performed by contractors or applicants used by USMS. When the USMS is the lead agency, USMS will choose the contractor to prepare an EIS, require the contractor to execute a disclosure statement stating that the contractor has no financial or other interest in the outcome of the project, and participate in the preparation of the EIS by providing guidance and an independent evaluation prior to approval,

(5) Consider alternatives to a proposed action where it involves unresolved conflicts concerning available resources. The USMS shall make available to the public, prior to a final decision, any NEPA documents and additional decision documents, or parts thereof, addressing alternatives,

(6) Conduct appropriate NEPA procedures for the proposed action as early as possible for consideration by the appropriate decision-maker, and ensure that all relevant environmental documents, comments, and responses accompany the proposal through the agency review process for the final decision,

(7) Include, as part of the administrative record, relevant environmental documents, comments, and responses in formal rulemaking or adjudicatory proceedings, and

(8) Where emergency circumstances require taking action that will result in a significant environmental impact, contact CEQ via the USMS Senior Environmental Advisor for consultation on alternative arrangements, which will be limited to those necessary to control the immediate impacts of the emergency.

9. Public Involvement

(a) In accordance with NEPA and CEQ regulations and to ensure public involvement in decision-making regarding environmental impact on local communities, the USMS shall also engage in the following procedures during its NEPA process:

(1) When preparing an EA, EIS, or FONSI, USMS personnel in charge of preparing the document will invite comment from affected Federal, tribal, State, local agencies, and other interested persons, as early as the scoping process;

(2) The USMS will disseminate information to potentially interested or affected parties, such as local communities and Indian tribes, through such means as news releases to various local media, announcements to local citizens groups, public hearings, and posted signs near the affected area;

(3) The USMS will mail notice to those individuals or groups who have requested one on a specific action or similar actions;

(4) For matters of national concern, the USMS will publish notification in the **Federal Register**, and will send notification by mail to national organizations reasonably expected to be interested;

(5) If a decision is made to develop an EIS, the USMS will publish a NOI in the **Federal Register** as soon as possible;

(6) The personnel in charge of preparing the NEPA analysis and documentation will invite public comment and maintain two-way communication channels throughout the NEPA process, provide explanations of where interested parties can obtain information on status reports of the NEPA process and other relevant documents, and keep all public affairs officers informed;

(7) The USMS will establish a Web site to keep the public informed; and

(8) During the NEPA process, responsible personnel will consult with local government and tribal officials, leaders of citizen groups, and members of identifiable population segments within the potentially affected environment, such as farmers and ranchers, homeowners, small business owners, minority and disadvantaged communities, and tribal members.

10. Scoping

Prior to starting the NEPA analysis, USMS personnel responsible for preparing either an EA or EIS, shall engage in an early scoping process to identify the significant issues to be examined in depth, and to identify and eliminate from detailed study those issues which are not significant or which have been adequately addressed by prior environmental review. The scoping process should identify any other environmental analyses being conducted relevant to the proposed action, address timing and set time limits with respect to the NEPA process, set page limits, designate respective responsibilities among the lead and cooperating agencies, identify any other environmental review and consultation requirements to allow for integration with the NEPA analysis, and hold an early scoping meeting that may be integrated with other initial planning meetings.

11. Mitigation and Monitoring

USMS personnel, who are responsible for preparing NEPA analyses and documents, will consider mitigation measures to avoid or minimize environmental harm. EAs and EISs will consider reasonable mitigation measures relevant to the proposed action and alternatives. Paragraph 5(b) of this Appendix describes the requirements for documenting mitigation measures in a ROD.

12. Supplementing an EA or EIS

When substantial changes are made to a proposed action that is relevant to environmental concerns, a supplement will be prepared for an EA or a draft or a final EIS. A supplement will also be prepared when significant new circumstances arise or new relevant information surfaces concerning and bearing upon the proposed action or its impacts. Any necessary supplement shall be processed in the same way as an original EA or EIS, with the exception that new scoping is not required. Any supplement shall be added to the formal administrative record, if such record exists.

13. Compliance With Other Environmental Statutes

To the extent practicable, a NEPA document shall include information necessary to assure compliance with all applicable environmental statutes.

Dated: November 8, 2006.

John F. Clark,

Director, United States Marshals Service.

[FR Doc. E6–20940 Filed 12–7–06; 8:45 am]

BILLING CODE 4410–04–P

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Parts 626 and 627

The Biological Defense Safety Program and Technical Safety Requirements

AGENCY: Department of the Army, DOD.

ACTION: Final rule; removals.

SUMMARY: The Department of the Army is removing its regulations concerning the biological Defense Safety Program and its requirements because it is now superseded through consolidation with other Army safety regulations into Army Regulation (AR) 385–10, Army Safety Program and does not affect the general public.

EFFECTIVE DATE: December 8, 2006.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth W. Proper, (703) 601–2408.

SUPPLEMENTARY INFORMATION: The Office of the Director of Army Safety (DACS–SF), is the proponent for the regulation represented by 32 CFR Part 626 and the DA PAM represented by 32 CFR 627. The Office of the Director of Army Safety has consolidated the Army regulation, represented by 32 CFR Part 626 into AR 385–10, Army Safety Program. This regulation was extensively revised during the consolidation process, and the new consolidated regulation does not affect the general public.

The Office of the Director of Army Safety has extensively revised the DA PAM, represented by 32 CFR 627 to reflect the consolidation effect and to update it to address new biological safety techniques and requirements and determined that the revised DA PAM does not affect the general public.

List of Subjects in 32 CFR Parts 626 and 627

Biologics, Government contracts, Hazardous substances, National defense, Occupational safety and health, Research.

PART 626 AND 627—[REMOVED]

■ Accordingly, for reasons stated in the preamble, under the authority of 5 U.S.C. 102, 10 U.S.C. 21, 111, 151–158, 42 U.S.C. 216; sec. 361, 50 U.S.C. 1431, Pub. L. 101–510, 104 Stat. 1516, 58 Stat. 703 and 264; 49 U.S.C. App 1803, 1804, 1807, and 1808, 29 CFR 1910. 1450(e), 32 CFR Part 626, Biological Defense Safety Program and 32 CFR Part 627, The Biological Defense Safety Program, Technical Safety Requirements (DA Pamphlet 385–69), are removed in their entirety.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 06–9598 Filed 12–7–06; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 656

Installations, Use of Off-Road Vehicles on Army Land

AGENCY: Department of the Army, DOD.

ACTION: Final rule; removal.

SUMMARY: The Department of the Army is resending AR 385–55, Prevention of Motor Vehicle Accidents, and has consolidated its requirements into AR 385–10, Army Safety Program. During consolidation, the section concerning the use of non-tactical off-road vehicles on Army land was removed.

EFFECTIVE DATE: December 8, 2006.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth W. Proper, (703) 601–2408.

SUPPLEMENTARY INFORMATION: The Office of the Director of Army Safety (DACS–SF), is the proponent for the regulation represented by 32 CFR Part 656. The Office of the Director of Army Safety has consolidated the Army regulation, represented by 32 CFR Part 656 into AR 385–10, Army Safety Program. This regulation was extensively revised

during the consolidation process, and the new consolidated regulation does not affect the general public. Similar requirements concerning the use of off-road vehicles on Army land are now provided by 32 CFR 650, Environmental Protection and Enhancement (AR 200–1) and 32 CFR 651, Environmental Analysis Of Army Actions (AR 200–2) which when taken into combination provided greater and wider protection on installation than did 32 CFR Part 656 or AR 385–55.

List of Subjects in 32 CFR Part 656

Environmental protection, Federal buildings and facilities, Traffic regulations.

PART 656—[REMOVED]

■ Accordingly, for reasons stated in the preamble, under the authority 10 U.S.C. 3012, 32 CFR Part 656, Installations, Use of Off-Road Vehicles on Army Land, is removed in its entirety.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 06–9599 Filed 12–8–06; 8:45 am]

BILLING CODE 3710–08–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0654; FRL–8093–4]

Cyproconazole; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of cyproconazole ((2RS,3RS)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H -1,2,4- triazole-1-yl)butan-2-ol) in or on soybean seed. This action is associated with EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on soybeans. This regulation establishes a maximum permissible level for residues of cyproconazole in this food commodity. The tolerance will expire and be revoked on December 31, 2009.

DATES: This regulation is effective December 8, 2006. Objections and requests for hearings must be received on or before February 6, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0654. All documents in the docket are listed on the regulations.gov website. 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, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive Arlington, VA 22202–3553. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Carmen Rodia, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; fax: (703) 308–8041; e-mail address: *rodia.carmen@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0654 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 6, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2006–0654, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP), Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive, Arlington, VA 22202–3553. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should

be made for deliveries of boxed information. The Docket telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and 346a(l)(6), is establishing a tolerance for residues of the fungicide cyproconazole, in or on soybean seed at 0.10 parts per million (ppm). This tolerance will expire and be revoked on December 31, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR).

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of the section 408 safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Cyproconazole on Soybeans and FFDCA Tolerances

Australasian soybean rust (SBR) is a plant disease caused by two fungal species, *Phakopsora pachyrhizi* and *P. meibomiae*, and is spread primarily by windborne spores that can be transported over long distances. SBR models suggest that most of the soybean acreage in the U.S. could be compromised by an SBR epidemic. In accordance with the 2002 Agricultural Bioterrorism Protection Act, SBR was identified by USDA as a select biological agent with the potential to pose a severe threat to the soybean industry and livestock production, in general. As such, USDA has invested in extensive readiness and outreach activities among soybean producers. The states of Minnesota and South Dakota petitioned EPA to allow under FIFRA section 18, the use of cyproconazole on soybeans for control of Australasian soybean rust in Minnesota and South Dakota. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of cyproconazole in or on soybeans. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance expires and is revoked on December 31, 2009, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on soybean seed after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether cyproconazole meets EPA's registration requirements for use on soybeans or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of cyproconazole by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for growers in any State other than those in which State lead agencies have obtained an exemption to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for cyproconazole, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of cyproconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for residues of cyproconazole in or on soybean seed at 0.10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent

in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10x to account for interspecies differences and 10x for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10x to account for interspecies differences and 10x for intraspecies differences), the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x 10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for cyproconazole used for human risk assessment is shown in the following Table:

SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYPROCONAZOLE FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (U.S. general population including infants and children)	Not applicable	None	An endpoint of concern (effect) attributable to a single exposure (dose) for the U.S. General Population was not identified in the oral toxicity studies reviewed.
Acute Dietary (Females 13-49 years of age)	LOAEL = 2.0 mg/kg/day UF = 300 Acute RfD = 2.0 mg/kg/day/300 = 0.01 mg/kg/day	FQPA SF = 1x aPAD = acute RfD ÷ FQPA SF = 0.01 mg/kg/day	Developmental toxicity - Chinchilla rabbits; LOAEL = 2.0 mg/kg/day based on hydrocephalus internus observed in one fetus at each treatment level.
Chronic Dietary (All populations)	NOAEL = 1.0 mg/kg/day UF = 100 Chronic RfD = 1.0 mg/kg/day/100 = 0.01 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD÷FQPA SF = 0.01 mg/kg/day	Chronic oral toxicity - dog; LOAEL = 3.2 mg/kg/day based on liver effects (P450 induction in females and histopathology, laminar eosinophilic intrahepatocytic bodies in males).
Short-Term Incidental Oral (1 to 30 days) Intermediate-Term Incidental Oral (1 to 6 months)	NOAEL = 1.5 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	90–day oral toxicity - rat; LOAEL = 27.3 mg/kg/day based on decreased body weight gain in males and increased liver weight in females.
Short-Term Dermal (1 to 30 days) Intermediate-Term Dermal (1 to 6 months)	NOAEL = 2.0 mg/kg/day (dermal absorption rate = 11%)	Residential LOC for MOE = 300 Occupational LOC for MOE = 300	Developmental toxicity - Chinchilla rabbits; LOAEL = 2.0 mg/kg/day based on hydrocephalus internus observed in one fetus at each treatment level.
Long-Term Dermal (>6 months)	NOAEL = 1.0 mg/kg/day (dermal absorption rate = 11%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Chronic oral toxicity - dog; LOAEL = 3.2 mg/kg/day based on liver effects (P450 induction in females and histopathology, laminar eosinophilic intrahepatocytic bodies in males).
Short-Term Inhalation (1 to 30 days) Intermediate-Term Inhalation (1 to 6 months)	NOAEL = 2.0 mg/kg/day (inhalation-absorption rate = 100% oral equivalent)	Residential LOC for MOE = 300 Occupational LOC for MOE = 300	Developmental toxicity - Chinchilla rabbits; LOAEL = 2.0 mg/kg/day based on hydrocephalus internus observed in one fetus at each treatment level.
Long-Term Inhalation (>6 months)	NOAEL = 1.0 mg/kg/day (inhalation-absorption rate = 100% oral equivalent)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Chronic oral toxicity - dog; LOAEL = 3.2 mg/kg/day based on liver effects (P450 induction in females and histopathology, laminar eosinophilic intrahepatocytic bodies in males).
Cancer (oral, dermal, inhalation)	Cyproconazole has been classified as a Group B2, probable human carcinogen; Q1* is 1.58 x 10^{-1} $(mg/kg/day)^{-1}$ in human equivalents, based on male mouse liver adenoma and/or carcinoma combined tumor rates.		

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

UF = uncertainty factor; FQPA SF = Special FQPA safety factor; NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level; PAD = population adjusted dose (a = acute, c = chronic); RfD = reference dose; MOE = margin of exposure; and LOC = level of concern.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* A tolerance has been established (40 CFR 180.485) for residues of cyproconazole in or on the imported agricultural commodity coffee, bean, green. There are no U.S. registrations for cyproconazole on raw agricultural commodities at this time. Risk assessments were conducted by EPA to assess dietary exposures from cyproconazole in food as follows:

i. *Acute exposure*. Acute dietary risk assessments are performed for a food use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The acute dietary exposure analysis for cyproconazole is based on Tier 1 assumptions of tolerance-level residues and 100% crop treated (CT).

ii. *Chronic exposure*. In conducting the chronic dietary risk assessment, the DEEM-FCID™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The chronic dietary exposure analysis for cyproconazole is refined in that it incorporates estimates of anticipated residues (AR) for all commodities, 10% CT for soybeans and empirical processing factors (a Tier 3 analysis).

iii. *Cancer*. The Q1* for cyproconazole is 1.58×10^{-1} milligrams/kilograms/day (mg/kg/day) in human equivalents, based on liver tumor data in male mice. The 10% CT (i.e., 7.4 million acres) resulted in an acceptable calculated dietary cancer risk of 1.1×10^{-6}, which is equivalent to the Agency's LOC (generally 1×10^{-6}).

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must, pursuant to section 408(f)(1), require that data be provided 5 years after the tolerance is established, modified or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such Data Call-Ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such Data Call-Ins will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information for cyproconazole as follows: As stated in Unit IV.B.1. acute and chronic dietary exposure and risk analyses were conducted to determine the exposure and risk estimates resulting from the use of cyproconazole in soybeans to control Australasian soybean rust. The acute analysis is based on Tier 1 assumptions of tolerance-level residues and 100% CT. The chronic analysis is refined in that it incorporates estimates of AR for all commodities, 10% CT for soybeans and empirical processing factors (a Tier 3 analysis).

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA finds that the PCT information described in Unit IV.B.1. and in the preceding paragraph for cyproconazole used on soybeans is reliable and has a valid basis. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which cyproconazole may be applied in a particular area.

2.—i. *Dietary exposure from drinking water*. The Agency used the Pesticide Root Zone Model and Exposure Analysis Modeling System (PRZM/EXAMS) to calculate estimated drinking water concentrations (EDWCs) for the use of cyproconazole in soybeans, using the standard Mississippi soybean scenario. Thus, the estimated exposure concentrations for water are based on the proposed highest use rate. The Agency used the Generic Expected Environmental Concentration model to calculate estimated environmental concentrations (EECs) for the use of cyproconazole in turf. Ground water concentrations were estimated with the Screening Concentration in Groundwater (SCI-GROW) model.

ii. *Ground water and surface water EDWCs*. A Tier 2 drinking water assessment was conducted for the proposed use of cyproconazole in soybeans using the proposed maximum application rate of 0.026 lbs. a.i./acre with 2 applications per year and a 7–day Retreatment interval (RTI). The Preharvest interval (PHI) will be 30 days. The linked PRZM and EXAMS models predicted a peak EDWC of 0.79 parts per billion (ppb) for aerial applications. The PRZM/EXAMS model predicted chronic EDWCs of 0.21 ppb (1-in-10 Year Annual Average) for aerial applications and 0.12 ppb (30–year Annual Average) for ground applications. The SCI-GROW model estimated the concentration of cyproconazole in shallow ground water sources to be 0.027 ppb.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Cyproconazole is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Cyproconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events (EPA, 2002). In conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects form substances found to have a common mechanism of toxicity see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

Cyproconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazole alanine and triazole acetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including cyproconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazole alanine and triazole acetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with the common metabolites (e.g., use of maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e, high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10x FQPA safety factor for the protection of infants and children. The assessment includes evaluations of risks for various population subgroups, including those comprised of infants and children.

The Agency's complete risk assessment is found in the propiconazole reregistration docket at *http://www.regulations.gov*, Docket ID number EPA–HQ–OPP–2005–0497–0013.

C. Safety Factor for Infants and Children

1. *In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and/or postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Developmental toxicity studies*. There is no evidence of increased susceptibility in either the developmental study in rats or in the 2–generation reproduction study in rats. The concern is low for the increased susceptibility in the New Zealand rabbit study since clear NOAELs/LOAELs were established for maternal and developmental toxicities. Similarly, the concern is low for the increased susceptibility in the Chinchilla rabbit study since the incidences of hydrocephaly were low, there was no dose response, the hydrocephaly was not seen at the same doses in the New Zealand White strain of rabbit and this endpoint of concern is used with a 3x FQPA safety factor for risk assessment.

A 3x safety factor (as opposed to a 10x) for the lack of a NOAEL in this critical study is adequate because the magnitude of the response was low (low incidences without dose response) and the effect of concern was seen in an unusual strain (Chinchilla) of rabbits and not in the New Zealand strain commonly used in developmental toxicity studies. The Agency evaluated the quality of the hazard and exposure data for cyproconazole and determined that the FQPA safety factor can be reduced to 1x. Therefore, there is no residual uncertainty for prenatal and/or postnatal exposure to cyproconazole.

3. *Reproductive toxicity study*. There was no evidence of reproductive toxicity in the 2–generation reproduction study in rats. In this study, cyproconazole was administered to rats at dose levels of 0, 0.4, 1.7 and 10.6 mg/kg/day. The parental systemic NOAEL is 1.7 mg/kg/day and LOAEL of 10.6 mg/kg/day, based on liver effects. The reproductive toxicity NOAEL is 10.6 mg/kg/day. Although gestation length was slightly increased and litter size decreased, these changes were not considered to be treatment-related.

4. *Prenatal and postnatal sensitivity*. Please refer to the explanation provided above in Unit IV.C.2. for a detailed discussion regarding ''prenatal and/or postnatal sensitivity.''

5. *Conclusion*. The Agency evaluated the quality of the hazard and exposure data and determined that, based on the hazard and exposure data, the special FQPA SF is reduced to 1x. In terms of hazard, there are low concerns and no residual uncertainties with regard to prenatal and/or postnatal toxicity.

D. Aggregate Risks and Determination of Safety

EPA conducted human health risk assessments for acute, chronic and cancer dietary exposures (food + drinking water only) for existing and proposed uses. Because there are no uses of cyproconazole that are expected to result in residential exposures, this aggregate risk assessment takes into consideration dietary food + drinking water exposure only; therefore, the acute and chronic aggregate estimates would be the same as the dietary exposure results.

1. *Acute risk*. Using the exposure assumptions discussed in this unit, the acute dietary exposure from food to cyproconazole will occupy 1.3% of the aPAD for females 13-49 years old. Given existing and proposed uses, the Agency has no risk concern for exposure to cyproconazole through food and/or drinking water. EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cyproconazole from

food will utilize 1% of the cPAD for all infants less than a year old. There are no residential uses for cyproconazole that will result in chronic residential exposure to cyproconazole. Given existing and proposed uses, the Agency has no risk concern for exposure to cyproconazole through food and/or drinking water. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and drinking water (considered to be a background exposure level). Cyproconazole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and drinking water, which were previously addressed.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and drinking water (considered to be a background exposure level). Cyproconazole is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and drinking water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population*. When relying on the exposure assumptions described in this notice, EPA calculated an acceptable cancer risk of 1.1 x 10^{-6}, which is equivalent to the Agency's LOC (generally 1.0 x 10^{-6}).

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. general population and to infants and children from aggregate exposure to cyproconazole residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

No CODEX, Canadian or Mexican MRLs or tolerances have been established for cyproconazole on soybeans. Therefore, international harmonization is not an issue at this time.

C. Conditions

EPA has concluded that the toxicological, residue chemistry, dietary exposure and occupational/residential exposure assessments are adequate to support a time-limited tolerance of 0.10 ppm for residues of cyproconazole per se in/on soybean, seed.

VI. Conclusion

Therefore, the tolerance is established for residues of cyproconazole per se, in or on soybean, seed at 0.10 ppm.

VII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under section 408 of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on 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, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, 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 in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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

List of Subjects 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 24, 2006.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—AMENDED

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.485 is amended by adding text and table to paragraph (b) to read as follows:

§ 180.485 Cyproconazole; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the fungicide cyproconazole per se ((2RS,3RS)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H -1,2,4- triazole-1-yl)butan-2-ol) in or on soybean seed in connection with the use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance will expire and be revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Soybean, seed	0.10	12/31/09

[FR Doc. E6–20897 Filed 12–7–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[EPA–HQ–OPPT–2005–0033; FRL–8103–2]

RIN 2070–AD16

Revocation of TSCA Section 4 Testing Requirements for Coke-Oven Light Oil (Coal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is amending the test rule entitled Testing of Certain High Production Volume Chemicals promulgated under section 4 of the Toxic Substances Control Act (TSCA). This amendment removes coke-oven light oil (coal) (CAS No. 65996–78–3) from the list of chemicals subject to the test rule. EPA is basing its decision on information it received after publication of the test rule. Also, upon the effective date of the revocation of the TSCA section 4 testing requirements for coke–oven light oil (coal), persons who export or intend to export coke–oven light oil (coal) are no longer subject to the TSCA section 12(b) export notification requirements to the extent that they were triggered by the testing requirements being revoked by this action.

DATES: This direct final rule is effective on February 6, 2007 without further notice, unless EPA receives adverse comment in writing, or a request to present comments orally, by January 8, 2007.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2005–0033, by one of the following methods:

Federal eRulemaking Portal: *http://www.regulation.gov*. Follow the on-line instructions for submitting comments.

Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

Hand Delivery: OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA–HQ–OPPT–2005–0033. The DCO is open from 8:00 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2005–0033. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website 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 regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/docket.htm*.

Docket: All documents in the docket are listed in the regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available electronically at *http://www.regulations.gov*, or, if only available in hard copy, at the OPPT Docket, EPA Docket Center (EPA/DC). The EPA/DC suffered structural damage due to flooding in June 2006. Although the EPA/DC is continuing operations, there will be temporary changes to the EPA/DC during the clean-up. The EPA/DC Public Reading Room, which was temporarily closed due to flooding, has been relocated in the EPA Headquarters Library, Infoterra Room (Room Number 3334) in EPA West, located at 1301 Constitution Ave., NW., Washington,

DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal 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. EPA visitors are required to show photographic identification and sign the EPA visitor log. Visitors to the EPA/DC Public Reading Room will be provided with an EPA/DC badge that must be visible at all times while in the EPA Building and returned to the guard upon departure. In addition, security personnel will escort visitors to and from the new EPA/DC Public Reading Room location. Up-to-date information about the EPA/DC is on the EPA website at *http://www.epa.gov/epahome/dockets.htm*.

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: Catherine Roman, Chemical Control Division (CCD) (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–4780; e-mail address: *roman.catherine@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of particular interest to those persons who manufacture (defined by statute to include import) or process coke-oven light oil (coal). Also, persons that export or intend to export coke-oven light oil (coal) may have an interest in this action. Upon the effective date of the revocation of the TSCA section 4 testing requirements for coke-oven light oil (coal), persons who export or intend to export coke-oven light oil (coal) are no longer subject to the TSCA section 12(b) export notification requirements to the extent that they were triggered by the testing requirements being revoked by this action. Because other persons may also be interested, the Agency has not attempted to describe all the specific persons that may be affected by this action. If you have any questions regarding the applicability of this action to a particular person, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

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

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

2. *Requesting an opportunity to present oral comments to the Agency.* When you submit a request for an opportunity to present oral comments, this request must be in writing. If a written request is received on or before January 8, 2007, EPA will hold a public meeting on this direct final rule in Washington, DC. Submit this written request to the Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. If a written request is received, EPA will announce the scheduling of the public meeting in a subsequent **Federal Register** document. If a public meeting is announced, and if you are interested in attending or presenting oral and/or written comments and data at the public meeting, you should follow the instructions provided in the subsequent **Federal Register** document announcing the public meeting.

3. *Tips for preparing your comments.* When submitting comments, remember to:

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

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

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

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

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

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

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

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

II. Background

A. What Action is the Agency Taking?

Pursuant to TSCA section 4, EPA published a test rule on March 16, 2006 (Ref. 1) (HPV test rule) requiring that manufacturers (including importers) and processors of 17 high production volume (HPV) chemicals conduct acute toxicity, repeat dose toxicity, developmental and reproductive toxicity, genetic toxicity (gene mutations and chromosomal aberrations), ecotoxicity (in fish, Daphnia, and algae), and environmental fate (including 5 tests for physical chemical properties and biodegradation) testing. EPA found that each of the 17 chemicals included in the final HPV test rule is produced in substantial quantities (TSCA section 4(a)(1)(B)(i)) and that there is or may be substantial human exposure (TSCA section 4(a)(1)(B)(i)(II)) to each of them. Moreover, EPA determined that there are insufficient data to reasonably determine or predict the effects on health or the environment of the manufacture, distribution in commerce, processing, use, or disposal of the chemicals, or any combination of these activities (TSCA section 4(a)(1)(B)(ii)). EPA concluded that the testing program described in the HPV test rule is necessary and appropriate for developing such data (TSCA section 4(a)(1)(B)(iii)). Data developed under the HPV test rule will provide critical, basic information about the environmental fate and potential hazards of the chemicals included in the HPV test rule which, when combined with information about exposure and uses, will allow the Agency and others to evaluate potential health and environmental risks at the screening level and take appropriate risk management or other actions, as necessary.

To support the TSCA section 4(a)(1)(B)(i)(II) substantial human exposure finding for the 17 chemicals in the HPV test rule, EPA relied upon worker exposure data available from the National Occupational Exposure Survey

(NOES) (Ref. 2). EPA used a threshold of 1,000 workers to make such a finding for each chemical included in the HPV test rule, consistent with the policy discussed in the **Federal Register** notice entitled *TSCA Section 4(a)(1)(B) Final Statement of Policy; Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure* (58 FR 28736, May 14, 1993). In the case of coke-oven light oil (coal), the substantial human exposure finding was supported by NOES data which indicated that 2,559 roofers were exposed to this chemical (Ref. 3). Because 2,559 workers far exceeds EPA's general threshold of 1,000 workers, EPA was confident there was support for the substantial human exposure finding for coke-oven light oil (coal) (Ref. 4).

Shortly after publication of the HPV test rule in the **Federal Register** (Ref. 1), EPA was contacted by the American Coke and Coal Chemicals Institute (ACCCI) on behalf of the Coke Oven Environmental Task Force (COETF). ACCCI did not believe there was substantial worker exposure to coke-oven light oil (coal) and, according to ACCCI, the chemical should not have been included in the HPV test rule. ACCCI had commented on the proposed HPV test rule, and had included a detailed analysis supporting its contention that only 103 workers were potentially exposed to coke-oven light oil (coal) in COETF member facilities, the two processing facilities, and the transportation companies that linked them. EPA did not reject ACCCI's argument concerning the extent of worker exposure in the manufacturing facilities, processing facilities, and transportation companies in its Response to Comments document prepared for the HPV test rule (Ref. 4). However, ACCCI's contention that there is no use of coke-oven light oil (coal) in the industry sector providing roofing services and that there also would have been no use of coke-oven light oil (coal) in that industry sector during the 1980's (Ref. 5) was at odds with the NOES data on roofer exposure. Therefore, EPA finalized its proposed finding for substantial human (worker) exposure to coke-oven light oil (coal) in the HPV test rule.

Since EPA was contacted by ACCCI after the publication of the HPV test rule, new information has come to EPA's attention. EPA asked NIOSH to investigate the underlying data obtained by NIOSH for NOES which led to the conclusion that 2,559 roofers were potentially exposed to coke-oven light oil (coal). NIOSH responded that during the data collection years for NOES, 1981 to 1983, roofers were observed being exposed to coke-oven light oil (coal) due to its presence in a coal-tar pitch product for which a Material Safety Data Sheet (MSDS) had been provided to NIOSH by the product manufacturer. EPA subsequently searched for more recent information on the composition of this product and determined that the product was apparently reformulated in the 1990's and that since its reformulation, it no longer contains coke-oven light oil (coal). The name of this product is Noah's Pitch and it is manufactured by the Jim Walter Company of the Celotex Corp. (Ref. 6).

Although the NOES data were an accurate representation of potential worker exposure to coke-oven light oil (coal) in the 1980's, subsequent review of this matter has led EPA to believe that roofers are no longer exposed to coke-oven light oil (coal) through contact. ACCCI (Ref. 7) and the two coke-oven light oil (coal) processing facilities have provided letters (Refs. 8–10) assuring EPA that they do not manufacture or sell coke-oven light oil (coal) for uses in roofing products (or other uses involving substantial worker exposure). Based upon this new information indicating a lack of potential substantial worker exposure, the Agency is revoking the requirements for coke-oven light oil (coal) from the HPV test rule.

B. What is the Agency's Authority for Taking this Action?

The HPV test rule requiring testing of coke-oven light oil (coal) (Ref. 1) was promulgated under TSCA section 4 (15 U.S.C. 2603), which mandates that EPA require that manufacturers and/or processors of chemicals and mixtures conduct testing if certain findings are made by EPA (see TSCA section 4(a)). One of the findings that EPA made in promulgating the HPV test rule was that there was substantial human (worker) exposure to each of the 17 chemicals in the HPV test rule (see TSCA section 4(a)(1)(B)(i)(II); see also Ref. 1). Information provided to EPA since finalization of the HPV test rule indicates that, at the time EPA finalized the rule, worker exposure to coke-oven light oil (coal) did not constitute ''substantial human exposure'' under TSCA section 4(a)(1)(B), and thus EPA does not have a basis for making the TSCA section 4(a)(1)(B)(i)(II) exposure finding.

III. Direct Final Rule

EPA is revoking the testing required by the HPV test rule (Ref. 1) for coke-oven light oil (coal) (CAS No. 65996–78–3). The testing is being revoked because new information does not support that, at the time EPA made its TSCA section 4(a) findings with respect to the chemical, a substantial number of workers were or might be exposed to this chemical. Therefore, EPA, in this amendment, is revoking the testing requirements for coke-oven light oil (coal) (CAS No. 65996–78–3) by removing it from the list of chemicals in Table 2 in 40 CFR 799.5085(j) for which testing is required (Ref. 1).

EPA is publishing this amendment without prior proposal because the Agency views this as a non–controversial amendment and anticipates no adverse comment as this action revokes testing for which new information has been provided to EPA which indicates that, at the time EPA finalized the HPV test rule, potential worker exposure to coke–oven light oil (coal) did not constitute ''substantial human exposure'' under TSCA section 4(a)(1)(B). Despite the revocation of the testing requirements, much of the data may be made available for coke-oven light oil (coal) because COETF, acting on behalf of ACCCI and the American Iron and Steel Institute (AISI), has informed EPA that it is prepared to assist EPA in assembling a summary of existing data on coke-oven light oil (coal), after the test rule requirements for coke-oven light oil (coal) are revoked.

This amendment is effective February 6, 2007 without further notice, unless EPA receives adverse comment or a written request for an opportunity to present oral comments by January 8, 2007. If EPA receives timely adverse comment or a request for an opportunity to present oral comments on the amendment in this direct final rule, the Agency will publish a timely withdrawal in the **Federal Register** indicating the amendment is being withdrawn due to adverse comment. If the Agency does not receive adverse comment or a request for an opportunity to present oral comments on the amendment in this direct final rule, the amendment is effective February 6, 2007. If the amendment in this direct final rule is withdrawn due to adverse comment or a request for an opportunity to present oral comments, EPA will publish a notice of proposed rulemaking in a future edition of the **Federal Register**. The Agency will address the comment or request for an opportunity to present oral comments on the amendment as part of that proposed rulemaking.

IV. Economic Analysis

In the economic analysis conducted for the HPV test rule, the Agency

estimated the total cost to industry of the testing to be $4.03 million for all 17 chemicals, with an average of $237,000 per chemical (Ref. 11). This total included an additional 25% in administrative costs. This amendment reduces the total testing cost by an estimated $313,000 or approximately 8%, by eliminating the testing for coke-oven light oil (coal). In addition, the 25% administrative cost is eliminated for those tests as they relate to coke-oven light oil (coal). The new total cost of the testing is estimated to be $3.7 million (i.e., $4.03 million–$313,000). The average compliance cost per chemical without coke-oven light oil (coal) is now $232,000 (Ref. 12).

V. Export Notification

Upon the effective date of the revocation of the TSCA section 4 test rule for coke-oven light oil (coal), persons who export or intend to export coke-oven light oil (coal) are no longer subject to the TSCA section 12(b) export notification requirements to the extent that they were triggered by the testing requirements being revoked by this action. For all of the other chemicals listed as subject to the requirements of the HPV test rule (Ref. 1), the TSCA section 12(b) export notification requirements remain in effect.

VI. References

1. EPA. Testing of Certain High Production Volume Chemicals; Final Rule. **Federal Register** (71 FR 13707, March 16, 2006) (FRL–7335–2). Available on line at: *http://www.epa.gov/fedrgstr*.

2. NIOSH. National Occupational Exposure Survey (NOES). Available on line at: *http://cdc.gov/noes*.

3. NIOSH. NOES. Estimated number of employees potentially exposed to light oil by occupation within 2-digit Standard Industrial Classification (SIC). 1981–1983.

4. EPA. Response to Public Comments. Prepared by Chemical Information and Testing Branch (CITB), OPPT. May 31, 2005.

5. ACCCI. Comments on EPA's Proposed Test Rule for Testing of Certain High Production Volume Chemicals submitted to the TSCA Public Docket Office, EPA. April 25, 2001.

6. EPA. Contact report of phone conversation between Greg Schweer, Chief, CITB, Chemical Control Division (CCD) and Randy Johnson, NIOSH. April 25, 2006.

7. ACCCI. Letter from Bruce A. Steiner to Charles Auer, OPPT, EPA. Coke-Oven Light Oil. June 16, 2006.

8. Marathon Petroleum Company LLC. Letter from Harold Rinehart to Charles Auer, OPPT, EPA. June 1, 2006.

9. Marathon Petroleum. E-mail from Harold E. Rinehart to Charles Auer, EPA. Coke-Oven Light Oil Clarification. August 29, 2006.

10. Citgo Petroleum Corporation. Letter from Glenn C. Rabinak to Charles Auer, EPA. July 10, 2006.

11. EPA. Economic Analysis for the Final Section 4 Test Rule for High Production Volume Chemicals. Prepared by Lynne Blake-Hedges, EETD, OPPT. October 28, 2005.

12. EPA. E-mail from Lynne Blake-Hedges to Catherine Roman. Dropping coke-oven light oil (coal) from HPV rule and revised economic analysis conclusions. June 15, 2006.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This direct final rule implements changes to 40 CFR 799.5085 resulting in eliminating a burden and reducing cost. Because this direct final rule does not impose any new requirements, it is not subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act

This direct final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*.

C. Regulatory Flexibility Act

Because this direct final rule eliminates reporting requirements, the Agency certifies pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), that this revocation of certain requirements under TSCA section 4 will not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

This action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

E. Executive Order 13132: Federalism

This direct final rule has no Federalism implications, because it will not have substantial direct effects on 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, entitled *Federalism* (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This direct final rule has no tribal implications because it will not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, nor on the distribution of power and responsibilities between the Federal Government and Indian tribes as specified in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000).

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined under Executive Order 12866, and it does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This direct final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

I. National Technology Transfer Advancement Act

Because this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., 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 the Comptroller General of the United States. EPA will submit a report containing this rule and other

required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 799

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 4, 2006.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 799—AMENDED

■ 1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

§ 799.5085 [Amended]

■ 2. By removing the entry ''CAS No. 65996–78–3, Light oil (coal), coke-oven, in Table 2 of paragraph (j) in § 799.5085.

[FR Doc. E6–20908 Filed 12–7–06; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, and 424

CMS–1321–CN

RIN 0938–AN84

Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, and Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Corrections

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

ACTION: Correction.

SUMMARY: This correction document corrects a limited number of technical and typographical errors in the final rule with comment period that appeared in the December 1, 2006 **Federal Register** (71 FR 69624). The final rule with comment period addressed Medicare Part B payment policy, including the physician fee schedule (PFS) that is applicable for calendar year (CY) 2007, finalized the CY 2006 interim relative value units (RVUs), and established interim RVUs for new and revised procedure codes for CY 2007.

EFFECTIVE DATE: This correction notice is effective January 1, 2007.

FOR FURTHER INFORMATION CONTACT: Diane Milstead, (410) 786–3355.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 06–9086 (71 FR 69624), the final rule with comment period entitled ''Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, and Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; Ambulance Inflation Factor Update for CY 2007'' (hereinafter referred to as the CY 2007 final rule with comment period), there were technical and typographical errors that are identified and corrected in this correction notice. The provisions of this correction notice are effective January 1, 2007.

II. Summary of Errors

A. Preamble

In the preamble of the CY 2007 final rule with comment period, there were a number of technical errors and omissions.

On page 69634, in step 8 of the Practice Expense (PE) methodology calculation, we erroneously stated in the parenthetical note that unadjusted work RVUs are used to calculate the service level allocators for indirect practice expenses (PEs) in this final rule.

On pages 69636 and 69637, in Table 1, ''Calculation of PE RVUs under Methodology For Selected Codes'', we found numerous errors that include amounts and row headings.

On page 69640, under the discussion titled, ''(4) Indirect PE RVUs Methodology'' in the last sentence of the first response concerning the use of budget-neutralized work RVUs, we erroneously stated that we did not use the budget-neutralized work RVUs to calculate indirect PE.

On page 69646, clarifying language was inadvertently omitted from the response.

On page 69654, in Table 6, ''Practice Expense Equipment Item Additions for CY 2007'', one of the equipment items is misspelled.

On page 69692, the word ''a'' was inadvertently omitted from a response.

On page 69694, the word ''receiving'' was erroneously omitted from a response.

On pages 69741 through 69743, in Table 15, ''AMA RUC and HCPAC recommendations and CMS' Decisions for New and Revised 2007 CPT Codes,'' the title of the last column ''2006 work RVUs'' is incorrect.

On page 69744, in Table 16, ''AMA RUC Anesthesia Recommendations and CMS Decisions for New and Revised CPT codes'', the RUC-recommended base value for CPT code 00626 is incorrect.

On page 69744, under section E. ''Discussion of Codes for Which There Were No RUC recommendations or For Which the RUC Recommendations Were Not Accepted'', we inadvertently omitted the discussion related to CPT code 15830.

On page 69747, we incorrectly stated that pricing information for an item was not provided.

On page 69760, in section B ''Anesthesia Fee Schedule Conversion Factor,'' the discussion concerning the adjustment factor in Table 32 did not address all the included adjustments. In addition, Table 32 did not reflect the additional adjustment.

On page 69768, in Table 35, a footnote was inadvertently omitted.

On page 69770, in Table 36, a footnote was inadvertently omitted.

These corrections are reflected in section III.A. of this correction notice.

B. Addenda

The following errors in Addenda B and C are revised under this correction notice. These addenda will not appear in the Code of Federal Regulations.

In Addendum B, pages 69796 through 70011, we are making the following corrections:

(1) An indicator ''+'' denoting that the published RVUs are not used was omitted from the following Physicians' Current Procedural Terminology (CPT) or alphanumeric Healthcare Procedure Coding System (HCPCS) codes:

- *11000:* 11975, 11977;
- *15000:* 15850;
- *37000:* 37216;
- *38000:* 38204, 38207, 38208, 38209, 38210, 38211, 38212, 38213, 38214, 38215;
- *43000:* 43842;
- *58000:* 58300;
- *61000:* 61630, 61635, 61640, 61641, 61642;
- *72000:* 72159, 72159–TC, 72159–26;
- *73000:* 73225, 73225–TC, 73225–26;
- *76000:* 76390, 76390–TC, 76390–26;
- *78000:* 78350, 78350–TC, 78350–26, 78351, 78890, 78890–TC, 78890–26, 78891, 78891–TC, 78891–26;
- *90000:* 90875, 90876, 90885, 90887, 90918, 90919, 90920, 90921, 90922, 90923, 90924, 90925;

- *92000:* 92015, 92310, 92314, 92340, 92341, 92342, 92352, 92353, 92354, 92355, 92358, 92370, 92371, 92551;
- *93000:* 93668, 93740, 93740–TC, 93740–26, 93770, 93770–TC, 93770–26;
- *94000:* 94005, 94150, 94150–TC, 94150–26;
- *96000:* 96040, 96155, 96902;
- *97000:* 97010, 97014, 97810, 97811, 97813, 97814;
- *98000:* 98943, 98960, 98961, 98962;
- *99000:* 99091, 99173, 99339, 99340, 99358, 99359, 99360, 99363, 99364, 99374, 99375, 99377, 99378, 99379, 99380, 99381, 99382, 99383, 99384, 99385, 99386, 99387, 99391, 99392, 99393, 99394, 99395, 99396, 99397, 99401, 99402, 99403, 99404, 99411, 99412, 99420;
- *G codes:* G0122, G0122–TC, G0122–26, G0252–26, G0337.

(2) Incorrect RVUs were listed for the following CPT codes: 38207, 38210, 38211, 38212, 38213, 38214, and 38215.

(3) Incorrect practice expense RVUs were listed for the following CPT and HCPCS codes: 73223, 73323–TC, 76775, 76775–TC, 76775–26, 95060, 95065, G0389, G0389–TC, G0389–26, G0392, and G0393.

(4) Incorrect status indicators and RVUs were listed for CPT codes 93235, 93624, and 93624–TC.

In Addendum C, page 70015, an indicator ''+'' denoting that the published RVUs are not used was omitted from the following Physicians' Current Procedural Terminology (CPT) or alphanumeric Healthcare Procedure Coding System (HCPCS) codes:

- *90000:* 94005, 96040, 99363, and 99364.

These corrections are reflected in section III.B. of this correction notice.

III. Correction of Errors

A. Correction of Errors in the Preamble

1. On page 69634, in the 2nd column, in the 8th full paragraph, lines 11 through 13, in step 8 of the PE methodology calculation, the sentence ''In this final rule, unadjusted work RVUs are used'' is removed.

2. On pages 69636 through 69637, in Table 1: Calculation of PE RVUs under Methodology for Selected Codes, the table is corrected to read as follows:

BILLING CODE 4120–01–P

TABLE 1: Calculation of PE RVUs under Proposed Methodology for Selected Codes

					99213	33533	71020	71020TC	7102026	93000	93005	93010
					Office visit, est	CABG, arterial, single	Chest x-ray	Chest x-ray	Chest x-ray	ECG, complete	ECG, tracing	ECG, report
		Step	Source	Formula	Nonfacility	Facility	Nonfacility	Nonfacility	Nonfacility	Nonfacility	Nonfacility	Nonfacility
(1)	Labor cost (Lab)	Step 1	AMA		$ 13.33	$ 77.59	$ 5.74	$ 5.74	$ -	$ 6.13	$ 6.13	$ -
(2)	Suppy cost (Sup)	Step 1	AMA		$ 2.99	$ 7.35	$ 3.39	$ 3.39	$ -	$ 1.20	$ 1.20	$ -
(3)	Equipment cost (Eqp)	Step 1	AMA		$ 0.19	$ 0.65	$ 8.18	$ 8.18	$ -	$ 0.12	$ 0.12	$ -
(4)	Direct cost (Dir)	Step 1		=(1)+(2)+(3)	$ 16.51	$ 85.59	$ 17.32	$ 17.32	$ -	$ 7.44	$ 7.44	$ -
(5)	Direct adjustment (Dir Adj)	Steps 2-4	See footnote*		0.606	0.606	0.606	0.606	0.606	0.606	0.606	0.606
(6)	Adjusted labor	Steps 2-4	=Lab*Dir Adj	=(1)*(5)	$ 8.07	$ 46.99	$ 3.48	$ 3.48	$ -	$ 3.71	$ 3.71	$ -
(7)	Adjusted supplies	Steps 2-4	=Sup*Dir Adj	=(2)*(5)	$ 1.81	$ 4.45	$ 2.06	$ 2.06	$ -	$ 0.72	$ 0.72	$ -
(8)	Adjusted equipment	Steps 2-4	=Eqp*Dir Adj	=(3)*(5)	$ 0.12	$ 0.40	$ 4.95	$ 4.95	$ -	$ 0.07	$ 0.07	$ -
(9)	Adjusted direct	Steps 2-4		=(6)+(7)+(8)	$ 10.00	$ 51.84	$ 10.49	$ 10.49	$ -	$ 4.51	$ 4.51	$ -
(10)	Conversion Factor (CF)	Step 5	MFS		$ 35.9848	$ 35.9848	$ 35.9848	$ 35.9848	$ 35.9848	$ 35.9848	$ 35.9848	$ 35.9848
(11)	Adj. labor cost converted	Step 5	=(Lab*Dir Adj)/CF	=(6)/(10)	0.22	1.31	0.10	0.10	-	0.10	0.10	
(12)	Adj. supply cost converted	Step 5	=(Sup*Dir Adj)/CF	=(7)/(10)	0.05	0.12	0.06	0.06	-	0.02	0.02	
(13)	Adj. equip cost converted	Step 5	=(Eqp*Dir Adj)/CF	=(8)/(10)	0.00	0.01	0.14	0.14	-	0.00	0.00	
(14)	Adj. direct cost converted	Step 5		=(11)+(12)+(13)	0.28	1.44	0.29	0.29	-	0.13	0.13	
(15)	Wrk RVU* Wrk Scaler	Setup File	MFS		0.83	30.26	0.20	-	0.20	0.15	-	0.15
(16)	Dir_pct	Steps 6, 7	Surveys		33.9%	32.5%	38.0%	38.0%	38.0%	37.6%	37.6%	37.6%
(17)	Ind_pct	Steps 6, 7	Surveys		66.1%	67.5%	62.0%	62.0%	62.0%	62.4%	62.4%	62.4%
(18)	Ind. Alloc. formula (1st part)	Step 8	See Step 8		((14)/(16))*(17)	((14)/(16))*(17)	((14)/(16))*(17)	((14)/(16))*(17)	((14)/(16))*(17)	((14)/(16))*(17)	((14)/(16))*(17)	((14)/(16))*(17)
(19)	Ind. Alloc. (1st part)	Step 8		See (18)	0.54	2.99	0.48	0.48	-	0.21	0.21	-
(20)	Ind. Alloc. formulas (2nd part)	Step 8	See Step 8		(15)	(15)	(15)+(11)	(11)	(15)	(15)+(11)	(11)	(15)
(21)	Ind. Alloc. (2nd part)	Step 8		See (20)	0.83	30.26	0.30	0.10	0.20	0.25	0.10	0.15
(22)	Indirect Allocator (1st+2nd)	Step 8		=(19)+(21)	1.37	33.25	0.77	0.57	0.20	0.46	0.31	0.15

					99213	33533	71020	71020TC	7102026	93000	93005	93010
					Office visit, est	CABG, arterial, single	Chest x-ray	Chest x-ray	Chest x-ray	ECG, complete	ECG, tracing	ECG, report
		Step	Source	Formula	Nonfacility	Facility	Nonfacility	Nonfacility	Nonfacility	Nonfacility	Nonfacility	Nonfacility
(23)	Indirect Adjustment (Ind Adj)	Steps 9-11	See footnote**		0.349	0.349	0.349	0.349	0.349	0.349	0.349	0.349
(24)	Adjusted Indirect Allocator	Steps 9-11	=Ind Alloc * Ind Adj		0.48	11.61	0.27	0.20	0.07	0.16	0.11	0.05
(25)	Ind.Practice Cost Index (PCI)	Steps 12-16	See Steps 12-16		0.970	0.931	0.869	0.869	0.869	1.300	1.300	1.300
(26)	Adjusted Indirect	Step 17	= Adj. Ind Alloc*PCI	=(24)*(25)	0.47	10.81	0.23	0.17	0.06	0.21	0.14	0.07
(27)	PE RVU	Steps 18-19	=(Adj Dir+Adj Ind) *budn	=((14)+(26)) *budn	0.74	12.26	0.53	0.47	0.06	0.33	0.27	0.07

* The direct adj = [current pe rvus * CF * avg dir pct] / [sum direct inputs] = [Step 2] / [Step 3].

** The indirect adj = [current pe rvus * avg ind pct] / [sum of ind allocators] = [Step 9] / [Step 10.

BILLING CODE 4120–01–C

3. On page 69640, in the 2nd column, the 1st full paragraph, the response beginning with the phrase ''As discussed in section III.D.3. of this final rule with comment period * * *'' and ending with the phrase ''* * * budget-neutralized work RVUs to calculate indirect PE'' is corrected to read as follows:

''As discussed elsewhere in this rule, we do not believe it would be appropriate to allow the increases in work RVUs for certain services as a result of the 5-Year Review to reduce aggregate payments for PEs and professional liability under the Medicare PFS. Our final policy to use the budget-neutralized work RVUs in the calculation of indirect PEs appropriately maintains the current relationships between the work, PE, and professional liability (malpractice insurance expense) components of the PFS. We also believe it is important to apply the revised, budget-neutralized work RVUs consistently within the PFS framework. It would not be consistent to apply one set of work RVUs for work payments, but a different set for purposes of calculating indirect PEs. Therefore, we will base the calculation of both the work payments and the indirect PEs on the revised, budget-neutralized work RVUs adopted as part of this final rule, and maintain the overall current relationships between work, PE, and professional liability. The PE RVUs in Addendum B and throughout the rest of this rule reflect this policy.''

4. On page 69646, in the 2nd column, the 4th full paragraph, the response ''We will implement these changes for CY 2007'' is corrected to read as follows: ''We are implementing these changes for CY 2007. Because we are implementing the bottom-up methodology, which utilizes the direct inputs to determine the PE RVUs for CY 2007, a separate payment for the contrast media used in various imaging procedures will be available. In addition to the CPT code representing the imaging procedure, providers are instructed to use the appropriate HCPCS Q-code, Q9942 through Q9964, to separately bill for the contrast medium utilized in performing the service.''

5. On page 69654, in Table 6, Practice Expense Equipment Item Additions for CY 2007, column 2, line 16, the word ''Acerine'' is corrected to read ''Aerocrine.''

6. On page 69692, in the 3rd column, 1st paragraph, line 10, the phrase ''verified in large trial'' is corrected to read as ''verified in a large trial.''

7. On page 69694, in the 3rd column, 3rd paragraph, lines 8 through 9, the phrase ''may also be FDA-approved'' is corrected to read ''may also be receiving FDA-approved.''

8. On pages 69741 through 69743, in Table 15, ''AMA RUC and HCPAC recommendations and CMS'' Decisions for New and Revised 2007 CPT Codes'', last column, the column heading, ''2006 work RVU'' is corrected to read ''2007 work RVU''.

9. On page 69744, in Table 16: AMA RUC Anesthesia Recommendations and CMS Decisions for New and Revised CPT Codes, column 3 (RUC-recommendation), line 2 (CPT code 00626), the value ''13.00'' is corrected to read ''15.00.''

10. On page 69744, in the 1st column, after the 2nd full paragraph following the table, after the sentence ''This summary refers only to work RVUs'' and before the sentence beginning ''For CPT code 22857 * * *'' the following paragraph is added to read as follows:

''For CPT code 15830, *Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy*, the RUC recommended 15.60 work RVUs. We reviewed the summary of recommendations for an add-on procedure to CPT code 15830, CPT code 15847, *Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial pilcation (List separately in addition to code for primary procedure)*, in which the RUC and the specialty society recommended that this code be carrier-priced to reduce the potential for abuse. In order to reduce the potential for abuse, we believe that, payment for CPT code 15830 should be similarly restricted and medical necessity should be established prior to payment. Therefore, we have assigned a status indicator of ''R'' (Restricted) to this code.''

11. On page 69747, in the 3rd column, 1st paragraph, lines 2 through 5, the sentence ''We were not able to include a price for the pedigree software equipment as it was not provided with the PE inputs'' is corrected to read as ''We included a price of $950 for the pedigree software desktop version as the typical equipment used in a physician office.''

12. On page 69760,

a. In the 3rd column, 1st full paragraph, lines 10 through 12, the sentence ''The adjustment factor in Table 32 includes the combined effect of the PE adjustment and the BN adjustment'' is corrected to read ''The adjustment factor in Table 32 includes the combined effect of the PE adjustment, the BN adjustment and the adjustment to anesthesia work to account for the increase in the work of the E/M codes.''

b. In the 3rd column, Table 32 is corrected as follows:

TABLE 32

2006 Anesthesia Conversion Factor.	$17.7663
2007 Update	−5.0 percent (0.94953)
2007 Combined Adjustment PE and BN.	0.9110
2007 Anesthesia Conversion Factor.	$15.3682

13. On page 69768, Table 35 is corrected by adding a footnote to read as follows:

''**Components may not sum due to rounding error.''

14. On page 69770, Table 36 is corrected by adding a footnote to read as follows:

''Note: When applying the 0.8994 work adjuster to the work relative values printed in Addendum B, you must round the product to two decimal places.''

B. Addenda

1. On pages 69796 through 70011, in Addendum B: Relative Value Units (RVUs) And Related Information the following entries are corrected to read as follows:

ADDENDUM B.—RELATIVE VALUE UNITS (RVUS) AND RELATED INFORMATION—CORRECTIONS

CPT [1]/ HCPCS [2]	Mod	Status	Description	Physician work RVUs [3]	Fully implemented non-facility PE RVUs	Year 2007 transitional non-facility PE RVUs	Fully implemented facility PE RVUs	Year 2007 transitional facility PE RVUs	Malpractice RVUs	Fully implemented non-facility total	Year 2007 transitional non-facility total	Fully implemented facility total	Year 2007 transitional facility total	Global
11975		N	Insert contraceptive cap	1.48+	1.52	1.45	0.34	0.51	0.17	3.17	3.10	1.99	2.16	XXX
11977		N	Removal/reinsert contra cap	3.30+	1.97	2.20	0.76	1.14	0.37	5.64	5.87	4.43	4.81	XXX
15850		B	Removal of sutures	0.78+	1.19	1.47	0.18	0.27	0.05	2.02	2.30	1.01	1.10	XXX
37216		N	Transcath stent, cca w/o eps	18.85+	NA	NA	5.75	8.05	1.04	NA	NA	25.64	27.94	090
38204		B	Bl donor search management	2.00+	0.91	0.91	0.91	0.91	0.06	2.97	2.97	2.97	2.97	XXX
38207		I	Cryopreserve stem cells	0.89+	0.41	0.41	0.41	0.41	0.01	1.31	1.31	1.31	1.31	XXX
38208		I	Thaw preserved stem cells	0.56+	0.25	0.25	0.25	0.25	0.02	0.83	0.83	0.83	0.83	XXX
38209		I	Wash harvest stem cells	0.24+	0.11	0.11	0.11	0.11	0.01	0.36	0.36	0.36	0.36	XXX
38210		I	T-cell depletion of harvest	1.57+	0.72	0.72	0.72	0.72	0.03	2.32	2.32	2.32	2.32	XXX
38211		I	Tumor cell deplete of harvst	1.42+	0.65	0.65	0.65	0.65	0.02	2.09	2.09	2.09	2.09	XXX
38212		I	Rbc depletion of harvest	0.94+	0.43	0.43	0.43	0.43	0.02	1.39	1.39	1.39	1.39	XXX
38213		I	Platelet deplete of harvest	0.24+	0.11	0.11	0.11	0.11	0.01	0.36	0.36	0.36	0.36	XXX
38214		I	Volume deplete of harvest	0.81+	0.37	0.37	0.37	0.37	0.01	1.19	1.19	1.19	1.19	XXX
38215		I	Harvest stem cell concentrte	0.94+	0.43	0.43	0.43	0.43	0.02	1.39	1.39	1.39	1.39	XXX
43842		N	V-band gastroplasty	20.90+	NA	NA	6.75	7.53	2.45	NA	NA	30.10	30.88	090
58300		N	Insert intrauterine device	1.01+	0.62	1.22	0.23	0.34	0.12	1.75	2.35	1.36	1.47	XXX
61630		N	Intracranial angioplasty	22.07+	NA	NA	6.44	10.98	2.02	NA	NA	30.53	35.07	090
61635		N	Intracran angioplsty w/stent	24.28+	NA	NA	6.95	11.89	2.21	NA	NA	33.44	38.38	090
61640		N	Dilate ic vasospasm, init	12.32+	NA	NA	2.85	2.85	0.71	NA	NA	15.88	15.88	000
61641		N	Dilate ic vasospasm add-on	4.33+	NA	NA	1.00	1.00	0.25	NA	NA	5.58	5.58	ZZZ
61642		N	Dilate ic vasospasm add-on	8.66+	NA	NA	2.00	2.00	0.50	NA	NA	11.16	11.16	ZZZ
72159		N	Mr angio spine w/o&w/dye	1.80+	14.49	13.31	NA	NA	0.74	17.03	15.85	NA	NA	XXX
72159	TC	N	Mr angio spine w/o&w/dye	0.00+	14.07	12.69	NA	NA	0.64	14.71	13.33	NA	NA	XXX
72159	26	N	Mr angio spine w/o&w/dye	1.80+	0.42	0.62	0.42	0.62	0.10	2.32	2.52	2.32	2.52	XXX
73223		A	Mri joint upr extr w/o&w/dye	2.15	16.74	23.38	NA	NA	0.94	19.83	26.47	NA	NA	XXX
73223	26	A	Mri joint upr extr w/o&w/dye	2.15	0.61	0.69	0.61	0.69	0.10	2.86	2.94	2.86	2.94	XXX
73225		N	Mr angio upr extr w/o&w/dye	1.73+	14.47	12.38	NA	NA	0.69	16.89	14.80	NA	NA	XXX
73225	TC	N	Mr angio upr extr w/o&w/dye	0.00+	14.07	11.78	NA	NA	0.59	14.66	12.37	NA	NA	XXX
73225	26	N	Mr angio upr extr w/o&w/dye	1.73+	0.40	0.60	0.40	0.60	0.10	2.23	2.43	2.23	2.43	XXX
76390		N	Mr spectroscopy	1.40+	9.31	10.94	NA	NA	0.66	11.37	13.00	NA	NA	XXX
76390	TC	N	Mr spectroscopy	0.00+	8.99	10.51	NA	NA	0.59	9.58	11.10	NA	NA	XXX
76390	26	N	Mr spectroscopy	1.40+	0.32	0.43	0.32	0.43	0.07	1.79	1.90	1.79	1.90	XXX
76775		A	Us exam abdo back wall, lim	0.58	2.23	1.77	NA	NA	0.11	2.92	2.46	NA	NA	XXX
76775	TC	A	Us exam abdo back wall, lim	0.00	2.06	1.58	NA	NA	0.08	2.14	1.66	NA	NA	XXX
76775	26	A	Us exam abdo back wall, lim	0.58	0.17	0.19	0.17	0.19	0.03	0.78	0.80	0.78	0.80	XXX
78350		N	Bone mineral, single photon	0.22+	0.00	0.82	NA	NA	0.06	0.28	1.10	NA	NA	XXX
78350	TC	N	Bone mineral, single photon	0.00+	0.00	0.75	NA	NA	0.05	0.05	0.80	NA	NA	XXX
78350	26	N	Bone mineral, single photon	0.22+	0.00	0.07	0.00	0.07	0.01	0.23	0.30	0.23	0.30	XXX
78351		N	Bone mineral, dual photon	0.30+	NA	NA	0.07	0.11	0.01	NA	NA	0.38	0.42	XXX
78890		B	Nuclear medicine data proc	0.05+	0.38	1.10	NA	NA	0.07	0.50	1.22	NA	NA	XXX
78890	TC	B	Nuclear medicine data proc	0.00+	0.37	1.08	NA	NA	0.06	0.43	1.14	NA	NA	XXX
78890	26	B	Nuclear medicine data proc	0.05+	0.01	0.02	0.01	0.02	0.01	0.07	0.08	0.07	0.08	XXX
78891		B	Nuclear med data proc	0.10+	0.86	2.22	NA	NA	0.14	1.10	2.46	NA	NA	XXX
78891	TC	B	Nuclear med data proc	0.00+	0.84	2.18	NA	NA	0.13	0.97	2.31	NA	NA	XXX
78891	26	B	Nuclear med data proc	0.10+	0.02	0.04	0.02	0.04	0.01	0.13	0.15	0.13	0.15	XXX
90875		N	Psychophysiological therapy	1.20+	0.52	0.81	0.28	0.42	0.04	1.76	2.05	1.52	1.66	XXX
90876		N	Psychophysiological therapy	1.90+	0.67	1.04	0.44	0.66	0.05	2.62	2.99	2.39	2.61	XXX
90885		B	Psy evaluation of records	0.97+	0.22	0.33	0.22	0.33	0.02	1.21	1.32	1.21	1.32	XXX
90887		B	Consultation with family	1.48+	0.61	0.77	0.34	0.51	0.04	2.13	2.29	1.86	2.03	XXX
90918		I	ESRD related services, month	11.16+	4.68	5.75	3.74	5.52	0.36	16.20	17.27	15.26	17.04	XXX
90919		I	ESRD related services, month	8.53+	3.02	3.76	2.55	3.64	0.29	11.84	12.58	11.37	12.46	XXX
90920		I	ESRD related services, month	7.26+	2.73	3.50	2.27	3.38	0.23	10.22	10.99	9.76	10.87	XXX
90921		I	ESRD related services, month	4.46+	1.70	2.26	1.61	2.23	0.14	6.30	6.86	6.21	6.83	XXX
90922		I	ESRD related services, day	0.37+	0.16	0.20	0.12	0.19	0.01	0.54	0.58	0.50	0.57	XXX
90923		I	Esrd related services, day	0.28+	0.10	0.12	0.08	0.12	0.01	0.39	0.41	0.37	0.41	XXX
90924		I	Esrd related services, day	0.24+	0.09	0.11	0.08	0.11	0.01	0.34	0.36	0.33	0.36	XXX

ADDENDUM B.—RELATIVE VALUE UNITS (RVUs) AND RELATED INFORMATION—CORRECTIONS—Continued

CPT [1]/ HCPCS [2]	Mod	Status	Description	Physician work RVUs [3]	Fully implemented non-facility PE RVUs	Year 2007 transitional non-facility PE RVUs	Fully implemented facility PE RVUs	Year 2007 transitional facility PE RVUs	Malpractice RVUs	Fully implemented non-facility total	Year 2007 transitional non-facility total	Fully implemented facility total	Year 2007 transitional facility total	Global
90925		I	Esrd related services, day	0.15+	0.05	0.07	0.05	0.07	0.01	0.21	0.23	0.21	0.23	XXX
92015		N	Refraction	0.38+	0.10	1.14	0.09	0.14	0.01	0.49	1.53	0.48	0.53	XXX
92310		N	Contact lens fitting	1.17+	1.05	1.10	0.27	0.41	0.04	2.26	2.31	1.48	1.62	XXX
92314		N	Prescription of contact lens	0.69+	1.13	0.99	0.16	0.24	0.01	1.83	1.69	0.86	0.94	XXX
92340		N	Fitting of spectacles	0.37+	0.44	0.64	0.08	0.13	0.01	0.82	1.02	0.46	0.51	XXX
92341		N	Fitting of spectacles	0.47+	0.46	0.67	0.11	0.16	0.01	0.94	1.15	0.59	0.64	XXX
92342		N	Fitting of spectacles	0.53+	0.48	0.69	0.12	0.19	0.01	1.02	1.23	0.66	0.73	XXX
92352		B	Special spectacles fitting	0.37+	0.56	0.65	0.08	0.13	0.01	0.94	1.03	0.46	0.51	XXX
92353		B	Special spectacles fitting	0.50+	0.59	0.70	0.12	0.17	0.02	1.11	1.22	0.64	0.69	XXX
92354		B	Special spectacles fitting	0.00+	0.28	6.72	NA	NA	0.10	0.38	6.82	NA	NA	XXX
92355		B	Special spectacles fitting	0.00+	0.44	3.36	NA	NA	0.01	0.45	3.37	NA	NA	XXX
92358		B	Eye prosthesis service	0.00+	0.23	0.79	NA	NA	0.05	0.28	0.84	NA	NA	XXX
92370		N	Repair & adjust spectacles	0.32+	0.39	0.51	0.07	0.12	0.02	0.73	0.85	0.41	0.46	XXX
92371		B	Repair & adjust spectacles	0.00+	0.24	0.53	NA	NA	0.02	0.26	0.55	NA	NA	XXX
92551		N	Pure tone hearing test, air	0.00+	0.25	0.25	NA	NA	0.01	0.26	0.26	NA	NA	XXX
93235		C	ECG monitor/report, 24 hrs	0.00	0.00	0.00	NA	NA	0.00	0.00	0.00	NA	NA	XXX
93624		C	Electrophysiologic evaluation	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	000
93624	TC	C	Electrophysiologic evaluation	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	000
93668		N	Peripheral vascular rehab	0.00+	0.40	0.40	NA	NA	0.01	0.41	0.41	NA	NA	XXX
93740		B	Temperature gradient studies	0.16+	0.04	0.15	NA	NA	0.02	0.22	0.33	NA	NA	XXX
93740	TC	B	Temperature gradient studies	0.00+	0.00	0.11	NA	NA	0.01	0.01	0.12	NA	NA	XXX
93740	26	B	Temperature gradient studies	0.16+	0.04	0.04	0.04	0.04	0.01	0.21	0.21	0.21	0.21	XXX
93770		B	Measure venous pressure	0.16+	0.04	0.07	NA	NA	0.02	0.22	0.25	NA	NA	XXX
93770	TC	B	Measure venous pressure	0.00+	0.00	0.02	NA	NA	0.01	0.01	0.03	NA	NA	XXX
93770	26	B	Measure venous pressure	0.16+	0.04	0.05	0.04	0.05	0.01	0.21	0.22	0.21	0.22	XXX
94005		B	Home vent mgmt supervision	1.50+	0.69	0.69	NA	NA	0.06	2.25	2.25	NA	NA	XXX
94150		B	Vital capacity test	0.07+	0.48	0.48	NA	NA	0.02	0.57	0.57	NA	NA	XXX
94150	TC	B	Vital capacity test	0.00+	0.46	0.45	NA	NA	0.01	0.47	0.46	NA	NA	XXX
94150	26	B	Vital capacity test	0.07+	0.02	0.03	0.02	0.03	0.01	0.10	0.11	0.10	0.11	XXX
95060		A	Eye allergy tests	0.00	0.72	0.44	0.72	0.44	0.02	0.74	0.46	0.74	0.46	XXX
95065		A	Nose allergy test	0.00	0.65	0.31	0.65	0.31	0.01	0.66	0.32	0.66	0.32	XXX
96040		B	Genetic counseling, 30 min	0.00+	0.97	0.97	NA	NA	0.01	0.98	0.98	NA	NA	XXX
96155		N	Interv hlth/behav fam no pt	0.44+	0.10	0.16	0.10	0.15	0.02	0.56	0.62	0.56	0.61	XXX
96902		B	Trichogram	0.41+	0.11	0.16	0.10	0.15	0.01	0.53	0.58	0.52	0.57	XXX
97010		B	Hot or cold packs therapy	0.06+	0.07	0.06	NA	NA	0.01	0.14	0.13	NA	NA	XXX
97014		I	Electric stimulation therapy	0.18+	0.18	0.19	NA	NA	0.01	0.37	0.38	NA	NA	XXX
97810		N	Acupunct w/o stimul 15 min	0.60+	0.26	0.35	0.14	0.21	0.03	0.89	0.98	0.77	0.84	XXX
97811		N	Acupunct w/o stimul addl 15m	0.50+	0.15	0.23	0.12	0.17	0.03	0.68	0.76	0.65	0.70	ZZZ
97813		N	Acupunct w/stimul 15 min	0.65+	0.27	0.37	0.15	0.23	0.03	0.95	1.05	0.83	0.91	XXX
97814		N	Acupunct w/stimul addl 15m	0.55+	0.19	0.27	0.13	0.19	0.03	0.77	0.85	0.71	0.77	ZZZ
98943		N	Chiropractic manipulation	0.40+	0.17	0.22	0.09	0.14	0.01	0.58	0.63	0.50	0.55	XXX
98960		B	Self-mgmt educ & train, 1 pt	0.00+	0.48	0.48	0.00	0.00	0.01	0.49	0.49	0.01	0.01	XXX
98961		B	Self-mgmt educ/train, 2–4 pt	0.00+	0.23	0.23	0.00	0.00	0.01	0.24	0.24	0.01	0.01	XXX
98962		B	Self-mgmt educ/train, 5–8 pt	0.00+	0.17	0.17	0.00	0.00	0.01	0.18	0.18	0.01	0.01	XXX
99091		B	Collect/review data from pt	1.10+	0.25	0.25	NA	NA	0.04	1.39	1.39	NA	NA	XXX
99173		N	Visual acuity screen	0.00+	0.06	0.06	NA	NA	0.01	0.07	0.07	NA	NA	XXX
99339		B	Domicil/r-home care supervis	1.25+	0.58	0.58	NA	NA	0.06	1.89	1.89	NA	NA	XXX
99340		B	Domicil/r-home care supervis	1.80+	0.76	0.76	NA	NA	0.07	2.63	2.63	NA	NA	XXX
99358		B	Prolonged serv, w/o contact	2.10+	0.51	0.51	0.51	0.51	0.09	2.70	2.70	2.70	2.70	ZZZ
99359		B	Prolonged serv, w/o contact	1.00+	0.26	0.26	0.26	0.26	0.04	1.30	1.30	1.30	1.30	ZZZ
99360		X	Physician standby services	1.20+	0.00	0.00	0.00	0.00	0.05	1.25	1.25	1.25	1.25	XXX
99363		B	Anticoag mgmt, init	1.65+	1.29	1.29	0.38	0.38	0.07	3.01	3.01	2.10	2.10	XXX
99364		B	Anticoag mgmt, subseq	0.63+	0.38	0.38	0.15	0.15	0.04	1.05	1.05	0.82	0.82	XXX
99374		B	Home health care supervision	1.10+	0.54	0.66	0.25	0.38	0.05	1.69	1.81	1.40	1.53	XXX
99375		I	Home health care supervision	1.73+	0.75	1.35	0.40	1.26	0.07	2.55	3.15	2.20	3.06	XXX
99377		B	Hospice care supervision	1.10+	0.54	0.66	0.25	0.38	0.05	1.69	1.81	1.40	1.53	XXX

99378		I	Hospice care supervision	1.73+	0.75	1.64	0.40	1.56	0.07	2.55	3.44	2.20	3.36	XXX
99379		B	Nursing fac care supervision	1.10+	0.54	0.66	0.25	0.38	0.04	1.68	1.80	1.39	1.52	XXX
99380		B	Nursing fac care supervision	1.73+	0.75	0.93	0.40	0.60	0.06	2.54	2.72	2.19	2.39	XXX
99381		N	Init pm e/m, new pat, inf	1.19+	0.99	1.37	0.27	0.41	0.05	2.23	2.61	1.51	1.65	XXX
99382		N	Init pm e/m, new pat 1–4 yrs	1.36+	1.03	1.41	0.31	0.47	0.05	2.44	2.82	1.72	1.88	XXX
99383		N	Prev visit, new, age 5–11	1.36+	1.02	1.37	0.31	0.47	0.05	2.43	2.78	1.72	1.88	XXX
99384		N	Prev visit, new, age 12–17	1.53+	1.06	1.43	0.35	0.53	0.06	2.65	3.02	1.94	2.12	XXX
99385		N	Prev visit, new, age 18–39	1.53+	1.06	1.43	0.35	0.53	0.06	2.65	3.02	1.94	2.12	XXX
99386		N	Prev visit, new, age 40–64	1.88+	1.14	1.59	0.43	0.65	0.07	3.09	3.54	2.38	2.60	XXX
99387		N	Init pm e/m, new pat 65+ yrs	2.06+	1.27	1.72	0.48	0.71	0.07	3.40	3.85	2.61	2.84	XXX
99391		N	Per pm reeval, est pat, inf	1.02+	0.86	0.98	0.24	0.35	0.04	1.92	2.04	1.30	1.41	XXX
99392		N	Prev visit, est, age 1–4	1.19+	0.89	1.04	0.27	0.41	0.05	2.13	2.28	1.51	1.65	XXX
99393		N	Prev visit, est, age 5–11	1.19+	0.89	1.02	0.27	0.41	0.05	2.13	2.26	1.51	1.65	XXX
99394		N	Prev visit, est, age 12–17	1.36+	0.93	1.08	0.31	0.47	0.05	2.34	2.49	1.72	1.88	XXX
99395		N	Prev visit, est, age 18–39	1.36+	0.93	1.10	0.31	0.47	0.05	2.34	2.51	1.72	1.88	XXX
99396		N	Prev visit, est, age 40–64	1.53+	0.97	1.18	0.35	0.53	0.06	2.56	2.77	1.94	2.12	XXX
99397		N	Per pm reeval est pat 65+ yr	1.71+	1.11	1.30	0.40	0.60	0.06	2.88	3.07	2.17	2.37	XXX
99401		N	Preventive counseling, indiv	0.48+	0.36	0.56	0.11	0.17	0.01	0.85	1.05	0.60	0.66	XXX
99402		N	Preventive counseling, indiv	0.98+	0.47	0.77	0.23	0.34	0.02	1.47	1.77	1.23	1.34	XXX
99403		N	Preventive counseling, indiv	1.46+	0.58	0.96	0.34	0.51	0.04	2.08	2.46	1.84	2.01	XXX
99404		N	Preventive counseling, indiv	1.95+	0.70	1.17	0.45	0.68	0.05	2.70	3.17	2.45	2.68	XXX
99411		N	Preventive counseling, group	0.15+	0.22	0.19	0.03	0.05	0.01	0.38	0.35	0.19	0.21	XXX
99412		N	Preventive counseling, group	0.25+	0.24	0.25	0.06	0.09	0.01	0.50	0.51	0.32	0.35	XXX
99420		N	Health risk assessment test	0.00+	0.22	0.22	NA	NA	0.01	0.23	0.23	NA	NA	XXX
G0122		N	Colon ca scrn; barium enema	0.99+	5.58	3.32	NA	NA	0.18	6.75	4.49	NA	NA	XXX
G0122	TC	N	Colon ca scrn; barium enema	0.00+	5.35	2.98	NA	NA	0.13	5.48	3.11	NA	NA	XXX
G0122	26	N	Colon ca scrn; barium enema	0.99+	0.23	0.34	0.23	0.34	0.05	1.27	1.38	1.27	1.38	XXX
G0252	26	N	PET imaging initial dx	1.50+	0.00	0.60	0.00	0.60	0.04	1.54	2.14	1.54	2.14	XXX
G0337		X	Hospice evaluation preelecti	1.34+	0.31	0.46	0.31	0.46	0.09	1.74	1.89	1.74	1.89	XXX
G0389		A	Ultrasound exam AAA screen	0.58	2.23	1.77	NA	NA	0.11	2.92	2.46	NA	NA	XXX
G0389	TC	A	Ultrasound exam AAA screen	0.00	2.06	1.58	NA	NA	0.08	2.14	1.66	NA	NA	XXX
G0389	26	A	Ultrasound exam AAA screen	0.58	0.17	0.19	0.17	0.19	0.03	0.78	0.80	0.78	0.80	XXX
G0392		A	AV fistula or graft arterial	9.48	47.48	53.95	3.25	3.48	0.62	57.58	64.05	13.35	13.58	000
G0393		A	AV fistula or graft venous	6.03	35.61	42.45	1.97	2.26	0.34	41.98	48.82	8.34	8.63	000

[1] CPT codes and descriptions only are copyright 2006 American Medical Association. All Rights Reserved. Applicable FARS/DFARS Apply.
[2] Copyright 2006 American Dental Association. All rights reserved.
[3] + Indicates RVUs are not used for Medicare payment.

■ 2. On page 70015, in Addendum C: Codes with Interim RVUs the following entries are corrected to read as follows:

ADDENDUM C.— CODES WITH INTERIM RVUS—CORRECTIONS

CPT [1]/ HCPCS [2]	Mod	Status	Description	Physician work RVUs [3]	Fully implemented non-facility PE RVUs	Year 2007 transitional non-facility PE RVUs	Fully implemented facility PE RVUs	Year 2007 transitional facility PE RVUs	Malpractice RVUs	Fully implemented non-facility total	Year 2007 transitional non-facility total	Fully implemented facility total	Year 2007 transitional facility total	Global
94005	.....	B	Home vent mgmt supervision	1.50+	0.69	0.69	NA	NA	0.06	2.25	2.25	NA	NA	XXX
96040	.....	B	Genetic counseling, 30 min	0.00+	0.97	0.97	NA	NA	0.01	0.98	0.98	NA	NA	XXX
99363	.....	B	Anticoag mgmt, init	1.65+	1.29	1.29	0.38	0.38	0.07	3.01	3.01	2.10	2.10	XXX
99364	.....	B	Anticoag mgmt, subseq	0.63+	0.38	0.38	0.15	0.15	0.04	1.05	1.05	0.82	0.82	XXX

[1] CPT codes and descriptions only are copyright 2006 American Medical Association. All Rights Reserved. Applicable FARS/DFARS Apply.
[2] Copyright 2006 American Dental Association. All rights reserved.
[3] + Indicates RVUs are not used for Medicare payment.

IV. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive the notice and comment procedures if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the rule.

Section 553(d) for the APA ordinarily requires a 30-day delay in effective date of final rules after the date of their publication. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued.

This correction notice addresses technical errors and omissions made in FR Doc. 06–9086, entitled ''Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, and changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; Ambulance Inflation Factor Update for CY 2007,'' which appeared in the December 1, 2006 **Federal Register** (71 FR 69624), and is effective January 1, 2007. The provisions of this final rule with comment period have been previously subjected to notice and comment procedures. These corrections are consistent with the discussion and text of the final rule with comment period, and do not make substantive changes to the CY 2007 published rule. As such, this correction notice is intended to ensure the CY 2007 final rule with comment period accurately reflects the policies adopted in that rule. Therefore, we find that undertaking further notice and comment procedures to incorporate these corrections into the final rule with comment is unnecessary and contrary to the public interest.

For the same reasons, we are also waiving the 30-day delay in effective date for this correction notice. We believe that it is in the public interest to ensure that the CY 2007 final rule with comment period accurately states our policies relating to the PFS and other Part B payment policies. Therefore, delaying the effective date of these corrections beyond the January 1, 2007 effective date of the final rule with comment period would be contrary to the public interest. In so doing, we find good cause to waive the 30-day delay in the effective date.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 30, 2006.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. 06–9550 Filed 12–4–06; 9:46 am]

BILLING CODE 4120–01–M

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 222, and 252

RIN 0750–AF11

Defense Federal Acquisition Regulation Supplement; Combating Trafficking in Persons

[DFARS Case 2004–D017]

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Interim rule; extension of comment period.

SUMMARY: DoD is extending the comment period for the interim rule published at 71 FR 62560 on October 26, 2006. The rule amended the Defense Federal Acquisition Regulation Supplement (DFARS) to address the prohibition on DoD contractor activities that support or promote trafficking in persons. The comment period is extended to provide additional time for interested parties to review the DFARS changes.

DATES: The ending date for submission of comments is extended to January 25, 2007.

FOR FURTHER INFORMATION CONTACT: Ms. Felisha Hitt, Defense Acquisition Regulations System, OUSD (AT&L) DPAP (DARS), IMD 3C132, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone (703) 602–0310; facsimile (703) 602–0350. Please cite DFARS Case 2004–D017.

Michele P. Peterson,

Editor, Defense Acquisition Regulations System.

[FR Doc. E6–20891 Filed 12–7–06; 8:45 am]

BILLING CODE 5001–08–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1802, 1805, 1819, 1825, 1827, 1828, and 1852

RIN 2700–31

NASA FAR Supplement Administrative Changes

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: This final rule makes administrative changes to the NASA FAR Supplement (NFS) to update dollar thresholds, correct a document title, and delete an obsolete clause.

EFFECTIVE DATE: This rule is effective December 8, 2006.

FOR FURTHER INFORMATION CONTACT: Tom O'Toole, NASA, Office of Procurement, Contract Management Division (Suite 5J86); (202) 358–0478; e-mail: *thomas.otoole@nasa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

This final rule makes several administrative changes to the NFS. The dollar thresholds in 1805.303(a)(i), 1819.7103, 1819.7219(a)(2), 1825.400(b), and 1828.103–70(a)(2) are revised to reflect the recent FAR changes made by Federal Acquisition Circular 2005–13 to adjust acquisition-related thresholds for inflation, in accordance with 41 U.S.C. 431a as added by section 807 of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005 (Pub. L. 108–375).

This rule deletes NFS Subpart 1827.6, Foreign License and Technical Assistance Agreements, and the clause at NFS 1852.227–87, Transfer of Technical Data Under Space Station International Agreements. This subpart and clause were developed for the Space Station Freedom Program, which was cancelled in 1993. In February 2000, the related subject matter was addressed for all NASA programs and projects (including the International Space Station Program) in the clause at 1852.225–70, Export Licenses, and its associated guidance at 1825.1103–70. The subject coverage was thus rendered obsolete, but its deletion was overlooked.

This rule also revises the ''Head of the contracting activity'' definition in 1802.101 to reflect an organizational change.

This rule corrects the outdated address for the Center for AeroSpace Information in the clauses at 1852.235–70, Center for AeroSpace Information,

and 1852.235–73, Final Scientific and Technical Reports, by deleting the street address and substituting the Internet address.

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

B. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this final rule. This final rule does not constitute a significant revision within the meaning of FAR 1.501 and Public Law 98–577, and publication for public comment is not required. However, NASA will consider comments from small entities concerning the affected NFS coverage in accordance with 5 U.S.C. 610. Interested parties should cite 5 U.S.C. 601, *et seq.*, in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act (Pub. L. 104-13) is not applicable because the NFS changes do not impose information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq*.

List of Subjects in 48 CFR Parts 1802, 1805, 1819, 1825, 1827, 1828, and 1852

Government procurement.

Sheryl Goddard,

Acting Assistant Administrator for Procurement.

■ Accordingly, 48 CFR Parts 1802, 1805, 1819, 1825, 1827, 1828, and 1852 are amended as follows:

■ 1. The authority citation for 48 CFR Parts 1802, 1805, 1819, 1825, 1827, 1828, and 1852 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1).

PART 1802—DEFINITIONS OF WORDS AND TERMS

■ 2. Amend section 1802.101 by removing the words ''Assistant Administrator for Management Systems'' in the first sentence of the definition of ''Head of the contracting activity (HCA)'' and adding ''Director for Headquarters Operations'' in its place.

PART 1805—PUBLICIZING CONTRACT ACTIONS

■ 3. Amend section 1805.303 by removing the reference to ''$3 million'' in paragraph (a)(i) and adding ''$3.5 million'' in its place.

PART 1819—SMALL BUSINESS PROGRAMS

■ 4. Amend section 1819.7103 by removing the reference to ''$500,000'' and adding ''$550,000'' in its place.

■ 5. Amend section 1819.7219 by removing the reference to ''$500,000'' in paragraph (a)(2) and adding ''$550,000'' in its place.

PART 1825—FOREIGN ACQUISITION

■ 6. Amend section 1825.400 by removing the reference to ''$2,500'' in paragraph (b) and adding ''$3,000'' in its place.

PART 1827—PATENTS, DATA, AND COPYRIGHTS

■ 7. Remove Subpart 1827.6.

PART 1828—BONDS AND INSURANCE

■ 8. Amend section 1828.103–70 by removing the reference to ''$25,000'' in paragraph (a)(2) and adding ''$30,000'' in its place.

PART 1852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 9. Remove section 1852.227–87.

■ 10. Amend section 1852.235–70 by revising the date of the clause and paragraph (c) to read as follows:

1852.235–70 Center for AeroSpace Information.

* * * * *

Center for Aerospace Information DEC/2006

* * * * *

(c) Information regarding CASI and the services available can be obtained at the Internet address contained in paragraph (a) of this clause.

* * * * *

■ 11. Amend section 1852.235–73 by revising the date of the clause and paragraph (d) to read as follows:

1852.235–73 Final Scientific and Technical Reports.

* * * * *

Final Scientific and Technical Reports DEC/2006

* * * * *

(d) In addition to the final report submitted to the Contracting Officer, the Contractor shall concurrently provide to the Center STI/Publication Manager and the NASA Center for AeroSpace Information (CASI) a copy of the letter transmitting the final report to the Contracting Officer. The copy of the letter shall be submitted to CASI at the address listed at *http://www.sti.nasa.gov* under the ''Get Help'' link.

* * * * *

[FR Doc. E6–20783 Filed 12–7–06; 8:45 am]

BILLING CODE 7510–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 050112008-5102-02; I.D.102406B]

Fisheries of the Northeastern United States; Atlantic Herring Fishery; Total Allowable Catch Harvested for Management Area 1B

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces that 95 percent of the Atlantic herring total allowable catch (TAC) allocated to Management Area 1B (Area 1B) for fishing year 2006 is projected to be harvested by December 8, 2006. Therefore, effective 0001 hours, December 8, 2006, federally permitted vessels may not fish for, catch, possess, transfer or land more than 2,000 lb (907.2 kg) of Atlantic herring in or from Area 1B per trip or calendar day until January 1, 2007, when the 2007 TAC becomes available, except for transiting purposes as described in this document. Regulations governing the Atlantic herring fishery require publication of this notification to advise vessel and dealer permit holders that 95 percent of the Atlantic herring TAC allocated to Area 1B has been harvested, and no TAC is available for the directed fishery for Atlantic herring harvested from Area 1B.

DATES: Effective 0001 hrs local time, December 8, 2006, through 2400 hrs local time, December 31, 2006.

FOR FURTHER INFORMATION CONTACT: Don Frei, Fishery Management Specialist, at (978) 281–9221.

SUPPLEMENTARY INFORMATION: Regulations governing the Atlantic herring fishery are found at 50 CFR part 648. The regulations require annual specification of optimum yield, domestic and foreign fishing, domestic and joint venture processing, and management area TACs. The 2006 TAC allocated to Area 1B for the fishing year (71 FR 10867, March 3, 2006) is 10,000 mt (22,046,226 lb).

The regulations at 50 CFR 648.202 require the Administrator, Northeast Region, NMFS (Regional Administrator) to monitor the Atlantic herring fishery in each of the four management areas designated in the Fishery Management Plan for the Atlantic Herring Fishery and, based upon dealer reports, state data, and other available information, to determine when the harvest of Atlantic herring is projected to reach 95 percent of the TAC allocated. When such a determination is made, NMFS is required to publish notification in the Federal Register of this determination. Effective upon a specific date, NMFS must notify vessel and dealer permit holders that vessels are prohibited from fishing for, catching, possessing, transferring or landing more than 2,000 lb (907.2 kg) of herring per trip or calendar day in or from the specified management area for the remainder of the closure period. Transiting of Area 1B is allowed under the conditions specified below.

The Regional Administrator has determined, based upon dealer reports and other available information, that 95 percent of the total Atlantic herring TAC allocated to Area 1B for the 2006 fishing year is projected to be harvested by December 8, 2006. Therefore, effective 0001 hrs local time, December 8, 2006, federally permitted vessels may not fish for, catch, possess, transfer or land more than 2,000 lb (907.2 kg) of Atlantic herring in or from Area 1B per trip or calendar day through December 31, 2006; except a vessel may transit, or land herring in Area 1B with more than 2,000 lb (907.2 kg) of herring on board, provided such herring were not caught in Area 1B, and provided all fishing gear is stowed and not available for immediate use as required by ' 648.23(b). Effective December 8, 2006, federally permitted dealers are also advised that they may not purchase Atlantic herring from federally permitted Atlantic herring vessels that harvest more than 2,000 lb (907.2 kg) of Atlantic herring from Area 1B through December 31, 2006, 2400 hrs local time.

Classification

This action is required by 50 CFR part 648 and is exempt from review under E.O. 12866.

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

Dated: December 4, 2006.

Alan D. Risenhoover,

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

[FR Doc. 06–9604 Filed 12–5–06; 1:36 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 71, No. 236
Friday, December 8, 2006

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

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 272 and 273

[Amendment No. 399]

RIN 0584–AB51

Food Stamp Program: Disqualified Recipient Reporting and Computer Matching Requirements That Affect the Food Stamp Program

AGENCY: Food and Nutrition Service, USDA.

ACTION: Proposed rule.

SUMMARY: In this rule the Food and Nutrition Service proposes to codify prisoner verification and death matching procedures mandated by legislation and previously implemented through agency directive. The proposed rule will require that State food stamp agencies use disqualified recipient data to screen all program applicants prior to certification to assure that they are not currently disqualified from the program and thus ineligible to participate. The proposed rule also addresses requirements that State food stamp agencies participate in a computer matching program using a system of records that adhere to provisions of the Computer Matching and Privacy Protection Act of 1988, as amended. Finally, publication of this proposed rule responds to findings of General Accounting Office and USDA Office of Inspector General audits that found, among other things, that the disqualified reporting subsystem process could be improved to enhance State agency ability to identify currently disqualified food stamp recipients.

DATES: Comments must be received on or before February 6, 2007.

ADDRESSES: The Food and Nutrition Service (FNS) invites interested persons to submit comments on this proposed rule by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- E-mail: Comments may be e-mailed to *Ed.Speshock@fns.usda.gov.* Include ''DRS Proposed Rule'' in the subject line of the message.
- Fax: Comments may be faxed to the attention of Edward Speshock at (703) 605–0795.
- Mail: Comments may be submitted to the Food and Nutrition Service, Food Stamp Program, Program Accountability Division, State Administration Branch, USDA, 3101 Park Center Drive, Alexandria, Virginia 22302.

All comments will be available for public inspection at the above address between the hours of 9:30 a.m. and 3:30 p.m. Monday through Friday. You may also download an electronic version of this proposed rule at *http://www.fns.usda.gov/fsp/rules/Regulations/default.htm.*

FOR FURTHER INFORMATION CONTACT: For questions about this proposed rule, contact Mr. Edward Speshock at (703) 305–2383.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This proposed rule has been determined to be significant and was reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Impact Analysis

Need for Action

This action is proposed to codify changes in procedures regarding prisoner verification mandated by the Balanced Budget Act of 1997 (Pub. L. 105–33) and amendments to the Food Stamp Act enacted in Public Law 105–379 (Food Stamp Fraud Prevention) regarding death matching. The Balanced Budget Act amendment requires each State to establish a system to ensure that persons under court ordered detention are not counted as members of food stamp households. The Public Law 105–379 amendment requires State agencies to ensure deceased individuals are not counted as household members. The proposed rule also includes requirements that State food stamp agencies participating in computer matching programs using a system of records adhere to provisions of the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503), as amended. In addition, this action proposes to revise Food Stamp Program (Program) regulations to enforce penalties for intentional Program violations (IPV) on disqualified food stamp recipients identified by the disqualified reporting system process.

Costs/Benefits

Prisoner verification and death match procedures were mandated by legislation and implemented by agency directive some years ago. Currently all States perform data matches of prisoner and death records at certification. However, with regard to matches with client disqualification information, currently States are only required to do periodic matches and only a few States perform routine matches at initial certification. The resultant annual Program savings from these ongoing matches at certification are estimated to be $100 million for the five-year period 2006–2010. Further, no State performs routine matches at recertification against prisoner records, death records, or records of client disqualification. Requiring all States to match against disqualification records at initial certification and to match against prisoner, death, and disqualification records at recertification will yield an estimated $51 million in Program savings during the five-year period 2006–2010, including $15 million in one-time savings from performing matches on long-term participants who never were matched at initial certification. Total Program savings for initial certification and recertification will total an estimated $30 million the first full year of implementation and $151 million for the period 2006–2010.

Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). Nancy Montanez Johner, Under Secretary for Food, Nutrition, and Consumer Services, has certified that this rule will not have a significant economic impact on a substantial number of small entities. State and local welfare agencies will be the most affected to the extent that they administer the Program. Applicants and participants may be affected to the extent that matching client information with Disqualified Recipient Subsystem (DRS) records may identify a current finding of an IPV and therefore prevent Program participation.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Under Section 202 of the UMRA, FNS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, Section 202 of the UMRA generally requires FNS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule. This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, and tribal governments or the private sector of $100 million or more in any one year. This rule, therefore, is not subject to the requirements of Sections 202 and 205 of the UMRA.

Executive Order 12372

The Food Stamp Program is listed in the Catalog of Federal Domestic Assistance under No. 10.551. For the reasons set forth in the Final Rule codified in 7 CFR part 3015, Subpart V and related Notice (48 FR 29115), this Program is excluded from the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's consideration in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13132.

Prior Consultation with State Officials

Prior to drafting this proposed rule, FNS consulted with State and local agencies at various times. Because the Food Stamp Program is a State administered, Federally funded program, FNS regional offices have formal and informal discussions with State and local officials on an ongoing basis regarding program implementation and policy issues. This arrangement allows State and local agencies to provide comments that form the basis for many discretionary decisions in this and other food stamp rules. FNS has responded to numerous written requests for policy guidance on IPV disqualification data reporting. Also, guidance for the prisoner verification and deceased data matching programs were implemented by agency directive with the consultation and input from State and local food stamp agencies.

Nature of Concerns and the Need to Issue This Rule

State and local food stamp agencies generally want greater flexibility in the implementation of Program administrative responsibilities. This proposed rule, in our opinion, will provide flexibility in this area and also address another major State concern, which is the need to conform FSP rules to the rules of other means-tested Federal programs. Specific policy questions submitted by State agencies helped FNS identify issues that needed to be addressed in the proposed rule.

Extent to Which We Meet Those Concerns

FNS has considered the impact of this proposed rule on State and local agencies. This rule proposes changes that are required by law, such as the prisoner verification and deceased person data match programs. These changes were implemented by agency directives in response to implementation time frames required in legislation. The proposed changes to Food Stamp Program rules describing State agency responsibility for reporting IPV disqualification information will clarify information access and follow-up procedures, and provide greater flexibility to State agencies for processing, retaining and sharing disqualification information. FNS is not aware of any case where the discretionary provisions of the rule would preempt State law. In addition, FNS invites State agencies to submit requests for waiver consideration of any discretionary provisions of this rule where a State agency can demonstrate that its own procedures would be more effective and efficient; such a waiver would not result in a material impairment of any statutory or regulatory rights of participants; and, such a waiver would otherwise be consistent with the waiver authority set out at §§ 272.3(c).

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State and local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full implementation.

This rule is not intended to have retroactive effect unless so specified in the Effective Dates paragraph of the final rule. Prior to any judicial challenge to the provisions of this rule or the application of its provisions, all applicable administrative procedures must be exhausted.

In the Food Stamp Program, the State administrative procedures for Program benefit recipients are issued pursuant to 7 U.S.C. 2020(e)(1) and set forth at § 273.15; the administrative procedures for State agencies are issued pursuant to 7 U.S.C. 2023 and are set out at § 276.7 (for rules related to non-QC liabilities) or 7 CFR Part 283 (for rules related to QC liabilities); and the administrative procedures for retailers and wholesalers are issued pursuant to 7 U.S.C. 2023 and set out at § 278.8 and 7 CFR Part 279.

Civil Rights Impact Analysis

FNS has reviewed this rule in accordance with the Department Regulation 4300–4, ''Civil Rights Impact Analysis,'' to identify and address any major civil rights impact the rule might have on protected classes, including minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, and the characteristics of food stamp households and individual participants, FNS has determined that there is no way to soften the effect on any of the protected classes. All data available to FNS indicate that protected individuals have the same opportunity to participate in the Food Stamp Program as non-protected individuals. FNS specifically prohibits State and local government agencies that administer the Program from engaging in actions that discriminate based on race, color, gender, age, disability, marital status or family status. (FSP nondiscrimination policy can be found at § 272.6(a)). Where State agencies have options, and they chose to implement a certain provision, they must implement it in such a way that it complies with the regulations at § 272.6.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 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. This proposed rule contains information collections that are subject to review and approval by OMB; therefore, FNS is submitting for public comment the changes in the information collection burden that would result from the adoption of the proposals in this rule.

Comments on the collection of information in this proposed rule must be received by February 6, 2007.

Send comments to Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for FNS, Washington, DC, 20503. Please also send a copy of your comments to Edward Speshock, State Administration Branch, Program Accountability Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, VA, 22302. For further information, or for copies of the information collection, please contact Mr. Speshock at the above address. Comments are invited on: (a) Whether the proposed collection of information is necessary for the performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimates of the burden of the proposed collection of information including the validity of the methodology and the assumptions used; (c) ways to enhance the equality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Title: Repayment Demand and Program Disqualification.

OMB Number: 0584–0492.

Expiration Date: April 30, 2008.

Type of Request: Revision of a currently approved collection.

Abstract: Under §§ 273.2(f)(11) and 273.16 State agencies are required to report and verify information on disqualified individuals to FNS. This is not a new requirement. Previously, State agencies have been required to report such information via paper report form to FNS regional offices to be entered into a disqualified recipient database. Printouts or computer tapes were then provided to the States for their use in meeting intentional Program violation requirements. This reporting is now handled electronically from the States to the FNS disqualified recipient database.

With the provisions in this rule, we are proposing to amend the data requirements and the frequency with which state agencies access the disqualified reporting subsystem. Other burden requirements remain unchanged.

Respondents: State Agencies.

Estimated Number of Respondents: 53.

Estimated Burden:

DISQUALIFICATION REPORTING *

Component	Number of respondents	Total annual responses	Time per response in hours	Annual burden hours
Applicant/Recipient Screening	53	10.1 million ..	.041667	423,333
Disqualified Penalty Screening	53	60,000	.041667	2,500

* Note: The burden for DRS applicant/recipient screening and penalty screening is in addition to the total currently approved of 166,329 hours. The revised total annual Burden is therefore 589,662 (166,329 plus 423,333).

REPAYMENT DEMAND AND PROGRAM DISQUALIFICATION

Component	Number of respondents	Total annual responses	Time per response in hours	Annual burden hours
Estimated Burden for Repayment Demand and Program Disqualification	53	1,600,981	0.10389	166,326

Total Annual Burden: Currently approved burden is 166,329 hours. This submission would increase total burden by 423,333 hours.

E-Government Act Compliance

The Food and Nutrition Service is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes. As described above, the information collection associated with this regulation is available for electronic submission.

Background

Prisoner Verification System (PVS) Matching Program

Section 1003 of the Balanced Budget Act of 1997 (Pub. L. 105–33) amended Section 11(e) of the Food Stamp Act of 1977 (7 U.S.C. 2020(e)) to require States to establish systems and take periodic action to ensure that an individual who is detained in a Federal, State, or local penal, correctional, or other detention facility for more than 30 days shall not be eligible to be counted as household members participating in the Food Stamp Program. The mandated requirements of the Balanced Budget Act of 1997 became effective on August 5, 1998. For the purpose of this rule the term ''Federal, State, or local penal, correctional or other detention facility'' includes, but is not limited to, city, county and multi-jurisdictional jails, work and boot camps, residential halfway houses (e.g., in conjunction with work release or community service programs), detention centers (including juvenile detention centers), and mental health and medical facilities housing prisoners on behalf of correctional institutions. Individuals who are detained in residential halfway houses or who are detained under house detention, should not be denied eligibility unless the State agency has determined that the individual's meals are provided by the institution. This requirement strengthens current regulations at § 273.1(a), which prohibit the inclusion of an individual who is currently in an institution described above as a member of a food stamp household. States should continue to follow the procedures at § 273.1(a) in

establishing household composition at certification and periodically thereafter. The required verification system should be used to verify that no household member is under detention in a prison facility, in conjunction with established verification rules at § 273.2(f). The law further provides that a State opting to obtain and use prisoner information collected by the Social Security Administration (SSA) under Section 1611(e)(1)(I)(i)(I) of the Social Security Act (42 U.S.C. 1382(e)(1)(I)(i)(I)) pursuant to Section 1611(e)(1)(I)(ii)(II) (42 U.S.C. 1382(e)(1)(I)(ii)(II)) of that Act, shall be considered in compliance with this provision. Finally, the law provides that such verification be performed ''periodically.'' However, it does not specify when verification must take place. FNS believes it is good administrative practice to prevent errors before they happen. Therefore, we are proposing to amend current regulations by adding a new § 272.13(c) to require States to conduct PVS checks at application and re-certification.

Matching Death Records

This proposed rule implements requirements to match death records enacted by Public Law 105–379 on November 12, 1998. Public Law 105–379, which amended Section 11 of the Food Stamp Act (7 U.S.C 2020), requires all State agencies to enter into a cooperative arrangement with the Social Security Administration (SSA) to obtain information on individuals who are deceased and use the information to verify and otherwise ensure that benefits are not issued to such individuals. The law was effective on June 1, 2000. The mandated requirements were implemented by FNS directive to all food stamp State agencies on February 14, 2000. State agencies are responsible for entering into a matching agreement with the SSA in order to access information on deceased individuals. This rule proposes to add a new § 272.14 to codify this requirement in regulation and to describe requirements for accessing the SSA death master file.

Under current rules at § 273.12(a) and § 273.21, it is the food stamp household's responsibility to report changes in household composition, such as the addition or loss of a household member. Households must report household composition changes within 10 days of becoming aware of the change or, if subject to periodic reporting, by the appropriate date. Thus, the accuracy of program benefits issued to a household relies on the accuracy of reported and verified information.

The SSA death master file database contains over 60 million records. SSA receives death reports from numerous sources, including the Centers for Medicare and Medicaid Services, Department of Veterans Affairs, postal authorities, and other internal and external sources. A small percentage of deaths reported to SSA are from family members and funeral homes.

FNS proposes in new § 272.14 that State agencies independently verify the records before taking adverse action against a household with an unreported deceased household member. This is consistent with amendments to the Computer Matching Act requiring that computer match information be verified before it can be used to take action against an individual.

State food stamp agencies are encouraged to use the SSA State Verification and Exchange System (SVES) for accessing deceased information. Use of SVES would be the most cost-effective method since State agencies already have agreements with SSA to access information through SVES.

In this rule, FNS is proposing standards for how often State agencies must conduct matches to be reasonably certain that food stamp benefits are not being issued to deceased individuals. Thus, consistent with other matches described in this rule, we are proposing that State agencies conduct a match for deceased household members at certification and recertification. This minimum standard for how often a match must be conducted is specified in the rule under newly proposed § 272.14.

Disqualified Recipient Matching

FNS participates in a computer matching program in which it serves as both a source and a recipient agency. This required Federal matching program known as the Disqualified Recipient Subsystem (DRS) uses a Computer Matching and Privacy Protection Act system of records and contains information about individuals who have been disqualified from the Food Stamp Program for an IPV (See 5 U.S.C. 552a (o), (p) and (q)). The database can be accessed by State agencies to assign the legally required penalty period for intentional Program violations. State agencies also use information from the system to screen new applicants and current food stamp recipients to determine if they should be serving a disqualification penalty imposed by another State. The Computer Matching and Privacy Protection Act provides that the Office of Management and Budget shall be responsible for computer matching guidance. Final guidance was published in the **Federal Register** on June 19, 1989, at 54 FR 25818, and is incorporated by reference in this proposed rule. FNS proposes to amend § 273.2(f) to address the verification requirements for the disqualified recipient matching program. Current regulations at § 273.16(i)(4) provide that, at a minimum, the disqualification data submitted to FNS by State agencies shall be used to determine the appropriate disqualification penalty to impose, based on past disqualifications, and the eligibility of individual Program applicants prior to certification in cases where the State agency has reason to believe a household member is subject to disqualification in another State. Under this proposed rule State food stamp agencies must also begin to use disqualified recipient data to screen all program applicants prior to certification. State agencies may also periodically match the entire database of disqualified individuals against their current recipient caseload to determine if the applicant or recipient should be serving a disqualification.

FNS proposes in new § 273.2(f)(11)(iii), that a State agency may not take any adverse action to terminate, deny, suspend, or reduce benefits to an applicant or food stamp recipient based on information produced by a disqualified recipient match unless the match information has been independently verified. This is consistent with the Computer Matching Act that ensures client due process protection by requiring the matching agency to provide applicants and/or recipients a notice and opportunity to contest when a specific match result may lead to an adverse action. FNS also proposes in new § 273.2(f)(11)(iv) that the State agency initiating the disqualified recipient search contact the State agency locality contact that originated the disqualification or the applicant or recipient household for verification prior to taking an adverse action. The disqualified recipient match information would be verified by obtaining a copy of the original document, or copies of documentation of an individual's disqualification history (past and current disqualifications) or confirmation of the existence of specific relevant documents that substantiate the disqualification record. Under the proposal, documentation would include, but not be limited to, court determinations, signed declarations by individuals waiving the right to an administrative disqualification hearing, signed disqualification consent agreements by individuals, a hearing authority's

decision, and the notification of disqualification. Any confirmation as to the existence of the above documentation shall be made by the originating State's locality contact or another designated State official. Written confirmation shall be documented in the case record with a copy of one of the documents described above. This is consistent with current verification procedures at § 273.2(f)(4) that documentary evidence shall be the primary source of verification.

To ensure interstate cooperation, FNS further proposes to require that disqualification documentation be transmitted to a requesting State agency in a timely fashion. To encourage cooperation in the exchange of documentation, FNS proposes to provide State agencies the flexibility to decide how the information can be exchanged. FNS will permit alternatives including, but not limited to, reviewing original documents related to prior disqualifications; written confirmation of having seen the documents; obtaining copies of original documents from each State that played a role in the determination and implementation of the prior disqualifications; and, obtaining copies of supporting documentation for all disqualifications from the last State agency to take a disqualification action against an individual. FNS intends by this proposed rule that requests and responses to requests for verification must be transmitted in a manner that protects the privacy of the individual household.

FNS does not intend to require a specific timeframe for State agencies to respond to various types of requests for verification. Prompt responses to verification requests, however, can help to expedite the delivery of benefits and avoid or reduce any overissuance to the household containing the individual in question. FNS believes it is in each State agency's interest to expedite requests for verification since all State agencies may find themselves in the position of a requesting agency at some point. Prudent management would suggest that a State agency that receives a request for documentation supporting disqualification information must be able to respond to the request within a reasonable amount of time from the date it receives the request. For this purpose the proposed rule will define a ''reasonable amount of time'' to be 20 working days or less from the postmarked date of request. FNS requests comments that support this definition or provide reasoned arguments suggesting a more workable definition of a ''reasonable amount of time''.

State agencies must act promptly to request verification to ensure that documentation can be made available to them in sufficient time to avoid the possibility of delays in the processing of applications pursuant to § 273.2(h). The State agency making the request should document in the case record the period of elapsed time taken by the State agency locality contact for verification to be provided.

In the event a State agency is not able to provide independent verification of a disqualified recipient match because of a lack of supporting documentation, the State agency would be required to advise the requesting State agency, or FNS (in the case of resolving a dispute about the accuracy of a disqualification record), as appropriate, and take immediate action to remove the unsupported disqualified record from the disqualification database. Procedures for reporting such disqualification records are proposed in § 273.16(i) of this rule. In such instances, the requesting State agency would be prohibited from taking any adverse action against the household based on the unverified disqualification information.

FNS proposes, in new § 273.2(f)(11)(vi), that the requesting State agency would enter the received information into the household's case record immediately upon receipt. The documentation should be reviewed to insure that the information pertains to the individual and disqualification in question. Once satisfied about the validity of the information, the requesting State shall provide the household notice of the IPV match result (along with the intended action to be taken based on the computer match) and an opportunity to contest by sending the appropriate notice to the household.

States are prohibited from denying benefits to an applicant household without first verifying the accuracy of the disqualification information. State agencies shall not deny an application if the independent verification is not available in time to satisfy the application processing standard. This policy is consistent with procedures at § 273.2(f). Also, the 30-day application processing standard at § 273.2(f) applies if a State agency is matching applicant information using the optional IVES and SAVE verification systems. FNS believes the policy pertaining to IPV matches should be consistent in order to provide the State agency a uniform procedure for reviewing and verifying all independently verified information. If the information under verification indicates that an individual is currently disqualified, then the individual would not be eligible to receive benefits and certifying eligibility would result in an overissuance. A State certifying the ineligible individual would, once corroboration is received, issue a notice of adverse action to remove the individual from the program, adjust the household's allotment, and possibly establish a recipient claim against the household for the overissued benefits. The proposed rule is intended to reduce the incidence of ineligibility determination and unnecessary administrative burden.

Application Screening To Determine Status of Eligibility

Current regulations at § 273.11(c) are silent regarding a disqualified individual who moves from one jurisdiction or State to another while disqualified and, either as a single household or as a member of another food stamp household, applies for benefits. Accordingly, FNS proposes to amend § 273.11(c)(4)(i) to require that the disqualified individual and, if applicable, the household, be informed of their eligibility status and the effect of the disqualification on the eligibility and benefits of the remaining household members. FNS intends that the State agency follow the procedures in § 273.11(c) for determining if the household is still eligible for benefits and what the new benefit amount will be.

Disqualified Recipient Data Requirements

Current food stamp regulations at § 273.16(i) provide that State agencies shall report individuals to FNS who have been disqualified due to an intentional Program violation. FNS proposes to amend § 273.16(i) to update the format used by State agencies to report and access intentional Program violation disqualification information. The new data elements to be included in the revised format are Decision Date; Gender; Type of Offense; and, Locality Contact Information. In addition, FNS proposes to include new language in § 273.16(i) that describes the ''electronic transmittal from the State agency'' to FNS of IPV information. State agencies have been provided extensive information and consultation by FNS to evaluate the options for submitting data including documentation, training and user manuals. FNS has worked with States to ensure the options are varied and flexible enough to make it technically feasible for all State agencies to electronically submit the information

required under this proposed rule. FNS therefore proposes to amend § 273.16 to include these four new elements to provide data clarification and to promote conformity with other Federal databases, such as those from the Social Security Administration, which includes this information as data fields in computer matches.

This proposed rule would also define ''disqualification decision date'' as the date a disqualification decision was rendered as a result of either an administrative or judicial hearing, or the date an individual signs either a waiver of his/her right to an administrative disqualification hearing or a disqualification consent agreement waiving his/her right to a court hearing. By signing a waiver or disqualification consent agreement, an individual agrees to accept a disqualification penalty in lieu of a hearing. Addition of the disqualification decision date makes it easier for State agencies to track and verify information about individual disqualifications. The above definition is included in § 273.16(i)(3)(i) of this proposed rule. In addition, proposed section § 273.16 (i)(3)(iii) defines a ''locality contact'' as a person, position or entity designated by the State agency as the point of contact for other State agencies to verify information in a disqualification record supplied by the locality contact's State.

FNS is proposing to include a field to record the type of offense—the action an individual took or failed to take which resulted in an intentional Program violation as defined in § 273.16(c)—in order to identify violations applicable to the increased penalties for illegally exchanging coupons for firearms, ammunition, explosives or controlled substances. In addition to providing statistical data on the number of violations affected by the new penalties, this field would make it easier for State agencies to track and assign the appropriate penalty. FNS also believes that valuable information can be obtained from the reporting of various types of violations that will be made available to States. Reporting of these violations could assist FNS in determining, for example, where stiffer penalties could be enforced for certain violations. FNS intends to produce a list of offenses by category for reporting purposes. Each category will be assigned its own code. State agencies would be required to report the type of offense by recording the appropriate code.

Current regulations at § 273.16(i)(4) describe the uses of the data. FNS intends to retain present mandatory uses of the data. FNS is proposing to amend this Section to require that State food stamp agencies use disqualification data in the determination of the eligibility of all applicants or current recipients of program benefits. FNS believes Congressional intent in requiring a database of disqualified recipient information is to give State agencies the ability to determine and assign the appropriate period of disqualification for persons who commit intentional Program violations and to ensure that the appropriate penalty is enforced. In order to ensure that individuals who are not entitled to benefits due to a disqualified recipient disqualification are prevented from participating, FNS believes States must screen applicants at certification and current recipient caseload periodically. FNS believes this requirement will strengthen the effectiveness of State agencies in reducing the potential for overissuance of program benefits.

Accordingly, the requirements at § 273.16(i)(4) are being expanded to describe the need to screen disqualified recipient data at certification and included under the proposed new § 273.2(f)(11) as paragraphs (f)(11)(i)(A), (f)(11)(i)(B), (f)(11)(iii)(A), and (f)(11)(iii)(B).

Disqualification Record Retention

The current regulations at § 272.1(f) require that program records be retained for a period of 3 years from the month of origin and that fiscal records such as those relating to claims and restored benefits and accountable documents be retained for 3 years from the date of fiscal or administrative closure. The current regulations at § 273.16(b) provide that an individual can be disqualified from participating in the program permanently. ''Permanent'' in this rule is defined as the remainder of the individual's lifetime or another shorter period established by FNS as administratively appropriate. Due to the nature of the disqualification penalties, FNS believes it is appropriate that case records relating to intentional Program violation disqualifications, associated client notices, and records generated as a result of using disqualification information be retained indefinitely, until the State agency receives reliable information that the person has died, or until advised by FNS that the individual is 80 years old and the State should remove the record from the database. Retaining such records indefinitely or until the disqualified individual reaches his/her 80th birthday will assure that accurate information is retained and available consistent with Congressional intent.

Accordingly, in addition to proposed requirements in § 273.16(i) of this proposed rule to update or delete disqualification records under certain circumstances, FNS proposes, in § 272.1(f)(3), that disqualification records provided to State agencies be maintained by the State agencies for as long as such records are accurate, timely, relevant, and complete. Each State shall be responsible for the destruction of disqualified recipient records in their possession when they are no longer accurate, timely, relevant, and complete. FNS expects that this records destruction will take place automatically each time a State food stamp agency receives a new or updated database from FNS or in accordance with a formal process of periodic review and purging of these records. State food stamp agencies would be permitted to follow prescribed records management programs to meet this requirement. Information about the State's records management program is included with the State agency plan as described in § 272.10(b)(3) of Program regulations.

Computer Match Benefit Adjustments

Food stamp households receiving benefits under Federal benefit programs may periodically receive cost-of-living adjustments (COLAs). State agencies are required under § 273.12(e)(3) to establish procedures for making changes to food stamp benefits to reflect these COLAs and to provide a notice of change to affected households. Current COLA adjustment procedures take two forms. Under the first method, a State agency may calculate the expected increase by applying the appropriate percentage adjustment to the household's current income. Under the second method, a State agency may use results of a computer match of the updated income information to adjust household income. The recalculated, or updated, income information then provides the basis for recalculating the household's food stamp benefit.

The second method for making benefit adjustments constitute a computer match covered by the Computer Matching Act. It compares information provided by a Federal source to a State record, using a computer to perform the comparison; and it affects eligibility or the amount of benefits for a Federal benefit program. Therefore, the information must be independently verified and the food stamp household must be provided notice and an opportunity to contest the adverse action if the adjustment would change the level of benefits or eligibility status of the household.

Accordingly, the Department is proposing to amend § 273.12(e)(3) to specify that there will be two procedures for states to apply in determining COLA adjustments. A new § 273.12(e)(3)(i) is proposed to allow the use of calculated percentage increases to present COLAs. A new § 273.12(e)(3)(ii) would allow the use of computer information from a Federal agency database to make the adjustment and require independent verification and notice in accordance with § 273.2(f)(9). The Department is also proposing to amend § 273.13(b)(1) to require that a notice of adverse action be sent when computer generated adjustments result in increased income and a change of food stamp benefits.

Implementation

State agencies have been instructed through FNS directive to implement the provisions of the prisoner verification (Pub. L. 105–33) and Death File matches (Pub. L. 105–379) as required in the applicable legislation and without waiting for formal regulations. Implementing requirements of the Computer Matching and Privacy Act (Pub. L. 100–503) as they may pertain to IPV matching agreements and procedures for denial of benefits resulting from these computer matches are incorporated by reference in this proposed rule. FNS proposes that the changes in this rule be effective and must be implemented the first day of the month 60 days from date of publication of the final rule. FNS intends to require that the provisions of the final rule which reformat database information elements would be implemented by requiring State food stamp agencies to begin identifying the new data elements for IPV reporting purposes described in § 273.16—locality contact, disqualification decision date, type of offense and gender—not later than 90 days from the effective date of the final rulemaking. State food stamp agencies shall have up to 180 days after the effective date of the final rule to implement one of the optional uses of disqualified reporting system identified at § 273.16(i). Finally, FNS proposes that State food stamp agencies would be required to comply with all remaining provisions of the final rulemaking not later than 180 days from the publication date of the final rulemaking.

List of Subjects

7 CFR Part 272

Civil rights, Food stamps, Grant programs-social programs, Reporting and recordkeeping requirements.

7 CFR Part 273

Administrative practice and procedure, Claims, Food stamps, Fraud, Grant programs-social programs, Penalties, Reporting and recordkeeping requirements, Social Security.

For the reasons set out in the preamble, 7 CFR Parts 272 and 273 are proposed to be amended as follows:

1. The authority citation for Parts 272 and 273 continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

PART 272—REQUIREMENTS FOR PARTICIPATING STATE AGENCIES

2. In § 272.1, paragraph (f) is revised to read as follows:

§ 272.1 General terms and conditions.

* * * * *

(f) *Retention of records.* Each State agency shall retain all program records in an orderly fashion, for audit and review purposes, for a period not less than 3 years from the month of origin of each record. In addition:

(1) The State agency shall retain fiscal records and accountable documents for 3 years from the date of fiscal or administrative closure. Fiscal closure means that obligations for or against the Federal Government have been liquidated. Administrative closure means that the State agency has determined and documented that no further action to liquidate the obligation is appropriate. Fiscal records and accountable documents include but are not limited to claims and documentation of lost benefits.

(2) Case records relating to intentional Program violation disqualifications and related notices to the household shall be retained indefinitely, until the State agency obtains reliable information that the record subject has died, or until FNS advises via the edit report that records for a particular individual should be permanently removed from the database because of the individual's 80th birthday.

(3) Disqualification records in a State agency's possession must be periodically purged when they are no longer accurate, relevant, timely, or complete. The State agency shall follow a prescribed records management program to meet this requirement. Information about this program shall be available for FNS review.

(4) Retention methods for Authorization to Participate cards are provided in Part 274 of this chapter.

* * * * *

3. New §§ 272.12, 272.13, and 272.14 are added to read as follows:

§ 272.12 Computer matching requirements.

(a) *General purpose.* The Computer Matching and Privacy Protection Act (CMA), as amended, addresses the use of information from computer matching programs that involve a Federal System of Records subject to the Privacy Act of 1974, as amended. Each State agency participating in a computer matching program shall adhere to the provisions of the CMA if it uses an FNS system of records for the following purposes:

(1) Establishing or verifying initial or continuing eligibility for Federal benefit programs;

(2) Verifying compliance with either statutory or regulatory requirements of the Federal benefit programs; or

(3) Recouping payments or delinquent debts under such Federal benefit programs.

(b) *Matching agreements.* State agencies must enter into written agreements with USDA/FNS, consistent with 5 U.S.C. 552a(o) of the CMA, in order to participate in a matching program involving a USDA/FNS Federal system of records.

(c) *Use of computer matching information.*

(1) A State agency shall not take any adverse action to terminate, deny, suspend, or reduce benefits to an applicant or recipient based on information produced by a Federal computer matching program that is subject to the requirements of the CMA, unless:

(i) The information has been independently verified by the State agency (in accordance with the independent verification requirements set out in the State agency's written agreement as required by paragraph (b) of this section) and a Notice of Adverse Action or Notice of Denial has been sent to the household, in accordance with § 273.2(f); or

(ii) The Federal agency's Data Integrity Board has waived the two-step independent verification and notice requirement and notice of adverse action has been sent to the household, in accordance with § 273.2(f).

(2) A State agency which receives a request for verification from another State agency, or from FNS pursuant to the provisions of § 273.16(i) shall, within 20 working days of receipt, respond to the request by providing necessary verification (including copies of appropriate documentation and any statement that an individual has asked to be included in their file), as provided in § 273.16(i)(4).

§ 272.13 Prisoner verification system (PVS).

(a) *General.* Each State agency shall establish a system to monitor and prevent individuals who are under detention in any Federal, State, and/or local detention or correctional institutions for more than 30 days from being included in a food stamp household.

(b) *Use of match data.* State prisoner verification systems shall provide for:

(1) The comparison of identifying information about each household member against identifying information about inmates of institutions at Federal, State and local levels;

(2) The reporting of instances where there is a match;

(3) The independent verification of match hits to determine their accuracy;

(4) Notice to the household of match results;

(5) An opportunity for the household to respond to the match prior to an adverse action to deny, reduce, or terminate benefits; and,

(6) The establishment and collections of claims as appropriate.

(c) *Match agreement.* States shall make a comparison of match data (at a minimum) at the time of application, at each recertification, and whenever a new member is added to a household. However, States that opt to obtain and use prisoner information collected under Section 1611(e)(1)(I)(i)(I) of the Social Security Act (42 U.S.C. 1382(e)(1)(I)(i)(I)) shall be considered in compliance with this section. Such States shall enter into a computer matching agreement with the SSA under authority contained in 42 U.S.C. 405(r)(3).

§ 272.14 Deceased matching system.

(a) *General.* Each State agency shall establish a system to verify and ensure that benefits are not issued to individuals who are deceased.

(b) *Data source.* States shall use the death master file data provided by the Social Security Administration (SSA). State agencies electing to obtain the data through the SSA State Verification and Exchange System (SVES) shall enter into a computer matching agreement with SSA pursuant to authority to share data contained in 42 U.S.C. 405(r)(3).

(c) *Use of match data.* States shall provide a system for:

(1) The comparison of identifying information about each household member against identifying information about deceased individuals. States shall make the comparison of match data at the time of application and periodically thereafter;

(2) The reporting of instances where there is a match;

(3) The independent verification of match hits to determine their accuracy;

(4) Notice to the household of match results;

(5) An opportunity for the household to respond to the match prior to an adverse action to deny, reduce, or terminate benefits; and,

(6) The establishment and collection of claims as appropriate.

PART 273—CERTIFICATION OF ELIGIBLE HOUSEHOLDS

4. In § 273.2, a new paragraph (f)(11) is added to read as follows:

§ 273.2 Application processing.

* * * * *

(f) * * *

(11) *Use of disqualification data.*

(i) Pursuant to § 273.16(i), information in the disqualified recipient database will be available for use by any State agency that executes a computer matching agreement with FNS. The State agency shall use the disqualified recipient database for the following purposes:

(A) Ascertain the appropriate penalty to impose based on past disqualifications in a case under consideration;

(B) Conduct matches on:

(1) Program application information prior to certification; and

(2) The current active and inactive disqualified individuals database against the current recipient caseload periodically but no less than a bi-monthly schedule.

(ii) State agencies shall not take any adverse action to terminate, deny, suspend, or reduce benefits to an applicant or food stamp recipient based on disqualified recipient match results unless the match information has been independently verified. The State agency shall provide to an applicant or recipient an opportunity to contest any adverse disqualified recipient match result pursuant to the provisions of § 273.13.

(iii) Independent verification shall take place separate from and prior to issuing a notice of adverse action—a two-step process. Independent verification for disqualification purposes means contacting the applicant or recipient household or the State agency that originated the disqualification record immediately to obtain corroborating information or documentation to support the reported disqualification information in the IPV database.

(A) Documentation may be in any form deemed appropriate and legally sufficient by the State agency. Such documentation may include but shall not be limited to, electronic or hard copies of court determinations, signed declarations by individuals waiving the right to an administrative disqualification hearing or consenting to a disqualification, a hearing authority's decision, and the notification of disqualification.

(B) A State may accept a verbal or written statement from another State agency attesting to the existence of the documentation listed in paragraph (f)(11)(iii)(A) of this section.

(C) A State may accept a verbal or written statement from the household affirming the accuracy of the disqualification information, provided such statement is properly documented and included in the case record.

(D) If a State agency is not able to provide independent verification because of a lack of supporting documentation, the State agency shall so advise the requesting State agency or FNS, as appropriate, and shall take immediate action to remove the unsupported information from the disqualified recipient database in accordance with § 273.16(i)(6).

(iv) Once received, the requesting State agency shall review and immediately enter the information into the case record and send the appropriate notice(s) to the record subject and any remaining members of the record subject's food stamp household.

(v) Information from the disqualified recipient database is subject to the disclosure provisions in § 272.1(c) and the routine uses described in the most recent ''Notice of Revision of Privacy Act System of Records'' published in the **Federal Register**.

* * * * *

5. In § 273.11, paragraph (c)(4)(i) is amended by adding a new sentence to the end of the paragraph to read as follows:

§ 273.11 Action on households with special circumstances.

* * * * *

(c) * * *

(4) * * *

(i) * * * However, a participating household is entitled to a notice of adverse action prior to any action to reduce, suspend or terminate its benefits, if a State agency determines that it contains an individual who was disqualified in another State and is still within the period of disqualification.

* * * * *

6. In § 273.12:

a. paragraph (e)(3) is amended by removing the last six sentences and adding four new sentences in their place

and by adding new paragraphs (e)(3)(i) and (e)(3)(ii); and

b. the introductory text of paragraph (e)(4) is revised.

The additions and revision read as follows:

§ 273.12 Reporting changes.

* * * * *

(e) * * *

(3) * * * A State agency may require monthly reporting households to report the change on the appropriate monthly report or may handle the change using the mass change procedures in this section. If the State agency requires the household to report the information on the monthly report, the State agency shall handle such information in accordance with its normal procedures. Households not required to report the change on the monthly report and households not subject to monthly reporting shall not be responsible for reporting these changes. The State agency shall be responsible for automatically adjusting these households' food stamp benefit levels in accordance with either paragraph (e)(3)(i) or (e)(3)(ii) of this section.

(i) The State agency may make mass changes by applying percentage increases communicated by the source agency to represent cost-of-living increases provided in other benefit programs. These changes shall be reflected no later than the second allotment issued after the month in which the change becomes effective.

(ii) The State agency may update household income information based on cost-of-living increase information supplied by a data source covered under the Computer Matching and Privacy Protection Act of 1988 (CMA) in accordance with § 272.13. The State agency shall take action, including proper notices to households, to terminate, deny or reduce benefits based on this information if it is considered verified upon receipt under § 273.2(f)(9). If the information is not considered verified upon receipt, the State agency shall initiate appropriate action and notice in accordance with § 273.2(f)(9).

(4) Notice for mass change. When the State agency makes a mass change in food stamp eligibility or benefits by simultaneously converting the caseload or that portion of the caseload that is affected using the percentage increase calculation provided for in § 273.12(e)(3)(i), or by conducting individual desk reviews using information not covered under the Computer Matching and Privacy Protection Act (CMA) in place of a mass change, it shall notify all households whose benefits are reduced or terminated in accordance with the requirements of this paragraph, except for mass changes made under § 273.12(e)(1); and

* * * * *

7. In § 273.13:

a. paragraph (a)(2) is amended by adding two new sentences to the end of the paragraph;

b. paragraph (b)(1) is revised; and

c. paragraph (b)(7) is amended by removing the first sentence of the paragraph and replacing it with three new sentences.

The additions and revision read as follows:

§ 273.13 Notice of adverse action.

(a) * * *

(2) * * * A notice of adverse action that combines the request for verification of information received through an IEVS computer match shall meet the requirements in § 273.2(f)(9). A notice of adverse action that combines the request for verification of information received through a SAVE computer match shall meet the requirements in § 273.2(f)(10).

* * * * *

(b) * * *

(1) The State initiates a mass change through means other than computer matches as described in § 273.12(e)(1), (e)(2), or (e)(3)(ii).

* * * * *

(7) A household member is disqualified for an intentional Program violation, in accordance with § 273.16, or the benefits of the remaining household members are reduced or terminated to reflect the disqualification of that household member, except as provided in § 273.11(c)(3)(i). A notice of adverse action must be sent to a currently participating household prior to the reduction or termination of benefits if a household member is found, through a disqualified recipient match, to be within the period of disqualification for an intentional Program violation penalty determined in another State. In the case of applicant households, State agencies shall follow the procedures in § 273.2(f)(11) for issuing notices to the disqualified individual and the remaining household members. * * *

* * * * *

8. In § 273.16, paragraph (i) is revised to read as follows:

§ 273.16 Disqualification for intentional program violation.

* * * * *

(i) *Reporting requirements.*

(1) Each State agency shall report to FNS information concerning individuals disqualified for an intentional Program violation, including those individuals disqualified based on the determination of an administrative disqualification hearing official or a court of appropriate jurisdiction and those individuals disqualified as a result of signing either a waiver of right to a disqualification hearing or a disqualification consent agreement in cases referred for prosecution. This information shall be submitted to FNS so that it is received in the month which is no more than 30 days after the date the disqualification took effect.

(2) State agencies shall report information concerning each individual disqualified for an intentional Program violation to FNS. FNS will maintain this information and establish the format for its use.

(i) State agencies shall report information to the disqualified recipient database in accordance with procedures specified by FNS.

(ii) State agencies shall access disqualified recipient information from the database that allows users to check for prior disqualifications.

(3) The elements to be reported to FNS are name, social security number, date of birth, gender, disqualification number, disqualification decision date, disqualification start date, length of disqualification period (in months), type of offense, locality code, and the title, location and telephone number of the locality contact. These elements shall be reported in accordance with procedures prescribed by FNS.

(i) The disqualification decision date is the date that a disqualification decision was made at either an administrative or judicial hearing, or the date an individual signed a waiver to forego an administrative or judicial hearing and accept a disqualification penalty.

(ii) The disqualification start date is the date the disqualification penalty was imposed by any of the means identified in § 273.16(c).

(iii) The locality contact is a person, position or entity designated by a State agency as the point of contact for other State agencies to verify information in a DRS disqualification record supplied by the locality contact's State.

(4) All data submitted by State agencies will be available for use by any State agency that is currently under a valid signed Matching Agreement with FNS.

(i) State agencies shall, at a minimum, use the data to determine the eligibility of individual Program applicants prior to certification in cases where the State agency has reason to believe a household member is subject to

disqualification in another jurisdiction; and

(ii) State agencies shall also use the disqualified recipient database for the following purposes:

(A) To screen all Program applicants prior to certification and at recertification; and

(B) To match the entire database of disqualified individuals against their current recipient caseload at application, and periodically thereafter.

(5) The disqualification of an individual for an intentional Program violation in one political jurisdiction shall be valid in another. However, one or more disqualifications for intentional Program violations which occurred prior to April 1, 1983 shall be considered as only one previous disqualification when determining the appropriate penalty to impose in a case under consideration, regardless of where the disqualification(s) took place. State agencies are encouraged to identify and report to FNS any individuals disqualified for an intentional Program violation prior to April 1, 1983. A State agency submitting such historical information should take steps to ensure the availability of appropriate documentation to support the disqualifications in the event it is contacted for independent verification.

(6) If a State determines that supporting documentation for a disqualification record that it has entered is inadequate or nonexistent, the State agency shall act to remove the record from the database.

(7) If a court of appropriate jurisdiction reverses a disqualification for an intentional Program violation, the State agency shall take action to delete the record in the database that contains information related to the disqualification that was reversed in accordance with instructions provided by FNS.

(8) If an individual disputes the accuracy of the disqualification record pertaining to him/her self, the State agency submitting such record(s) shall be responsible for providing FNS with prompt verification of the accuracy of the record.

(i) If a State agency is unable to demonstrate to the satisfaction of FNS that the information in question is correct, the State agency shall immediately, upon direction from FNS, take action to delete the information from the IPV database.

(ii) In those instances where the State agency is able to demonstrate to the satisfaction of FNS that the information in question is correct, the individual shall have an opportunity to submit a brief statement representing his or her position for the record. The State agency shall make the individual's statement a permanent part of the case record documentation on the disqualification record in question, and shall make the statement available to each State agency requesting an independent verification of that disqualification.

* * * * *

Dated: December 1, 2006.

Nancy Montanez Johner,

Under Secretary, Food, Nutrition and Consumer Services.

[FR Doc. E6–20765 Filed 12–7–06; 8:45 am]

BILLING CODE 3410–30–P

FEDERAL ELECTION COMMISSION

11 CFR Part 104

[Notice 2006–21]

Proposed Statement of Policy Regarding Treasurer's Best Efforts To Obtain, Maintain, and Submit Information as Required by the Federal Election Campaign Act

AGENCY: Federal Election Commission.

ACTION: Proposed statement of policy.

SUMMARY: The Federal Election Commission (the ''Commission'') seeks comments on a proposal to clarify its enforcement policy with respect to the circumstances under which it intends to consider a political committee and its treasurer to be in compliance with the recordkeeping and reporting requirements of the Federal Election Campaign Act, as amended (''FECA''), based on the ''best efforts'' defense. Section 432(i) of Title 2 provides that when the treasurer of a political committee demonstrates that best efforts were used to obtain, maintain, and submit the information required by FECA, any report or any records of such committee shall be considered in compliance with FECA (and/or chapters 95 and 96 of Title 26). In the past, the Commission has interpreted this section to apply only to a treasurer's efforts to obtain required information from contributors to a political committee, and not to maintaining information or the submission of reports. However, in light of *Lovely* v. *Federal Election Commission*, 307 F. Supp. 2d 294 (D. Mass. 2004), the Commission intends to apply Section 432(i) to obtaining, maintaining, and submitting information and records to the Commission for the purpose of complying with FECA's disclosure and reporting requirements. Further information is provided in the supplementary information that follows.

DATES: Comments must be received on or before January 8, 2007. The Commission intends to issue a final policy statement after the close of the comment period.

ADDRESSES: All comments must be in writing, must be addressed to Mr. J. Duane Pugh, Jr., Acting Assistant General Counsel, and must be submitted in e-mail, facsimile, or paper copy form. Commenters are strongly encouraged to submit comments by e-mail or fax to ensure timely receipt and consideration. E-mail comments must be sent to *bepolicy@fec.gov.* If e-mail comments include an attachment, the attachment must be in either Adobe Acrobat (.pdf) or Microsoft Word (.doc) format. Faxed comments must be sent to (202) 219–3923, with paper copy follow-up. Mailed comments and paper copy follow-up of faced comments must be sent to the Federal Election Commission, 999 E Street, NW., Washington, DC 20463. All comments must include the full name and postal service address of the commenter or they will not be considered. The Commission will post comments on its Web site after the comment period ends.

FURTHER INFORMATION CONTACT: Mr. J. Duane Pugh, Jr., Acting Assistant General Counsel, or Ms. Margaret G. Perl, Attorney, 999 E Street, NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Commission's regulation implementing Section 432(i) is promulgated at 11 CFR 104.7. This proposed policy statement makes clear that the Commission's intent is to apply this regulation consistent with the holding of the Federal court in *Lovely.* A political committee and its treasurer, regardless of the type of enforcement action before the Commission (the administrative fines program excepted, see below), will be considered to be in compliance with FECA's requirements if the committee or its treasurer can show that best efforts were made to obtain, maintain, and submit all information required to be reported to the Commission. With respect to 11 CFR 104.7(a), the Commission intends to consider that best efforts were made when the treasurer of a political committee demonstrates that the failure to properly obtain, maintain or submit required information and reports was beyond the control of the committee. The Commission intends to generally consider the following: (1) The actions taken, or systems implemented, by the committee to ensure that required information is obtained, maintained, and submitted; (2) the cause of the

failure to obtain, maintain, or submit the information or reports at issue; and (3) the specific efforts of the committee to obtain, maintain, and submit the information or reports at issue. Where appropriate, the Commission may issue additional policy statements or implement regulations setting forth more specific requirements to govern the best efforts defense in particular contexts.

This policy does not affect or modify the Commission's best efforts standards set forth at 11 CFR 104.7(b) that apply specifically with respect to obtaining the identification (*see* 11 CFR 100.12) of each person whose contributions aggregate more than $200 in a calendar year. Additionally, this policy does not affect or modify the Commission's current administrative fines program. The Commission will consider the applicability of the best efforts defense in the context of the administrative fines program in a separate rulemaking. Current 11 CFR 111.35 sets forth the defenses available to a respondent in the administrative fines context. Any revisions to those available defenses will be addressed in a separate rulemaking, which will allow the Commission to give due consideration to the special issues raised by the administrative fines program not present in other portions of the Commission's enforcement docket.

The Commission requests comments on all aspects of this proposed policy statement.

I. Statutory and Regulatory Provision

The Commission proposes clarifying its current enforcement practice with respect to consideration of the best efforts of the treasurer of a political committee to comply with the recordkeeping and reporting requirements of FECA, as interpreted by the *Lovely* court. Pursuant to 2 U.S.C. 432(i), FECA provides that:

> When the treasurer of a political committee shows that best efforts have been used to obtain, maintain, and submit the information required by this Act for the political committee, any report or any records of such committee shall be considered in compliance with this Act or chapter 95 or chapter 96 of title 26.

This provision of FECA was implemented by the Commission at 11 CFR 104.7. Paragraph (a) of this section is virtually identical to the statutory provision:

> When the treasurer of a political committee shows that best efforts have been used to obtain, maintain, and submit the information required by the Act for the political committee, any report of such committee shall be considered in compliance with the Act.

Paragraph (b) of section 104.7 provides standards for a treasurer of a political committee to satisfy in obtaining and reporting ''the identification as defined at 11 CFR 100.12 of each person whose contribution(s) to the political committee and its affiliated political committees aggregate in excess of $200 in a calendar year (or in an election cycle in the case of an authorized committee).'' [1] ''Identification'' includes the person's full name, mailing address, occupation, and name of employer. *See* 11 CFR 100.12.

The language of FECA, and the Commission's regulation at section 104.7(a), applies the best efforts defense broadly to efforts by treasurers to ''obtain, maintain and submit'' the information required to be disclosed by FECA. However, the Commission has in past enforcement actions interpreted the statutory language to apply only to efforts to ''obtain'' contributor information.[2] This interpretation is based on an example contained in the provision's legislative history. *See* H.R. Rep. No. 96–422, at 14 (1979) (''One illustration of the application of this [best efforts] test is the current requirement for a committee to report the occupation and principal place of business of individual contributors who give in excess of $100).

II. Administrative Fines Program

Congress authorized the Commission's administrative fines program in 1999 to ''create[] a simplified procedure for the FEC to administratively handle reporting violations.'' [3] H.R. Rep. No. 106–295, at 11 (1999). As the Commission explained in its *Final Rule on Administrative Fines*, 65 FR 31787 (May 19, 2000),

> [p]rior to enactment of the [administrative fines program] amendment to the FECA, the Commission handled failures to file the reports in a timely manner under the enforcement procedures in 11 CFR part 111. The purpose of the administrative fines program is to institute streamlined 0procedures, while preserving the respondents' due process rights, to process violations of the reporting requirements of 2 U.S.C. 434(a) and assess a civil money penalty based on the schedules of penalties for such violations.

65 FR at 31787. However, ''the Commission has discretion to apply either the administrative fines procedures or the current enforcement procedures set forth in §§ 111.9 through 111.19 to violations of the reporting requirements of 2 U.S.C. 434(a).'' *Id.* at 31788; *see also* 11 CFR 111.31.

Under current Commission regulations, a respondent may challenge a proposed civil penalty in the administrative fines program for three reasons: ''(i) [t]he existence of factual errors; and/or (ii) [t]he improper calculation of the civil money penalty; and/or (iii) [t]he existence of extraordinary circumstances that were beyond the control of the respondent and that were for a duration of at least 48 hours and that prevented the respondent from filing the report in a timely manner.'' 11 CFR 111.35(b)(1). The regulation limits the scope of circumstances that will be considered ''extraordinary'' to exclude negligence, problems with vendors or contractors, illness, inexperience, or unavailability

[1] The U.S. Court of Appeals for the District of Columbia Circuit referred to 11 CFR 104.7(b) as a ''Commission regulation interpreting what political committees must do under [FECA] to demonstrate that they have exercised their 'best efforts' to encourage donors to disclose certain personally identifying information.'' *Republican Nat'l Comm.* v. *FEC*, 76 F.3d 400, 403 (DC Cir. 1996).

[2] In 1980, the Commission explained that ''[i]n determining whether or not a committee has exercised 'best efforts,' the Commission's primary focus will be on the system established by the committee for obtaining disclosure information'' (emphasis added). 45 FR 15080, 15086 (Mar. 7, 1980). In 1993, the Commission referred to ''the requirement of [FECA] that treasurers of political committees exercise best efforts to obtain, maintain and report the complete identification of each contributor whose contributions aggregate more than $200 per calendar year.'' *Final Rule on Recordkeeping and Reporting by Political Committees: Best Efforts*, 58 FR 57725, 57725 (Oct. 27, 1993). And in 1997, the Commission stated that ''[t]reasurers of political committees must be able to show they have exercised their best efforts to obtain, maintain and report [contributor identification information].'' *Final Rule on Recordkeeping and Reporting by Political Committees: Best Efforts*, 62 FR 23335, 23335 (Apr. 30, 1997). In 2003, the Commission asserted in its Supplemental Brief in the *Lovely* litigation that ''the Commission has long interpreted the best efforts provision as creating a limited safe harbor regarding committees' obligations to report substantive information that may be beyond their ability to obtain.'' Commission's Supplemental Brief in *Lovely* v. *FEC* at 1. Furthermore, ''when Congress originally enacted the 'best efforts'' provision, it could not have been more clear that it was creating a limited defense regarding the inability to obtain specific information that was supposed to be disclosed, not the failure to file reports on time.'' *Id.* at 12–13. The *Lovely* court summarized the Commission's argument: ''The FEC in its briefing claims that it limits the reach of the best efforts statute to best efforts to 'obtain' contributor information.'' *Lovely*, 307 F. Supp. 2d at 300.

[3] *See* Treasury and General Government Appropriations Act, 2000, Public Law 106–58, section 640, 113 Stat. 430, 476–77 (1999). The program has been reauthorized twice, *see* Consolidated Appropriations Act, 2004, Public Law 108–199, section 639, 118 Stat. 3, 359 (2004) and Transportation, Treasury, Housing and Urban Development, the Judiciary, the District of Columbia, and Independent Agencies Appropriations Act, 2006, Public Law 109–115, section 721, 119 Stat. 2396, 2493–94 (2005), and will sunset on December 31, 2008. *See also Final Rule on Extension of Administrative Fines Program*, 70 FR 75717 (Dec. 21, 2005).

of staff, computer failures (except failures of the Commission's computers), and other similar circumstances. 11 CFR 111.35(b)(4).

The Commission deemed this limitation of defenses to be an appropriate component of the administrative fines program, and asserted that it had

> sound policy reasons for limiting the respondents' defenses beyond streamlining the administrative process. A key cornerstone of campaign finance law is the full and timely disclosure of the political committee's financial activity. Such disclosure is essential to providing the public with accurate and complete information regarding the financing of federal candidates and political campaigns. Thus, violations of the reporting requirements of 2 U.S.C. 434(a) are strict liability offenses * * *ensp . Absent extraordinary circumstances beyond the committees' control, the Commission sees no reason why committees cannot file their reports by the deadline. The rationale behind the '48-hour extraordinary circumstances' exception is that the Commission recognizes there may be instances such as natural disasters where a committee's office is located in the disaster area and the committee cannot timely file a report because of lack of electricity or flooding or destruction of committee records.

65 FR at 31789–90.

In light of these considerations, this proposed policy statement shall not affect the Commission's current administrative fines program. Rather, the Commission's position will be re-evaluated in the context of a separate rulemaking concerning the application of the best efforts defense in the administrative fines program.

III. The Lovely Decision

In *Lovely* v. *FEC*, 307 F. Supp. 2d 294 (D. Mass. 2004), a congressional candidate's political committee and its treasurer brought an action against the Commission challenging the imposition of an administrative fine for allegedly late filing of a required report. On the day of the filing deadline, the committee's treasurer experienced difficulty electronically filing the committee's report via the Internet. Upon advice of Commission staff, the treasurer mailed a paper copy of the committee's report, along with a copy on computer diskette, to the Commission. The diskette was improperly formatted, and rejected by the Commission, but the paper copy was made public and posted to the Commission's Web site. The committee filed a properly formatted report 27 days after the filing deadline. Pursuant to the Commission's administrative fines program, the Commission's Office of Administrative Review recommended a $3,100 civil penalty, based on the number of days the report was late, the committee's lack of prior violations, and the fact that the treasurer had not raised any of the three defenses permitted by 11 CFR 111.35(b) to contest the imposition of a civil penalty. The Commission found reason to believe that the committee and the treasurer violated FECA with the late filing. Subsequently, the Commission made a final determination that plaintiff had violated 2 U.S.C. 434(a), but also voted to decrease the civil penalty to $1,800. *Lovely* at 296–97.

In its lawsuit, the plaintiff argued that the Commission's imposition of a fine was contrary to FECA's best efforts provision. *Id.* at 296. The Commission argued that ''it limits the reach of the best efforts statute to best efforts to 'obtain' contributor information.'' *Lovely* at 300. The Court concluded that ''the FEC's argument that the phrase does not apply to the submission of reports conflicts with the plain statutory language. While the Commission can refine by regulation what best efforts means in the context of submitting a report, it cannot define it away by providing that submission of reports is governed by a 'strict liability' standard.'' *Id.* Thus, the court rejected the Commission's primary rationale for limiting respondents' potential defenses to late- or non-reporting in the administrative fines program, holding that the submission of reports is not governed by a strict liability standard. Rather, the fault-based standard of the best efforts defense must apply.

The court also drew on the legislative history of the best efforts provision. As noted, the 1979 amendments to FECA specifically amended the best efforts provision to make it ''applicable to the entirety of FECA, rather than merely to one subsection.'' *Lovely* at 299. The court cited the provision's legislative history:

> The best efforts test is *specifically made applicable to recordkeeping and reporting requirements in both Title 2 and Title 26.* The test of whether a committee has complied with the statutory requirements is whether its treasurer has exercised his or her best efforts to obtain, maintain, and submit the information required by the Act. If the treasurer has exercised his or her best efforts, the committee is in compliance. Accordingly, *the application of the best efforts test is central to the enforcement of the recordkeeping and reporting provisions of the Act.* It is the opinion of the Committee that the Commission has not adequately incorporated the best efforts test into its administration procedures, such as the systematic review of reports.

Id. (emphasis added) (quoting H.R. Rep. No. 96–422, at 14 (1979), *reprinted in* 1979 U.S.C.C.A.N. 2860, 2873).

As the Commission stated in its Statement of Reasons after remand of the *Lovely* case, ''the Court held that FECA's 'best efforts' provision * * * requires the Commission to consider whether a committee's treasurer exercised best efforts to submit timely disclosure reports.'' *Commission's Statement of Reasons in Administrative Fines Case #549 on Remand From the United States District Court for the District of Massachusetts, at 1* (Oct. 4, 2005) (''*Lovely Statement of Reasons*''). On remand, the Commission indicated its intention to ''pursue its view that 2 U.S.C. 432(i) does not require the Commission to recognize a 'best efforts' defense as part of the administrative fines program,'' and decided that the court had not ''construe[d] Section 432(i) beyond requiring its application in this instance.'' *Id.* at 1–2. The Commission determined that the committee's treasurer had not put forth best efforts in filing the report in question. *Id.* at 5.

IV. Application of the Court's Holding

Upon further consideration, the Commission has determined that despite the limited breadth of *Lovely*, implementation of the *Lovely* court's interpretation of the best efforts defense best reflects the language of FECA and the intent of Congress. While the Commission's enforcement practices formerly reflected the view that the best efforts defense was limited to obtaining certain contributor identification information, *see supra* footnote 2, the Commission recognizes that its application of the defense in previous enforcement matters derives from a single example of the defense's application in its 1979 legislative history.[4] In light of these considerations, the Commission hereby notifies the public and the regulated community through this proposed policy statement that henceforth it intends to apply the best efforts defense of 2 U.S.C. 432(i), as promulgated at 11 CFR 104.7, with respect to obtaining contributor information as currently set forth at 11 CFR 104.7(b), and also to obtaining other information, maintaining any and all information required by the statute,

[4] A respondent's assertion in an enforcement matter that best efforts were made to maintain and/or submit required information was formerly considered by the Commission to be a mitigating factor, but not an outright defense to an alleged violation of the recordkeeping and reporting requirements.

and submitting said information in the form of disclosure reports.

The standards for determining whether the best efforts defense is applicable in the context of obtaining specific contributor information is set forth at current 11 CFR 104.7(b). This proposed policy statement does not affect or modify those standards.

With respect to 11 CFR 104.7(a), which applies to obtaining, maintaining and submitting information and reports, the Commission intends to consider that best efforts were made when the treasurer of a political committee demonstrates that the failure to properly obtain, maintain or submit required information and reports to the Commission was beyond the control of the committee. The Commission intends to generally consider the following: (1) The actions taken, or systems implemented, by the committee to ensure that required information is obtained, maintained, and submitted; (2) the cause of the failure to obtain, maintain, or submit the information or reports at issue; and (3) the specific efforts of the committee to obtain, maintain, and submit the information or reports at issue.

Under this proposed policy, the following list sets forth possible reasons for a committee's failure to obtain, maintain or submit information or reports that the Commission may consider to be indicative that the best efforts defense is applicable:

- A failure of Commission computers or Commission-provided software;
- Severe weather or other disaster-related incidents;
- Electronic filing problems caused by widespread and reported problems with the Internet;
- Utilization of the Commission's three approved filing methods (via Internet, direct modem, and mailing an electronic copy);
- Delivery failures caused by mail/courier services such as U.S. Postal Service, Federal Express, UPS, DHL, etc.; or
- Unforeseen circumstances beyond the control of the respondent.

The above-listed reasons, along with any other defenses presented, may be considered by the Commission in light of all the facts and circumstances relevant to the committee's obtaining and maintenance of information and efforts to submit reports (or other information) in a timely fashion in determining the applicability of the best efforts defense.

If a failure to obtain, maintain, or submit information or reports is due to committee staff unavailability, inexperience, illness, negligence or error; the committee's computer or software failure; delays caused by committee vendors or contractors; a committee's failure to know filing dates; or a committee's failure to use Commission software properly; then the Commission intends to conclude that the best efforts standard has not been met.

Under the proposed policy, if presented with information sufficient to form a best efforts defense, the Commission intends to consider the best efforts of a committee under Section 432(i) when reviewing all violations of the recordkeeping and reporting requirements of FECA, whether arising in its normal enforcement docket (Matters Under Review) or the Alternative Dispute Resolution Program. The ''best efforts'' standard is an affirmative defense and the burden rests with the political committee and its treasurer to present facts that demonstrate that ''best efforts'' were made. The Commission does not intend to consider the best efforts defense in any enforcement matter unless the facts that form the basis of that defense are asserted by a respondent.

The Commission considers ''best efforts'' to be ''a standard that has diligence as its essence.'' E. Allan Farnsworth, *On Trying to Keep One's Promises: The Duty of Best Efforts in Contract Law*, 46 U. Pitt. L. Rev. 1, 8 (1984). As the Commission explained in its *Lovely Statement of Reasons* at 2,

> Section 432(i) creates a safe harbor for treasurers who ''show[] that best efforts'' have been made to report the information required to be reported by the Act. ''Best'' is an adjective of the superlative degree. ''Best efforts'' must therefore require more than ''some'' or ''good'' efforts. Congress's choice of a ''best efforts'' standard, rather than a ''good faith'' standard, suggests that a treasurer cannot rely upon his or her earnestness or state of mind to gain the shelter of Section 432(i)'s safe harbor. Rather, a treasurer has the burden of showing that the actions taken—the efforts he or she made to comply with applicable reporting deadlines—meet the statute's demanding benchmark.

As explained above, the Commission does not intend to apply 11 CFR 104.7(b) as limiting the applicability of the best efforts defense of 2 U.S.C. 432(i) and 11 CFR 104.7(a) *only* to efforts made to obtain certain specific information from contributors. 11 CFR 104.7(b) does not in any way modify or limit the applicability of section 104.7(a) to the efforts of treasurers to obtain, maintain and submit information and reports.

The above provides general guidance concerning the applicability of the Commission's proposed best efforts defense and announces the general course of action that the Commission intends to follow. This proposed policy statement sets forth the Commission's intentions concerning the exercise of its discretion in its enforcement program. However, the Commission retains that discretion and will exercise it as appropriate with respect to the facts and circumstances of each matter it considers. Consequently, this policy statement does not bind the Commission or any member of the general public. As such, it does not constitute an agency regulation requiring notice of proposed rulemaking, opportunities for public participation, prior publication, and delay in effective date under 5 U.S.C. 553 of the Administrative Procedure Act (''APA''). The provisions of the Regulatory Flexibility Act, which apply when notice and comment are required by the APA or another statute, are not applicable. Where appropriate, the Commission may issue additional policy statements or initiate rulemakings to set forth more specific requirements to govern the best efforts defense in particular contexts.

V. Conclusion.

Effective as of the date that a final Policy Statement is published in the **Federal Register**, the Commission intends to apply the best efforts standard to all matters currently before the Commission in which a respondent has asserted such a defense, and that come before the Commission in the future involving information and reports that must be obtained, maintained, and submitted by the treasurers of political committees, although the Commission will consider the application of the best efforts defense to the administrative fines program in a separate rulemaking. The Commission intends to consider that ''best efforts'' were made when the treasurer of a political committee demonstrates that the failure to properly obtain, maintain or submit required information and reports was beyond the control of the committee. When treasurers are able to show that a committee made best efforts to comply with the Act's requirements to obtain, maintain, and submit information, the Commission intends that the treasurers or committees shall be considered in compliance with FECA and no civil penalties or other remedial measures shall be imposed.

Dated: November 30, 2006.

Michael E. Toner,

Chairman, Federal Election Commission.

[FR Doc. E6–20752 Filed 12–7–06; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

11 CFR Part 111

[Notice 2006–19]

Proposed Policy Statement Establishing a Pilot Program for Probable Cause Hearings

AGENCY: Federal Election Commission.

ACTION: Draft Statement of Policy with Request for Comments.

SUMMARY: The Commission is issuing a proposed policy statement to establish a pilot program offering probable cause hearings to respondents in enforcement actions pending before the Commission. The pilot program would allow respondents to request a hearing directly before the Commission prior to the Commission's consideration of the General Counsel's probable cause recommendation. The program would provide respondents with the opportunity to present directly arguments to the Commission and give the Commission an opportunity to ask relevant questions. The Commission requests comments on this proposed pilot program.

DATES: Comments must be submitted on or before January 5, 2007.

ADDRESSES: All comments should be addressed to Mark D. Shonkwiler, Assistant General Counsel, Enforcement Division, and must be submitted in either electronic or written form. Electronic mail comments should be sent to *probablecausehearings@fec.gov* and must include the full name, electronic mail address and postal service address of the commenter. Electronic mail comments that do not contain the full name, electronic mail address and postal service address of the commenter will not be considered. If the electronic mail comments include an attachment, the attachment must be in the Adobe Acrobat (.pdf) or Microsoft Word (.doc) format. Faxed comments should be sent to (202) 219–3923, with printed copy follow-up to ensure legibility. Written comments and printed copies of faxed comments should be sent to the Federal Election Commission, 999 E Street, NW., Washington, DC 20463. Commenters are strongly encouraged to submit comments electronically to ensure timely receipt and consideration. The Commission will make every effort to post public comments on its Web site within ten business days of the close of the comment period.

FOR FURTHER INFORMATION CONTACT: Mark D. Shonkwiler, Assistant General Counsel, 999 E Street, NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Federal Election Commission is establishing a pilot program to afford respondents in pending enforcement matters the opportunity to participate in hearings before the Commission. During such a hearing, a respondent (generally through counsel) may present oral arguments directly to the Commissioners, prior to any Commission determination of whether to find probable cause to believe that respondents violated the Federal Election Campaign Act.

On June 11, 2003, the Commission held a hearing concerning potential changes to its enforcement procedures. The Commission received comments from those in the regulated community, many of whom argued for increased transparency in Commission procedures and expanded opportunities to contest allegations.[1] The Commission designed this pilot program with those concerns in mind. Proposed procedures for probable cause hearings are outlined below. The Commission seeks comment on all aspects of this proposal.

Opportunity To Request a Hearing

A hearing may take place before the Commission considers whether or not to make a finding of ''probable cause to believe'' that a respondent has violated the Act or Commission regulations.[2] A probable cause hearing may be requested by any respondent who reaches the probable cause determination stage (see 11 CFR 111.16–111.17) and submits a probable cause response brief to the Office of General Counsel. A cover letter attached to the probable cause brief will inform the respondent of the opportunity to request an oral hearing before the Commission. Hearings are voluntary and no adverse inference will be drawn by the Commission with respect to the request or waiver of such a hearing.

The General Counsel must receive the written request for a hearing at the same time that a respondent submits his or her timely response brief. 11 CFR 111.16(c). Any request for a hearing must state with specificity why the hearing is being requested and what issues the respondent expects to address. Absent good cause, to be determined at the sole discretion of the Commission, late requests will not be accepted. Respondents may make their request for a hearing by mail (including private delivery services), hand delivery, facsimile or email. Respondents are responsible for ensuring that their request is timely received.

The Commission will grant a request for an oral hearing when it concludes that a hearing would help resolve significant or novel legal issues, or significant questions about the application of the law to the facts. Within 30 days of receiving a request for a hearing, the Commission will grant a request for a probable cause hearing if any two commissioners agree to hold a hearing.

Hearing Procedures

The purpose of the oral hearing is to provide a respondent an opportunity to present his or her arguments in person to the Commissioners *before* the Commission makes a determination that there is ''probable cause to believe'' that the respondent violated the Act or Commission regulations. Consistent with current Commission regulations, any respondent may be represented by counsel, at the respondent's own expense, or may appear *pro se* at any probable cause hearing. See 11 CFR 111.23. Respondents will have the opportunity to present their arguments, and Commissioners, the General Counsel, and the Staff Director will have the opportunity to pose questions. Respondents may discuss any issues presented in the enforcement matter, including potential liability and calculation of a civil penalty.

The Commission will determine the format and time allotted for each hearing at its discretion. Among the factors that the Commission may consider are agency time constraints, the complexity of the issues raised, the number of respondents involved, and Commission interest. The Commission will determine the amount of time allocated for each portion of the hearing, and these time limits may vary from hearing to hearing. The Commission anticipates that most hearings will begin with a brief opening statement by Respondent or Respondent's counsel, followed by questioning from the Commissioners, General Counsel, and Staff Director. Hearings will normally conclude with the respondent's closing remarks.

The Commission will have transcripts made of the hearings. The transcripts will become a part of the record for the enforcement matter and may be relied upon for determinations made by the

[1] These comments are available at *http://www.fec.gov/agenda/agendas2003/notice2003-09/comments.shtml.*

[2] The Commission is appending to this statement a general description of its enforcement procedures (''Basic Commission Enforcement Procedure''). These procedures are prescribed by statute and regulation, and the Commission is not requesting comment on them at this time.

Commission. Respondent may be bound by any representations made by Respondent or Respondent's counsel at a hearing. The Commission will make the transcripts available to the respondent, who may, at his or her own expense, purchase copies of the transcript. Respondents will have access to the transcripts from their own hearing, but not transcripts of other co-respondents' separate hearings, unless co-respondents in the same matter specifically provide written consent to the Commission granting access to such transcript(s). Transcripts will be made public after the matter is closed in accordance with Commission policies on disclosure.[3]

Third party witnesses or other co-respondents may not be called to testify at a respondent's oral hearing. However, the Commission may request that supplementary information be submitted after the probable cause hearing. The Commission discourages voluminous submissions. Supplementary information may not be submitted more than ten days after the oral hearing, unless submitted in response to a Commission request that imposes a different, Commission-approved deadline. Materials requested by the Commission, and materials considered by the Commission in making its ''probable cause to believe'' determination, may be made part of the record pursuant to the Commission's *Statement of Policy Regarding Disclosure of Closed Enforcement and Related Files*, 68 FR 70426 (Dec. 18, 2003). Hearings are confidential and not open to the public; only Respondents and their counsel may attend. Attendance by any other parties must be approved by the Commission in advance.

Cases Involving Multiple Respondents

In cases involving multiple respondents, the Commission will decide on a case-by-case basis how to structure any hearing(s). Respondents are encouraged to advise the Commission of their preferences. Such respondents may request joint hearings if each participating respondent provides an unconditional waiver of confidentiality with respect to other participating co-respondents and their counsel and a nondisclosure agreement.

Scheduling of Hearings

The Commission will seek to hold the hearing in a timely manner after receiving Respondents' request for a hearing. The Commission will attempt to schedule the hearings on a mutually acceptable date and time. However, if a respondent is unable to accommodate the Commission's schedule, the Commission may decline to hold a hearing. The Commission reserves the right to reschedule any hearing. Where necessary, the Commission reserves the right to request from a respondent an agreement tolling any upcoming deadline, including any statutory deadline or other deadline found in 11 CFR part 111.

Pilot Program

The pilot program will last eight months from the time that this policy is approved. After eight months, a vote will be scheduled on whether the program should continue. The program will remain in effect until that vote is taken. Four votes will be required to extend or make permanent the program. The program will be terminated after that vote if there are not four affirmative votes to make the program permanent or to extend it for some time period. The Commission may modify or terminate this pilot program prior to the eighth month of the program if there are four affirmative votes for modification or early termination. If the pilot program is terminated, any previously requested hearings will still be held.

Conclusion

The Commission urges Respondents to consider carefully the costs and benefits of proceeding to probable cause briefings and/or hearings. The hearings are optional and no negative inference will be drawn if Respondents do not request a hearing. The majority of the agency's cases are settled through pre-probable cause conciliation. Proceeding to probable cause briefing requires a substantial investment of the Commission's limited resources. Consistent with the goal of expeditious resolution of enforcement matters, the Commission seeks to promote pre-probable cause conciliation. To encourage this, the Commission has a practice in many cases of reducing the civil penalty it seeks through its opening settlement offer. However, once the Office of General Counsel has terminated pre-probable cause conciliation negotiations, this reduction (normally 25%) is no longer available and the civil penalty will generally increase.

All requests for hearings, scheduling and format inquiries, document submissions, and anything else related to the probable cause hearings should be directed to the Office of General Counsel.

This notice represents a general statement of policy announcing the general course of action that the Commission intends to follow. This policy statement does not constitute an agency regulation requiring notice of proposed rulemaking, opportunities for public participation, prior publication, and delay effective under 5 U.S.C. 553 of the Administrative Procedures Act (''APA''). As such, it does not bind the Commission or any member of the general public. The provisions of the Regulatory Flexibility Act, 5 U.S.C. 605(b), which apply when notice and comment are required by the APA or another statute, are not applicable.

Dated: December 1, 2006.

Michael E. Toner,

Chairman, Federal Election Commission.

Appendix

Basic Commission Enforcement Procedure [4]

The Commission's enforcement procedures are set forth at 11 CFR part 111. An enforcement matter may be initiated by a complaint or on the basis of information ascertained by the Commission in the normal course of carrying out its supervisory responsibilities. 11 CFR 111.3. If a complaint substantially complies with certain requirements set forth in 11 CFR 111.4, within five days of receipt the Office of General Counsel notifies each party determined to be a respondent that a complaint has been filed, provides a copy of the complaint, and advises each respondent of Commission compliance procedures. 11 CFR 111.5. A respondent then has 15 days from receipt of the notification from the Office of General Counsel to submit a letter or memorandum to the Commission setting forth reasons why the Commission should take no action on the basis of the complaint. 11 CFR 111.6.

Following receipt of such letter or memorandum, or expiration of the 15-day period, the Office of General Counsel may recommend to the Commission whether or not it should find ''reason to believe'' that a respondent has committed or is about to commit a violation of the Act or Commission regulations. 11 CFR 111.7(a).[5] With respect to internally-generated matters (*e.g.*, referrals from the Commission's Audit or Reports Analysis Divisions), the Office of General Counsel may recommend that the Commission find ''reason to believe'' that a respondent has committed or is about to commit a violation of the Act or Commission

[3] *Statement of Policy Regarding Disclosure of Closed Enforcement and Related Files*, 68 FR 70426 (Dec. 18, 2003) is hereby amended to include disclosure of transcripts from probable cause hearings.

[4] The Commission provides this overview of enforcement procedures for informational purposes only. The Commission is not seeking comment on this section.

[5] The Office of General Counsel may also recommend that the Commission find no ''reason to believe'' that a violation has been committed to is about to be committed, or that the Commission otherwise dismiss a complaint without regard to the provisions of 11 CFR 111.6(a). 11 CFR 111.7(b).

regulations on the basis of information ascertained by the Commission in the normal course of carrying out its supervisory responsibilities, or on the basis of a referral from an agency of the United States or any State. If the Commission determines by an affirmative vote of four members that it has ''reason to believe'' that a respondent violated the Act or Commission regulations, the respondent must be notified by letter of the Commission's finding(s). 11 CFR 111.9(a).[6] The Office of General Counsel will also provide the respondent with a Factual and Legal Analysis, which will set forth the bases for the Commission's finding of reason to believe.

After the Commission makes a ''reason to believe'' finding, an investigation is conducted by the Office of General Counsel., in which the Commission may undertake field investigations, audits, and other methods of information-gathering. 11 CFR 111.10. Additionally, the Commission may issue subpoenas to order any person to submit sworn written answers to written questions, to provide documents, or to appear for a deposition. 11 CFR 111.11–111.12. Any person who is subpoenaed may motion the Commission for it to be quashed or modified. 11 CFR 111.15.

Following a ''reason to believe'' finding, the Commission may attempt to reach a conciliation agreement with the respondent(s) prior to reaching the ''probable cause'' stage of enforcement (*i.e.*, a pre-probable cause conciliation agreement). See 11 CFR 111.18(d). If the Commission is unable to reach a pre-probable cause conciliation agreement with the respondent, or determines that such a conciliation agreement would not be appropriate, upon completion of the investigation referenced in the preceding paragraph, the Office of General Counsel prepares a brief setting forth its position on the factual and legal issues of the matter and containing a recommendation on whether or not the Commission should find ''probable cause to believe'' that a violation has occurred or is about to occur. 11 CFR 111.16(a).

The Office of General Counsel notifies the respondent(s) of this recommendation and provides a copy of the probable cause brief. 11 CFR 111.16(b). The respondent(s) may file a written response to the probable cause brief within fifteen days of receiving said brief. 11 CFR 111.16(c). After reviewing this response, the Office of General Counsel shall advise the Commission in writing whether it intends to proceed with the recommendation or to withdraw the recommendation from Commission consideration. 11 CFR 111.16(d).

If the Commission determines by an affirmative vote of four members that there is ''probable cause to believe'' that a respondent has violated the Act or Commission regulations, the Commission authorizes the Office of General Counsel to notify the respondent by letter of this determination. 11 CFR 111.17(a). Upon a Commission finding of ''probable cause to believe,'' the Commission must attempt to reach a conciliation agreement with the respondent. 11 CFR 111.18(a). If no conciliation agreement is finalized within the time period specified in 11 CFR 111.18(c), the Office of General Counsel may recommend to the Commission that it authorize a civil action for relief in the appropriate court. 11 CFR 111.19(a). Commencement of such civil action requires an affirmative vote of four members of the Commission. 11 CFR 111.19(b). The Commission may enter into a conciliation agreement with respondent after authorizing a civil action. 11 CFR 111.19(c).

[6] If the Commission finds no ''reason to believe,'' or otherwise terminates its proceedings, the Office of General Counsel shall advise the complainant and respondent(s) by letter. 11 CFR 111.9(b).

[FR Doc. E6–20844 Filed 12–7–06; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

11 CFR Part 111

[Notice 2006–20]

Proposed Policy Regarding Self-Reporting of Campaign Finance Violations; (Sua Sponte Submissions)

AGENCY: Federal Election Commission.

ACTION: Draft statement of policy with request for comments.

SUMMARY: The Commission is seeking comments on a proposed policy statement to clarify and memorialize its approach to enforcement actions arising from self-reported violations (also known as *sua sponte* submissions). In order to encourage the self-reporting of violations about which the Commission would not otherwise have learned, the Commission proposes, in appropriate cases warranting such mitigation, to offer significantly lower penalties than the Commission would otherwise have sought in complaint-generated matters involving similar circumstances. The Commission is also outlining a new expedited procedure that it intends to use in a limited number of situations through which the Commission may allow individuals and organizations that self-report violations and that make a complete report of their internal investigation to proceed directly into conciliation prior to the Commission determining whether their conduct may have violated statutes or regulations within its jurisdiction. The proposed policy also addresses various issues that can arise in connection with parallel criminal, administrative or civil proceedings. The Commission requests comments on this proposed policy.

DATES: All comments must be submitted on or before January 29, 2007.

ADDRESSES: All comments should be addressed to Mark Shonkwiler, Assistant General Counsel, or April Sands, Attorney, and must be submitted in either electronic or written form. Electronic mail comments should be sent to *selfreportpolicy@fec.gov* and must include the full name, electronic mail address and postal service address of the commenter. Electronic mail comments that do not contain the full name, electronic mail address and postal service address of the commenter will not be considered. If the electronic mail comments include an attachment, the attachment must be in the Adobe Acrobat (.pdf) or Microsoft Word (.doc) format. Faxed comments should be sent to (202) 219–3923, with printed copy follow-up to ensure legibility. Written comments and printed copies of faxed comments should be sent to the Federal Election Commission, 999 E Street, NW., Washington, DC 20463. Commenters are strongly encouraged to submit comments electronically to ensure timely receipt and consideration. The Commission will make every effort to post public comments on its Web site within ten business days of the close of the comment period.

FOR FURTHER INFORMATION CONTACT: Mark D. Shonkwiler, Assistant General Counsel, or April J. Sands, Attorney, Enforcement Division, Federal Election Commission, 999 E Street, NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION:

I. Goals and Scope of the Policy

The Commission periodically receives submissions from persons who self-report statutory or regulatory violations of which the Commission had no prior knowledge. The Commission considers such self-reports (which also are referred to as *sua sponte* submissions) as information ascertained in the normal course of carrying out its supervisory responsibilities pursuant to 2 U.S.C. 437g(a)(2), and may investigate if it determines there is reason to believe a violation has occurred. The Commission also investigates complaints reporting the potentially illegal conduct of another, submitted pursuant to 2 U.S.C. 437g(a)(1), but which also, by implication, provide a basis for investigating the complainant itself.[1] As a general proposition, self-reported

[1] If a person who self-reports a violation of the FECA also makes specific allegations as to other persons not joining in the submission, and particularly where the person making the submission seeks to assign primary responsibility for the violations to another person (including an organization's former officers or employees), the Commission, acting through its Office of General Counsel, may advise the self-reporting person that a portion of the relevant materials should be re-submitted as a complaint to which other persons would be allowed to respond prior to any findings by the Commission.

matters, when accompanied by full cooperation, may be resolved more quickly and on more favorable terms than matters arising by other means (*e.g.*, those arising via external complaints, referrals from other government agencies, or referrals from the Commission's Audit or Reports Analysis Divisions).[2]

The Commission recently has seen an increase in self-reported violations, which may be attributable, at least in part, to greater attention being placed on compliance programs for areas of potential organizational liability, and recognition that addressing a problem through self-auditing and self-reporting may help minimize reputational harm. The increase in the number of self-reported matters has highlighted the need to increase the transparency of Commission policies and procedures. Moreover, the Commission seeks to provide appropriate incentives for this demonstration of cooperation and responsibility.

This policy provides an overview of the factors that influence the Commission's handling and disposition of certain kinds of matters. It should be noted that while cooperation in general, and self-reporting in particular, will be considered by the Commission as mitigating factors, they do not excuse a violation of the Act or end the enforcement process. Also, this policy does not confer any rights on any person and does not in any way limit the right of the Commission to evaluate every case individually on its own facts and circumstances.[3] Nevertheless, as explained below, the Commission may provide appropriate consideration to respondents who voluntarily disclose and who fully cooperate with the Commission's disposition of the matter.

II. Self-Reporting of FECA Violations

Self-reporting of violations typically allows respondents to resolve their civil liability in a manner which has the potential to: (1) Reduce the investigative burden on both the Commission and themselves; (2) demonstrate their acceptance of organizational or personal responsibility and commitment to internal compliance; and (3) conclude their involvement in the Commission's enforcement process on an expedited basis. A person who brings to the Commission's attention violations of the FECA and Commission regulations and who cooperates with the resulting investigation may also receive appropriate consideration in the terms of an eventual conciliation agreement. For example, the Commission may do one or more of the following:

- Take no action against particular respondents;
- Offer a significantly lower penalty than what the Commission otherwise would have sought in a complaint-generated matter involving similar circumstances or, where appropriate, no civil penalty;
- Offer conciliation before a finding of probable cause to believe a violation occurred, and in certain cases proceed directly to conciliation without the Commission first finding reason to believe that a violation occurred (see discussion below);
- Refrain from making a formal finding that a violation was knowing and willful, even where the available information would otherwise support such a finding;
- Proceed only as to an organization, rather than as to various individual agents or, where appropriate, proceed only as to individuals rather than organizational respondents;
- Include language in the conciliation agreement that indicates the level of cooperation provided by respondents and the remedial action taken by the persons.

III. Factors Considered in Self-Reported Matters

The Commission may take into account various factors in considering how to proceed regarding self-reported violations. In general, more expedited processing and a more favorable outcome will be possible when the self-reporting party can show that upon discovery of the potential violations, there was an immediate end to the activity giving rise to the violation(s); the Respondent made a timely and complete disclosure to the Commission and fully cooperated in the disposition of the matter; and the Respondent implemented appropriate and timely corrective measures, including internal safeguards necessary to prevent any recurrence. Further detail as to these factors is supplied below.

Nature of the Violation

(1) *The type of violation:* Whether the violation was (a) Knowing and willful, or resulted from reckless disregard for legal requirements or deliberate indifference to indicia of wrongful conduct; (b) negligent; (c) an inadvertent mistake; or (d) based on the advice of counsel;[4]

(2) *The magnitude of the violation:* Whether the violation resulted from a one-time event or an ongoing pattern of conduct repeated over an extended period of time (and whether there was a history of similar conduct); how many people were involved in or were aware of the violation and the relative level of authority of these people within the organization; whether individuals were coerced into participating in the violation; the amount of money involved either in terms of absolute dollar amount or in terms of the percentage of an entity's activity; and the impact the violation may have had on any Federal election;

(3) *How the violation arose:* Whether the conduct was intended to advance the organization's interests or to defraud the organization for the personal gain of a particular individual; whether there were compliance procedures in place to prevent the type of violation now uncovered and, if so, why those procedures failed to stop or deter the wrongful conduct; and whether the persons with knowledge of the violation were high-level officials in the organization.

Extent of Corrective Action and New Self-Governance Measures

(4) *Have all needed investigative and corrective actions been taken:* Whether the violation immediately ceased upon its discovery; how long it took after discovery of the violation to take appropriate corrective measures, including disciplinary action against persons responsible for any misconduct; whether there was a thorough review of the nature, extent, origins, and consequences of the conduct and related behavior; whether the respondent expeditiously corrected and clarified the public record by making appropriate and timely disclosures as to the source and recipients of any funds involved in a violation; whether a Federal political committee promptly made any necessary refunds of excessive or prohibited contributions; and whether an organization or individual respondent waived its claim to refunds of excessive or prohibited contributions and instructed recipients to disgorge such funds to the U.S. Treasury.

(5) *Have more effective compliance measures been implemented:* Whether there are assurances that the conduct is unlikely to recur; whether the

[2] When violations are found, FECA requires the Commission to attempt to correct or prevent violations through conciliation agreements before suit may be filed in Federal district court.

[3] Some violations, for instance, are subject to a mandatory minimum penalty prescribed by statute. *See* 2 U.S.C. 437g(a)(6)(C).

[4] A respondent seeking to defend conduct based on advice of counsel may not simultaneously withhold documentary or other evidence supporting that assertion based on the attorney-client privilege.

respondent has adopted and ensured enforcement of more effective internal controls and procedures designed to prevent a recurrence of the violation; and whether the respondent provided the Commission with sufficient information for it to evaluate the measures taken to correct the situation and ensure that the conduct does not recur.

Disclosure and Cooperation

(6) *Was the violation fully disclosed to the Commission:* Whether steps were taken upon learning of the violation; whether the disclosure was voluntary or made in recognition that the violation had been or was about to be discovered, or in recognition that a complaint was filed, or was about to be filed, by someone else; and whether a comprehensive and detailed disclosure of the results of its internal review was provided to the Commission in a timely fashion;

(7) *Was there full cooperation with the Commission:* Whether the respondent promptly made relevant records and witnesses available to the Commission, and made all reasonable efforts to secure the cooperation of relevant employees, volunteers, vendors, donors and other staff without requiring compulsory process; whether the respondent agreed to waive or toll the statute of limitations for activity that previously had been concealed or not disclosed in a timely fashion.

The Commission recognizes that all of the above-listed factors will not be relevant in every instance of self-reporting of potential FECA violations, nor is the Commission required to take all such factors into account. In addition, these factors should not be viewed as an exhaustive list. The Commission will continue to resolve matters based on the facts and circumstances of each case.

The Commission seeks to encourage the self-reporting of violations. To that end, the Commission will consider reducing opening civil penalty offers [5] by up to 75%. The amount of the reduction depends on the facts and circumstances of a particular case. The Commission will consider the factors set forth above. In order to provide more concrete guidance, the Commission may establish a policy setting forth the weight it will give to some of the facts and circumstances.

The Commission is considering adopting a policy of granting a civil penalty reduction of up to 50% to respondents who meet the following criteria:

- Respondents alert the Commission to potential violations before the violation had been or was about to be discovered by any outside party, including the FEC;
- Respondents amend reports or disclosures to correct past errors, if applicable;
- Any appropriate refunds, transfers, and disgorgements are made and/or waived;
- The violation immediately ceased upon discovery; and
- Respondents fully cooperate with the Commission in ensuring that the sua sponte submission is complete and accurate and in taking corrective measures.

The Commission is considering adopting a policy of granting a civil penalty reduction of up to 75% to respondents who meet the above criteria plus the following criteria:

- Respondents hired independent experts to conduct a thorough review, investigation, or audit;
- Respondents provide the Commission with all documentation of the experts' review, investigation, or audit; and
- Respondents took appropriate corrective action(s) such as disciplinary action against any persons responsible for misconduct and made changes to internal procedures to prevent a recurrence of the violation.

Alternatively, the Commission is considering adopting a policy of generally granting a civil penalty reduction of 50% to respondents that voluntarily self-report violations to the Commission, and of raising or lowering that discount depending on the aggravating and mitigating factors outlined above. The discount could be as high as 75% or as low as 25%, depending on the facts of the case in question.

The Commission will be the sole arbiter of whether the facts of each case warrant a particular reduction in the penalty. The Commission will generally not give a respondent the benefit of this policy if the respondent is the subject of a criminal or other government investigation. In considering appropriate penalties, the Commission will also consider the presence of aggravating factors, such as knowing and willful conduct or involvement by senior officials of an entity. The Commission may also consider other factors not enumerated in this policy for the purposes of applying or withholding a possible discount.

IV. Fast-Track Resolution

The Commission will generally not make a reason-to-believe finding or open a formal investigation for respondents that self-report violations, if: (1) All potential respondents in a matter have joined in a self-reporting submission that acknowledges their respective violations of the FECA; (2) those violations do not appear to be knowing and willful; and (3) the disclosure is substantially complete and the submission reasonably addresses the significant questions or issues related to the violation. Accordingly, the Commission is modifying its current practice to allow for an expedited Fast-Track Resolution (''FTR'') for a limited number of matters involving self-reported violations. This procedure would be available at the Commission's discretion, but may be requested by respondents.

Respondents eligible for the FTR process will meet with the Office of General Counsel to negotiate a proposed conciliation agreement before the Commission makes any formal findings in the matter. Although the Commission is always free to reject or seek modifications to a proposed conciliation agreement, it is expected that this process will allow for more expedited processing of certain types of violations where factual and legal issues are reasonably clear. It also will allow respondents to resolve certain matters short of the Commission finding that there is reason to believe that a violation has occurred. Examples of matters that might be eligible for such treatment include:

- Matters in which an individual contributor discovers that he or she inadvertently violated the individual aggregate election cycle contribution limit contained in 2 U.S.C. 441a(a)(3);
- Matters in which a political committee seeks to disclose and correct relatively straightforward reporting violations;
- Matters in which a contributor and a political committee jointly seek to resolve their liability for a simple and clearly inadvertent excessive or prohibited contribution; and
- Matters in which the initial self-reporting submission by the respondents is so thorough that only very limited follow-up by the Office of the General Counsel is necessary to complete the factual record.

[5] The Commission normally applies standard civil penalty calculations and then adjusts the figure for aggravating or mitigating circumstances. For example, if the standard civil penalty calculation were $20,000 it might be raised for an aggravating factor, such as failure to timely file an election sensitive report. Once the initial calculation is reached, respondents normally receive a 25% discount off of this penalty for settling during the pre-probable cause conciliation stage. Any discounts pursuant to this policy will be applied after this reduction.

V. Parallel Proceedings

The Commission recognizes that persons self-reporting to the Commission may face special concerns in connection with parallel criminal investigations, State administrative proceedings, and/or civil litigation. The Commission expects that persons who self-report to the Commission will inform the Commission of any existing parallel proceedings. The Commission encourages persons who self-report to the Commission also to self-report related violations to any law enforcement agency with jurisdiction over the activity. This will assist the Commission, where appropriate and possible, in working with other Federal, State, and local agencies to facilitate a global and/or contemporaneous resolution of related violations by a self-reporting person. The possibility of such a resolution is enhanced when the self-reporting person expresses a willingness to engage other government agencies that may have jurisdiction over the conduct and to cooperate with joint discovery and disclosure of facts and settlement positions with respect to the different agencies.

In situations where contemporaneous resolution of parallel matters is not feasible, the Commission will consider whether terms contained in a conciliation agreement with the Commission may affect potential liability the same respondent realistically faces from another agency. In appropriate cases, where there has been self-reporting and full cooperation, the Commission may agree to enter into conciliation without requiring respondents to admit that their conduct was ''knowing and willful,'' even where there is evidence that may be viewed as supporting this conclusion. (The civil penalty, however, may be based on ''knowing and willful'' conduct.) The Commission has followed this practice in several self-reported matters where the organizational respondents promptly self-reported and took comprehensive and immediate corrective action that included the dismissal of all individual corporate officers whose actions formed the basis for the organization's potential ''knowing and willful'' violation.

The Commission, which has the statutory authority to refer ''knowing and willful'' violations of the FECA to the Department of Justice for potential criminal prosecution, 2 U.S.C. 437g(a)(5)(C), and to report information regarding violations of law not within its jurisdiction to appropriate law enforcement authorities, 2 U.S.C. 437d(a)(9), will not negotiate whether it refers, reports, or otherwise discusses information with other law enforcement agencies. Although the Commission cannot disclose information regarding an investigation to the public, it can and does share information on a confidential basis with other law enforcement agencies.

VI. Conclusion

In light of the considerations explained above, the Commission is considering issuing a policy statement to clarify how it exercises its discretion in enforcement matters involving self-reported violations of the FECA. The Commission invites comments on any aspect of the proposed policy statement, including:

(A) Whether and to what extent the Commission should consider the various factors described above, and/or other factors, in resolving self-reported violations of the FEC; and

(B) Whether and how to apply the new proposed Fast Track Resolution process in resolving self-reported violations of the FECA.

Dated: December 1, 2006.

Michael E. Toner,

Chairman, Federal Election Commission.

[FR Doc. E6–20845 Filed 12–7–06; 8:45 am]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

11 CFR Part 111

[Notice 2006–22]

Best Efforts in Administrative Fines Challenges

AGENCY: Federal Election Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Election Commission seeks public comment on proposed revisions to its regulations regarding the Commission's administrative fines program. The administrative fines program is a streamlined process through which the Commission finds and penalizes violations of 2 U.S.C. 434(a), which requires committees registered with the Commission to file periodic reports. Current Commission regulations set forth several grounds upon which a respondent may base a challenge to an administrative fine. The proposed regulations replace the current ''extraordinary circumstances'' defense with a ''best efforts'' defense. The proposed regulations would also provide for Commission statements of reasons on administrative fines final determinations. The Commission has made no final decision on the issues presented in this rulemaking. Further information is provided in the supplementary information that follows.

DATES: Comments must be received on or before January 8, 2007.

ADDRESSES: All comments must be in writing, must be addressed to Mr. J. Duane Pugh Jr., Acting Assistant General Counsel, and must be submitted in either e-mail, facsimile, or paper copy form. Commenters are strongly encouraged to submit comments by e-mail to ensure timely receipt and consideration. E-mail comments must be sent to either *afbestefforts@fec.gov* or submitted through the Federal eRegulations Portal at *http://www.regulations.gov*. If e-mail comments include an attachment, the attachment must be in either Adobe Acrobat (.pdf) or Microsoft Word (.doc) format. Faxed comments must be sent to (202) 219–3923, with paper copy follow-up. Paper comments and paper copy follow-up of faxed comments must be sent to the Federal Election Commission, 999 E Street, NW., Washington, DC 20463. All comments must include the full name and postal service address of the commenter or they will not be considered. The Commission will post comments on its Web site after the comment period ends.

FOR FURTHER INFORMATION CONTACT: Mr. J. Duane Pugh Jr., Acting Assistant General Counsel, or Ms. Margaret G. Perl, Attorney, 999 E Street, NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: Under the administrative fines program, the Commission may assess a civil money penalty for a violation of the reporting requirements of 2 U.S.C. 434(a) (such as not filing or filing late) without using the traditional enforcement procedures. 2 U.S.C. 437g(a)(4)(C). Congress intended the Commission to process these straightforward violations through a ''simplified procedure'' that would ease the enforcement burden on the Commission. H.R. Rep. No. 106–295 at 11 (1999). In the final rules establishing and governing the administrative fines program, the Commission created a streamlined procedure that balances the respondent's rights to notice and opportunity to be heard with the Congressional intent that the administrative fines program work in an expeditious manner to resolve these reporting violations without additional administrative burden. *Final Rule on Administrative Fines,* 65 FR 31787–88 (May 19, 2000).

The Federal Election Campaign Act (''FECA'') provides that ''[w]hen the treasurer of a political committee shows

that best efforts have been used to obtain, maintain, and submit the information required by this Act for the political committee, any report or any records of such committee shall be considered in compliance with [FECA].'' 2 U.S.C. 432(i).[1] The current administrative fines regulations enumerate grounds upon which a respondent may challenge a Commission determination that an administrative fine should be imposed, but a best efforts defense is not explicitly listed among these grounds.

In *Lovely* v. *FEC*, 307 F. Supp. 2d 294 (D. Mass. 2004), the court addressed a political committee's challenge to an administrative fine assessed by the Commission for the committee's failure to timely file a report. The committee argued that it had made best efforts to file the report and that this constituted a valid and complete defense to the fine. The court concluded that the plain language of the Act requires the Commission to entertain a best efforts defense in the administrative fines context, and that it was unclear from the record in the *Lovely* case whether the Commission had considered the best efforts defense raised by the committee. The court remanded the case to the Commission for further proceedings.[2] On remand, the Commission determined that the committee had failed to show best efforts and left the administrative fine in place. *Commission's Statement of Reasons in Administrative Fines Case #549 on Remand From the United States District Court for the District of Massachusetts,* Oct. 4, 2005, *available at http://www.fec.gov/members/toner/sor/soraf549.pdf*.

The proposed regulations would explicitly incorporate a best efforts defense into the process for challenging an administrative fine, would clarify the scope of the ''factual errors'' defense, and would provide for statements of reasons for administrative fines final determinations. These proposed changes are intended to address the concerns raised by the *Lovely* court as well as to provide greater clarity regarding permissible grounds for challenging administrative fines.

I. 11 CFR 111.35—Grounds for Challenging an Administrative Fines Reason To Believe Finding

Under the administrative fines regulations, if the Commission determines that it has reason to believe (''RTB'') that a committee has failed to timely file a required report, it notifies the respondent of this finding and of the proposed civil penalty. 11 CFR 111.32. The Commission makes RTB findings based on an internal process that identifies late filers. The amount of the penalty is determined using the schedules at 11 CFR 111.43. Following an RTB finding, a respondent has forty days to challenge the alleged violation. 11 CFR 111.35. Challenges are reviewed by Commission staff and ultimately decided by the Commission. 11 CFR 111.36, 111.37.

The current regulations set forth three permissible grounds upon which to challenge an administrative fines RTB finding. Respondents are permitted to challenge administrative fines on the basis of ''factual errors,'' the improper calculation of a penalty, or ''extraordinary circumstances that were beyond the control of the respondent and that were for a duration of at least 48 hours and that prevented the respondent from filing the report in a timely manner.'' 11 CFR 111.35(b)(1). The regulations also provide examples of situations that will not be considered ''extraordinary circumstances,'' including negligence, problems with vendors or contractors, illness, inexperience, or unavailability of staff, and computer failures (except failures of the Commission's computers). 11 CFR 111.35(b)(4).

This NPRM proposes a revision of 11 CFR 111.35 that clarifies the scope of the regulation's ''factual errors'' defense and also replaces the ''extraordinary circumstances'' defense with a best efforts defense.

A. 11 CFR 111.35(b)(1)(i)—Changes to the ''Factual Errors'' Defense

The proposed regulation retains a ''factual errors'' defense, currently at 11 CFR 111.35(b)(1)(i), but clarifies the boundaries of this defense by stating that the facts alleged to be in error must be facts upon which the Commission relied in its RTB finding. *Proposed* 11 CFR 111.35(b)(1). The proposed regulation also provides two examples of such factual errors: that the respondent was not required to file the report in question, and that the respondent did in fact timely file as described in 11 CFR 100.19. *Id.* For instance, a paper filer that has ''timely filed'' a report under the definition in 11 CFR 100.19 would be considered to have timely filed for purposes of the administrative fines program. This would be true even if the Commission does not ultimately receive the filing, due, for instance, to errors by the overnight delivery service or in the handling of the mail. The Commission seeks comment on this approach. Should other types of factual errors be allowed as grounds for challenge to the finding of a violation? Should the regulation include additional examples of qualifying factual errors?

B. 11 CFR 111.35(b)(1)(iii)—Replacing the ''Extraordinary Circumstances'' Defense With a Best Efforts Defense

The proposed regulation replaces the ''extraordinary circumstances'' defense currently at 11 CFR 111.35(b)(1)(iii) with a best efforts defense. The proposed regulation makes clear that a respondent may base a challenge to an administrative fine on a showing that respondent made best efforts to timely file the report in question. To show that it made best efforts to timely file, a respondent would be required to demonstrate that both (i) Respondent was prevented from filing in a timely manner because of unforeseen circumstances that were beyond the control of the respondent, and (ii) respondent filed the report in question within 24 hours of the respondent's no longer being prevented from filing. *Proposed* 11 CFR 111.35(b)(3). The proposed regulation gives two examples of unforeseen circumstances that were beyond the control of the respondent: a failure of Commission computers, Commission software, or the internet; and severe weather or other disaster-related incident. *Proposed* 11 CFR 111.35(c). The proposed regulation also gives examples of circumstances that will not be considered unforeseen and beyond the control of the respondent, including negligence; delays caused by committee vendors or contractors; illness, inexperience, or unavailability of the treasurer or other staff; committee computer or software failures; a committee's failure to know filing dates; or a committee's failure to use FEC filing software properly. *Proposed* 11 CFR 111.35(d). Like the current regulations, the proposed regulations would require a respondent to explain the factual basis supporting the respondent's challenge. *Proposed* 11 CFR 111.35(e).

The best efforts defense set forth in the proposed regulation would serve as a proxy for a full factual investigation of a respondent committee's internal

[1] The Commission has long interpreted the ''best efforts'' provision as a statutory safe harbor limited to political committees' obligation to report certain substantive information that may be beyond the control of the committees to obtain. 11 CFR 104.7 (defining ''best efforts'' for purposes of obtaining and submitting contributor information).

[2] The *Lovely* case did not involve a challenge to the validity of the administrative fines program rules, and those rules have continued in full force and effect since the district court order. However, the court stated that the Commission could ''refine by regulation what best efforts means in the context of submitting a report.'' *Lovely*, 307 F. Supp. 2d at 300.

practices regarding filing of reports and an analysis of whether such practices were sufficient to constitute best efforts. Such an investigation would be particularly burdensome in the context of the administrative fines program, which is meant to be a ''streamlined procedure.'' *Final Rule on Administrative Fines*, 65 FR at 31787.

The Commission seeks comment on the proposed best efforts defense. Will the proposed test serve as a sufficient proxy for a full best efforts investigation? Are there other circumstances not contemplated by the proposed regulations that could prevent a respondent from timely filing, notwithstanding the respondent having taken best efforts to ensure that the report would be timely filed? Should the Commission apply a ''but for'' test, a ''contributing factor'' test, or some other test for determining whether a respondent was prevented from timely filing by particular circumstances? Should the Commission retain an extraordinary circumstances defense? Should the Commission entertain defenses based on extreme financial hardship? Should the regulations be more specific as to what constitutes computer or Internet failures, or severe weather or disaster? Should the list of circumstances that will not be considered unforeseen and beyond the control of the respondent be expanded or contracted, and if so by which elements? Should the 24 hour period be longer or shorter, or should committees be required to file as soon as would be practicable? What sort of supporting evidence should a respondent be required to provide? Are there other important factors that the Commission should incorporate into a best efforts defense? Alternatively, should the Commission refrain from adding a specific best efforts defense to the administrative fines regulation? Does Lovely preclude this approach?

II. 11 CFR 111.37—Commission Action on Administrative Fines Challenges

Section 111.37 of the Commission's rules guides Commission decisions regarding the final determination of administrative fines challenges. The proposed regulations direct the Commission to conclude that no violation has occurred if the Commission based its RTB finding on a factual error or if the respondent made best efforts to timely file. *Proposed* 11 CFR 111.37(b). The proposed regulations also include a new section 111.37(d), which makes clear that the staff recommendation regarding the challenge, including any changes made by the Commission, will serve as the Commission's statement of reasons regarding the administrative fine at issue. This change is intended to satisfy the *Lovely* court's concern that, in that case, the Commission had issued no opinion or statement of reasons along with its final determination. *Lovely*, 307 F. Supp. 2d at 301. Finally, the proposed regulations amend section 111.37(d) to eliminate reference to the ''extraordinary circumstances'' defense, which would no longer be applicable.

The Commission seeks comment on these changes. Are there additional conforming amendments required to implement the proposed best efforts defense?

Certification of No Effect Pursuant to 5 U.S.C. 605(b) (Regulatory Flexibility Act)

The Commission certifies that the attached proposed rules would not, if promulgated, have a significant economic impact on a substantial number of small entities. The basis for this certification is that any individuals and not-for-profit entities that would be affected by these proposed rules are not ''small entities'' under 5 U.S.C. 601. The definition of ''small entity'' does not include individuals, but classifies a not-for-profit enterprise as a ''small organization'' if it is independently owned and operated and not dominant in its field. 5 U.S.C. 601(4). State political party committees are not independently owned and operated because they are not financed and controlled by a small identifiable group of individuals, and they are affiliated with the larger national political party organizations. In addition, the State political party committees representing the Democratic and Republican parties have a major controlling influence within the political arena of their State and are thus dominant in their field. District and local party committees are generally considered affiliated with the State committees and need not be considered separately. To the extent that any State party committees representing minor political parties or any other political committees might be considered ''small organizations,'' the number that would be affected by this proposed rule is not substantial.

Furthermore, any separate segregated funds that would be affected by these proposed rules are not-for-profit political committees that do not meet the definition of ''small organization'' because they are financed by a combination of individual contributions and financial support for certain expenses from corporations, labor organizations, membership organizations, or trade associations, and therefore are not independently owned and operated. Most of the other political committees that would be affected by these proposed rules are not-for-profit committees that do not meet the definition of ''small organization.'' Most political committees are not independently owned and operated because they are not financed by a small identifiable group of individuals. In addition, most political committees rely on contributions from a large number of individuals to fund the committees' operations and activities.

The proposed rules also would not impose any additional restrictions or increase the costs of compliance for respondents within the administrative fines program. Instead, the proposed rules would provide additional defenses available to respondents in the administrative fines program, thereby and potentially increasing the situations in which the Commission imposes no civil money penalty. Moreover, the proposed rules would apply only in the administrative fines program, where penalties are proportionate to the amount of a political committee's financial activity. Any political committee meeting the definition of ''small entity'' would be subject to lower fines than larger committees with more financial activity. Therefore, the attached proposed rules, if promulgated, would not have a significant economic impact on a substantial number of small entities.

List of Subjects in 11 CFR Part 111

Administrative practice and procedures, Elections, Law enforcement.

For the reasons set out in the preamble, the Federal Election Commission proposes to amend Subchapter A of Chapter I of Title 11 of the *Code of Federal Regulations* as follows:

PART 111—COMPLIANCE PROCEDURE (2 U.S.C. 437g, 437d(a))

1. The authority citation for part 111 is revised to read as follows:

Authority: 2 U.S.C. 432(i), 437g, 437d(a), 438(a)(8); 28 U.S.C. 2461 nt.

2. Section 111.35 is revised to read as follows:

§ 111.35 If the respondent decides to challenge the alleged violation or proposed civil money penalty, what should the respondent do?

(a) To challenge a reason to believe finding or proposed civil money penalty, the respondent must submit a written response to the Commission within forty days of the Commission's reason to believe finding.

(b) The respondent's written response must establish at least one of the following grounds for challenging the reason to believe finding and/or civil money penalty:

(1) The Commission's reason to believe finding is based on a factual error. Examples of a factual error include, but are not limited to, that the committee was not required to file or that the committee timely filed as described in 11 CFR 100.19 (such as by timely depositing a paper filing with an overnight delivery service);

(2) The Commission improperly calculated the civil money penalty; or

(3) The respondent made best efforts to file in a timely manner in that:

(i) The respondent was prevented from filing in a timely manner because of unforeseen circumstances that were beyond the control of the respondent; and

(ii) The respondent filed within 24 hours thereafter.

(c) Circumstances that will be considered unforeseen and beyond the control of respondent include, but are not limited to, a failure of Commission computers, Commission-provided software, or the Internet, and severe weather or other disaster-related incident.

(d) Circumstances that will not be considered unforeseen and beyond the control of respondent include, but are not limited to, negligence; delays caused by committee vendors or contractors; illness, inexperience, or unavailability of the treasurer or other staff; committee computer or software failures; a committee's failure to know filing dates; or a committee's failure to use filing software properly.

(e) Respondent's written response must detail the factual basis supporting the grounds and include any supporting documentation.

3. In § 111.37, paragraphs (b) and (d) are revised to read as follows:

§ 111.37 What will the Commission do once it receives the respondent's written response and the reviewing officer's recommendation?

* * * * *

(b) If the Commission, after reviewing the reason to believe finding, the respondent's written response, and the reviewing officer's written recommendation, determines by an affirmative vote of at least four (4) of its members, that no violation has occurred (either because the Commission had based its reason to believe finding on a factual error or because the respondent made best efforts to file in a timely manner) or otherwise terminates its proceedings, the Commission shall authorize the reviewing officer to notify the respondent by letter of its final determination.

* * * * *

(d) When the Commission makes a final determination under this section, the statement of reasons for the Commission action consists of the reasons provided in the reviewing officer's recommendation, if adopted by the Commission, subject to any Commission amendments, additions, substitutions, or statements of reasons.

Dated: November 30, 2006.

Michael E. Toner,

Chairman, Federal Election Commission.

[FR Doc. E6–20735 Filed 12–7–06; 8:45 am]

BILLING CODE 6715–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–26462; Directorate Identifier 2006–NM–221–AD]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170–100 LR, –100 STD, –100 SE, –100 SU, –200 LR, –200 STD, and –200 SU Airplanes and Model ERJ 190 Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain EMBRAER Model ERJ 170–100 LR, –100 STD, –100 SE, –100 SU, –200 LR, –200 STD, and –200 SU airplanes and Model ERJ 190 airplanes. This proposed AD would require inspecting to determine the part number and serial number of the deployment actuator of the ram air turbine (RAT) and related investigative and corrective actions if necessary. This proposed AD results from reports that the RAT may not fully deploy due to galling between the piston rod and gland housing of the deployment actuator. We are proposing this AD to prevent the RAT from failing to deploy, which could result in loss of control of the airplane during in-flight emergencies.

DATES: We must receive comments on this proposed AD by January 8, 2007.

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

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590.
- Fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343–CEP 12.225, Sao Jose dos Campos–SP, Brazil, for service information identified in this proposed AD.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed in the **ADDRESSES** section. Include the docket number ''FAA–2006–26462; Directorate Identifier 2006–NM–221–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

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

Examining the Docket

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

Discussion

The Agência Nacional de Aviação Civil (ANAC), which is the airworthiness authority for Brazil, notified us that an unsafe condition may exist on all EMBRAER Model ERJ 170 and ERJ 190 airplanes. The ANAC advises that it has received reports that the ram air turbine (RAT) may not fully deploy due to galling between the piston rod and gland housing of the deployment actuator. The galling resulted in material becoming wedged between the piston rod and the gland housing. This condition, if not corrected, could lead to the RAT failing to deploy, which could result in loss of control of the airplane during in-flight emergencies.

Relevant Service Information

EMBRAER has issued Service Bulletins 170–24–0026 and 190–24–0003, both dated December 22, 2005. The service bulletins describe procedures for inspecting to determine the part number (P/N) and serial number (S/N) of the RAT deployment actuator. For deployment actuators having P/N 1703785 and S/N 0004, 0005, or 0101 through 0190 inclusive, the service bulletins describe procedures for investigative and corrective actions, including:

- Deploying the RAT and inspecting for evidence of galling between the piston rod and gland housing of the deployment actuator;
- Repeating the inspection of the actuator of any RAT that fully deploys and displays no evidence of galling as specified above, until that actuator is replaced with a modified and reidentified or new, improved actuator, which eliminates the need for the repetitive inspections only for that actuator;
- Replacing the deployment actuator of any RAT that fails to fully deploy or that displays any evidence of galling, as specified above, with a modified and reidentified or new, improved actuator; and
- Eventually replacing all subject actuators with modified and reidentified or new, improved actuators, which eliminates the need for the repetitive inspections for all subject actuators.

For actuators having P/N 1703785 and S/Ns 0191 through 0242 inclusive, the service bulletins describe procedures for re-identifying the actuators.

Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. The ANAC mandated the service information and issued Brazilian airworthiness directives 2006–05–06, effective June 14, 2006, and 2006–05–09, effective June 19, 2006, to ensure the continued airworthiness of these airplanes in Brazil.

The EMBRAER service bulletins refer to Hamilton Sundstrand Service Bulletin ERPS37A–24–1, dated December 6, 2005, as an additional source of service information for inspecting for galling of the piston rod of the RAT deployment actuator and re-identifying the actuator. The Hamilton Sundstrand service bulletin is included as Appendix 1 of the EMBRAER service bulletins.

FAA's Determination and Requirements of the Proposed AD

These airplane models are manufactured in Brazil and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the ANAC has kept the FAA informed of the situation described above. We have examined the ANAC's findings, evaluated all pertinent information, and determined that we need to issue an AD for airplanes of this type design that are certificated for operation in the United States.

Therefore, we are proposing this AD, which would require doing the actions described previously, except as discussed under ''Differences Among the Proposed AD, the Brazilian Airworthiness Directives, and the Service Information.''

Differences Among the Proposed AD, the Brazilian Airworthiness Directives, and the Service Information

The EMBRAER service bulletins specify to inspect for galling between the piston rod and gland housing in the deployment actuator; however, this proposed AD would require a ''general visual inspection'' for such galling. We have included a definition of this type of inspection in Note 2 of this proposed AD.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this proposed AD, at an average labor rate of $80 per hour.

ESTIMATED COSTS

Action	Work hours	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Inspection to determine part and serial numbers	1	$80	76	$6,080.
Inspection of piston rod	1	$80, per inspection cycle	Up to 76	Up to $6,080, per inspection cycle.
Replacement of RAT deployment actuator	4	$320	Up to 76	Up to $24,320.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

Empresa Brasileira de Aeronautica S.A. (EMBRAER): Docket No. FAA–2006–26462; Directorate Identifier 2006–NM–221–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by January 8, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all EMBRAER Model ERJ 170–100 LR, –100 STD, –100 SE, –100 SU, –200 LR, –200 STD, and –200 SU airplanes, as identified in EMBRAER Service Bulletin 170–24–0026, dated December 22, 2005; and Model ERJ 190–100 STD, –100 LR, and –100 IGW airplanes, as identified in EMBRAER Service Bulletin 190–24–0003, dated December 22, 2005; certificated in any category.

Unsafe Condition

(d) This AD results from reports that the ram air turbine (RAT) may not fully deploy due to galling between the piston rod and gland housing of the RAT deployment actuator. We are issuing this AD to prevent the RAT from failing to deploy, which could result in loss of control of the airplane during in-flight emergencies.

Compliance

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

Service Bulletin Reference

(f) The term ''service bulletin,'' as used in this AD, means the Accomplishment Instructions of the service bulletins identified in paragraphs (f)(1) and (f)(2) of this AD. Where these service bulletins specify returning affected parts to Hamilton Sundstrand, this AD does not require that action.

(1) For Model ERJ 170–100 LR, –100 STD, –100 SE, and –100 SU airplanes: EMBRAER Service Bulletin 170–24–0026, dated December 22, 2005.

(2) For Model ERJ 190–100 STD, –100 LR, and –100 IGW airplanes: EMBRAER Service Bulletin 190–24–0003, dated December 22, 2005.

Note 1: The EMBRAER service bulletins refer to Hamilton Sundstrand Service Bulletin ERPS37A–24–1, dated December 6, 2005, as an additional source of service information for inspecting for galling of the piston rod of the RAT deployment actuator and re-identifying the actuator. The Hamilton Sundstrand service bulletin is included as Appendix 1 of the EMBRAER service bulletins.

Inspection To Determine Part Number (P/N) and Serial Number (S/N)

(g) Within 600 flight hours or 3 months after the effective date of this AD, whichever occurs first: Inspect to determine the part number and serial number of the RAT deployment actuator, in accordance with the applicable service bulletin. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number and serial number of the RAT deployment actuator can be conclusively determined from that review.

(1) If the part number of the actuator is not P/N 1703785: No further action is required by this AD, except as provided by paragraph (i) of this AD.

(2) If the part number of the actuator is P/N 1703785 and the serial number is S/N 0004, 0005, or 0101 through 0190 inclusive, or the part number or serial number cannot be conclusively determined: Within 600 flight hours or 3 months after the effective date of this AD, whichever occurs first, deploy the RAT, and do the actions specified in paragraph (g)(2)(i) or (g)(2)(ii) of this AD, as applicable, in accordance with the applicable service bulletin.

(i) If the RAT does not fully deploy or if it deploys with hesitation: Before further flight, replace the RAT deployment actuator with a modified and reidentified or new, improved actuator, having P/N 1703785A.

(ii) If the RAT fully deploys without hesitation: Before further flight, perform a general visual inspection for galling of the piston rod of the RAT deployment actuator. If no evidence of galling is detected, repeat the inspection for galling at intervals not to exceed 1,200 flight hours or 5 months, whichever occurs first, and before further flight after each deployment of the RAT. If any evidence of galling is found, before further flight, replace the RAT deployment actuator with a modified and reidentified or new, improved RAT deployment actuator having P/N 1703785A. Replacing the RAT deployment actuator terminates the repetitive inspections required by this paragraph for that RAT deployment actuator only.

Note 2: For the purposes of this AD, a general visual inspection is: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to ensure visual access to all surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

(3) If the part number of the RAT deployment actuator is P/N 1703785, and the serial number is S/N 0191 through 0242 inclusive: Within 3,000 flight hours or 12 months after the effective date of this AD, whichever occurs first, reidentify the RAT deployment actuator with new P/N 1703785A in accordance with the applicable service bulletin.

Terminating Action for Repetitive Inspections

(h) Within 3,000 flight hours or 12 months after the effective date of this AD, whichever occurs first: Replace all RAT deployment actuators having P/N 1703785 and having S/N 0004, 0005, or 0101 through 190 inclusive, with modified and reidentified or new, improved actuators having P/N 1703785A, in accordance with the applicable service bulletin. Replacing all of the RAT deployment actuators terminates the repetitive inspections required by paragraph (g)(2)(ii) of this AD.

Parts Installation

(i) As of the effective date of this AD, no person may install a RAT deployment actuator having P/N 1703785 on any airplane.

Alternative Methods of Compliance (AMOCs)

(j)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(k) Brazilian airworthiness directives 2006–05–06, effective June 14, 2006, and 2006–05–09, effective June 19, 2006, also address the subject of this AD.

Issued in Renton, Washington, on November 24, 2006.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6–20856 Filed 12–7–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–26441; Directorate Identifier 2006–NM–204–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747 Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Boeing Model 747 airplanes. This proposed AD would require an inspection of the number (No.) 2 and No. 3 windows on the left and right sides of the airplane to determine their part numbers, and related investigative and corrective actions if necessary. This proposed AD results from loss of a No. 3 window in-flight. We are proposing this AD to detect and correct cracking in the fail-safe interlayer of certain No. 2 and No. 3 glass windows, which could result in loss of the window and consequent rapid loss of cabin pressure. Loss of the window could also result in crew communication difficulties or incapacitation of the crew.

DATES: We must receive comments on this proposed AD by January 22, 2007.

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

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- Fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207, for the service information identified in this proposed AD.

FOR FURTHER INFORMATION CONTACT: Gary Oltman, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6443; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed in the **ADDRESSES** section. Include the docket number ''FAA–2006–26441; Directorate Identifier 2006–NM–204–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

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

Examining the Docket

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

Discussion

We have received a report indicating that a number (No.) 3 window departed in-flight from a Boeing Model 747 airplane. Loss of the window resulted in rapid loss of cabin pressure, and the flightcrew made an emergency landing. The airplane had accumulated 36,131 total flight hours and 5,607 total flight cycles. Investigation revealed that a crack was present in the fail-safe interlayer of the No. 3 window, along the inner edge of the window's aluminum edge insert. When the structural inner glass pane cracked due to an electrical arcing event unassociated with the interlayer cracking, the interlayer was not able to support the cabin pressurization load and the window departed from the airplane. Subsequently, Boeing and some operators have also found cracks in the fail-safe interlayer of certain No. 2 and No. 3 glass windows, on many Model 747 airplanes. This condition, if not corrected, could result in loss of the window and consequent rapid loss of cabin pressure. Loss of the window could also result in crew communication difficulties or incapacitation of the crew.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 747–56A2012, dated August 24, 2006. The service bulletin describes procedures for doing a one-time inspection of the No. 2 and No. 3 windows on the left and right sides of the airplane to determine their part numbers (P/Ns) and doing related investigative and corrective actions if necessary. The service bulletin states that, instead of an inspection to determine the part number of a window, a review of maintenance records is acceptable if the part number of the window can be positively determined from that review. The service bulletin also states that if acrylic windows having P/N 65B07639–( ) or 65B07640–( ) are installed, no further inspections are necessary. The service bulletin also states that if the part number of the left No. 2 window, left No. 3 window, right No. 2 window, or right No. 3 window cannot be identified, you must assume that it is P/N 65B27042–1, 65B27043–1, 65B27042–2, or 65B27043–2, respectively. If glass windows having

65B27046–( ), or 65B27047–( ) are installed, the service bulletin specifies doing the related investigative actions, which are repetitive detailed inspections for cracking or damage to the window. The corrective action is replacement of the affected window with a new window, if any of the following conditions are found during a detailed inspection: cracks in any fail-safe interlayer, cracks in a glass pane, chips in a structural glass pane, evidence of electrical arcing, or any non-clear damage to the window.

For the one-time inspection to determine the part numbers of the No. 2 and No. 3 windows, Table 1 of the service bulletin specifies doing the inspection at the earlier of the following compliance times: (1) Within 5,500 flight hours after the window was installed or 1,000 flight hours after the date of the service bulletin, whichever occurs last, or (2) within 2 years after the date of the service bulletin. Table 1 states that if the number of flight hours since the window was installed is not known, you must assume that the window is beyond the 5,500 flight-hour limit.

For a window having P/N 65B27042–( ) or 65B27043–( ), Table 2 of the service bulletin specifies doing the related investigative action (detailed inspection) at the earlier of the following compliance times: (1) Within 5,500 flight hours after the window was installed or 1,000 flight hours after the date of the service bulletin, whichever occurs last, or (2) within 2 years after the date of the service bulletin. Table 2 states that if the number of flight hours since the window was installed is not known, you must assume that the window is beyond the 5,500 flight-hour limit. Table 2 specifies repeating the detailed inspection at intervals not to exceed 3,000 flight hours or 3 years, whichever occurs first. Table 2 also specifies replacing the window before further flight after the inspection, if necessary.

For a window having P/N 65B27046–( ) or 65B27047–( ), Table 3 of the service bulletin specifies doing the related investigative action (detailed inspection) at the earlier of the following compliance times: (1) Within 22,000 flight hours after the window was installed or 1,000 flight hours after the date of the service bulletin, whichever occurs last, or (2) within 3 years after the date of the service bulletin. Table 3 states that if the number of flight hours since the window was installed is not known, you must assume that the window is beyond the 22,000 flight-hour limit. Table 3 specifies repeating the detailed inspection at intervals not to exceed 7,500 flight hours or 5 years, whichever occurs first. Table 3 also specifies replacing the window before further flight, if necessary.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. For this reason, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously.

Interim Action

This is considered to be interim action until final action is identified, at which time we may consider further rulemaking.

Costs of Compliance

There are about 949 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 153 airplanes of U.S. registry. The proposed inspection to determine the window part numbers would take about 4 work hours per airplane, at an average labor rate of $80 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $48,960, or $320 per airplane.

The proposed detailed inspection, if necessary, would take about 1 work hour per airplane, at an average labor rate of $80 per work hour. Based on these figures, the estimated cost of the proposed detailed inspection for U.S. operators is $80 per airplane, per inspection cycle.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2006–26441; Directorate Identifier 2006–NM–204–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by January 22, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Boeing Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from loss of a number (No.) 3 window in-flight. We are issuing this AD to detect and correct cracking in the fail-safe interlayer of certain No. 2 and No. 3 glass windows, which could result in loss of the window and consequent rapid loss of cabin pressure. Loss of the window could also result in crew communication difficulties or incapacitation of the crew.

Compliance

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

Inspection, Related Investigative Actions, and Corrective Action

(f) Inspect the No. 2 and No. 3 windows on the left and right sides of the airplane to determine their part numbers (P/Ns), and do all the applicable related investigative and corrective actions, by accomplishing all of the actions specified in Accomplishment Instructions of Boeing Alert Service Bulletin 747–56A2012, dated August 24, 2006, as applicable. Do all of these actions at the compliance times specified in Tables 1, 2, and 3 of paragraph 1.E. of the service bulletin, as applicable, except as provided by paragraph (g) of this AD. A review of airplane maintenance records is acceptable in lieu of the inspection if the part numbers of the windows can be conclusively determined from that review. Repeat the related investigative and corrective actions thereafter at the interval specified in Table 2 or 3 of the service bulletin, as applicable.

Exception to Compliance Times

(g) Where Tables 1, 2, and 3 of paragraph 1.E. of Boeing Alert Service Bulletin 747–56A2012, dated August 24, 2006, specify counting the compliance time from ''* * * after the date on this service bulletin,'' this AD requires counting the compliance time from the effective date of this AD.

Alternative Methods of Compliance (AMOCs)

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

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

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

Issued in Renton, Washington, on November 20, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6–20863 Filed 12–7–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–26272; Directorate Identifier 2006–NM–153–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A318, A319, A320, and A321 Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus Model A318, A319, A320, and A321 airplanes. This proposed AD would require repetitive inspections of the operation of the main landing gear (MLG) door opening sequence to determine if a defective actuator is installed, and replacing any defective actuator with a new actuator. This proposed AD results from reports of slow operation of the MLG door opening/closing sequence due to a defective actuator. We are proposing this AD to detect and correct defective actuators of the MLG door, which could result in slow operation of the MLG door and consequent non-extension of the MLG during an emergency freefall operation.

DATES: We must receive comments on this proposed AD by January 8, 2007.

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

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, room PL–401, Washington, DC 20590.
- Fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for service information identified in this proposed AD.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, WA 98057–3356; telephone (425) 227–2141; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed in the **ADDRESSES** section. Include the docket number ''FAA–2006–26272; Directorate Identifier 2006–NM–153–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

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

Examining the Docket

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

Discussion

The European Aviation Safety Agency (EASA), which is the airworthiness

authority for the European Union, notified us that an unsafe condition may exist on all Airbus Model A318, A319, A320, and A321 airplanes. The EASA advises that there have been several reports of slow operation of the MLG door opening/closing sequence due to a defective actuator. This could lead to the generation of electronic centralized aircraft monitor warnings during the landing gear retraction or extension sequence. Investigation revealed that the affected MLG doors were difficult to open manually (unusually high pressure was required to extend the actuator to open the door) due to a problem with the door actuator. The damping ring and associated retaining ring were found broken, with subsequent damage to the damping housing from resulting debris. The resulting high friction delays the MLG extension/retraction sequence. This condition, if not corrected, could result in slow operation of the MLG door and consequent non-extension of the MLG during an emergency freefall operation.

Relevant Service Information

Airbus has issued Service Bulletin A320–32–1309, dated March 7, 2006. The service bulletin describes procedures for repetitive inspections of the operation of the main landing gear door (MLG) opening sequence to determine if a defective actuator is installed, and replacing any defective actuator with a new actuator. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. The EASA mandated the service information and issued airworthiness directive 2006–0112, dated May 15, 2006, to ensure the continued airworthiness of these airplanes in France.

FAA's Determination and Requirements of the Proposed AD

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. As described in FAA Order 8100.14A, ''Interim Procedures for Working with the European Community on Airworthiness Certification and Continued Airworthiness,'' dated August 12, 2005, the EASA has kept the FAA informed of the situation described above. We have examined the EASA's findings, evaluated all pertinent information, and determined that we need to issue an AD for airplanes of this type design that are certificated for operation in the United States.

Therefore, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously, except as discussed under ''Difference Between Proposed AD and the Service Information.''

Difference Between Proposed AD and the Service Information

Although the Accomplishment Instructions of the service bulletin describe procedures for submitting certain information to the manufacturer and sending defective actuators back to the component manufacturer for investigation, this AD does not include those requirements.

Interim Action

We consider this proposed AD interim action. If final action is later identified, we may consider further rulemaking then.

Clarification of Inspection Terminology

In this proposed AD, the ''inspection'' specified in the service bulletin is referred to as a ''general visual inspection.'' We have included the definition for a general visual inspection in a note in the proposed AD.

Costs of Compliance

This proposed AD would affect about 700 airplanes of U.S. registry. The proposed inspection would take about 1 work hour per airplane, at an average labor rate of $80 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $56,000, or $80 per airplane, per inspection cycle.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA–2006–26272; Directorate Identifier 2006–NM–153–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by January 8, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Airbus Model A318, A319, A320, and A321 airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from reports of slow operation of the main landing gear (MLG) door opening/closing sequence due to a defective actuator. We are issuing this AD to detect and correct defective actuators of the MLG door, which could result in slow operation of the MLG door and consequent non-extension of the MLG during an emergency freefall operation.

Compliance

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

Repetitive Inspections/Replacement

(f) At the time specified in paragraph (f)(1) or (f)(2) of this AD, as applicable: Do a general visual inspection of the operation of the MLG door opening sequence to determine if a defective actuator is installed by doing all the applicable actions, including replacing the door actuator, as applicable, specified in the Accomplishment Instructions of Airbus Service Bulletin A320–32–1309, dated March 7, 2006. Do all applicable replacements before further flight. Repeat the inspection thereafter at intervals not to exceed 900 flight cycles.

(1) For airplanes on which a record of the total number of flight cycles on the MLG door actuator is available: Before the accumulation of 3,000 total flight cycles on the MLG door actuator, or within 800 flight cycles after the effective date of this AD, whichever is later.

(2) For airplanes on which a record of the total number of flight cycles on the MLG door actuator is not available: With 800 flight cycles after the effective date of this AD.

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

(g) Although the Accomplishment Instructions of Airbus Service Bulletin A320–32–1309, dated March 7, 2006, specifies submitting certain information to the manufacturer and sending defective actuators back to the component manufacturer for investigation; this AD does not include those requirements.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(i) EASA airworthiness directive 2006–0112, dated May 15, 2006, also addresses the subject of this AD.

Issued in Renton, Washington, on November 21, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6–20852 Filed 12–7–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–26516; Directorate Identifier 2006–NM–173–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A318, A319, A320, and A321 Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede an existing airworthiness directive (AD) that applies to all Airbus Model A318–100 and A319–100 series airplanes, Model A320–111 airplanes, and Model A320–200, A321–100, and A321–200 series airplanes. The existing AD currently requires repetitive inspections of the upper and lower attachments of the trimmable horizontal stabilizer actuator (THSA) to measure for proper clearance and to detect cracks, damage, and metallic particles. The existing AD also requires corrective actions, if necessary, and reports of inspection findings. This proposed AD would shorten the repetitive interval for inspecting the upper THSA attachment. This proposed AD results from new test results on the secondary load path, which indicated the need to shorten the repetitive interval for inspecting the upper THSA attachment. We are proposing this AD to detect and correct failure of the THSA's primary load path, which could result in latent (undetected) loading and eventual failure of the THSA's secondary load path and consequent uncontrolled movement of the horizontal stabilizer and loss of control of the airplane.

DATES: We must receive comments on this proposed AD by January 8, 2007.

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

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590.
- Fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for service information identified in this proposed AD.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2141; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed in the **ADDRESSES** section. Include the docket number ''Docket No. FAA–2006–26516; Directorate Identifier 2006–NM–173–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

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

Examining the Docket

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

Discussion

On March 22, 2006, we issued AD 2006–07–09, amendment 39–14536 (71 FR 16203, March 31, 2006), for all Airbus Model A318–100 and A319–100 series airplanes, Model A320–111 airplanes, and Model A320–200, A321–100, and A321–200 series airplanes. That AD requires repetitive inspections of the upper and lower attachments of the trimmable horizontal stabilizer actuator (THSA) to measure for proper clearance and to detect cracks, damage, and metallic particles. That AD also requires corrective actions, if necessary, and reports of inspection findings. That AD resulted from a report indicating that, during lab testing to verify the performance of the THSA's secondary load path with a simulated failure of the THSA's primary load path, the secondary load path's nut did not jam (as it was supposed to do). We issued that AD to ensure the integrity of the THSA's primary load path, which, if failed, could result in latent (undetected) loading and eventual failure of the THSA's secondary load path and consequent uncontrolled movement of the horizontal stabilizer and loss of control of the airplane.

Actions Since Existing AD Was Issued

Since we issued AD 2006–07–09, the European Aviation Safety Agency (EASA), which is the airworthiness authority for the European Union, has advised us that further tests on the secondary load path have indicated the need to shorten the repetitive interval for inspecting the upper THSA attachment.

Relevant Service Information

AD 2006–07–09 cited Airbus Service Bulletin A320–27–1164, Revision 03, dated August 24, 2005, as the appropriate source of service information for required actions. Airbus has since issued Revision 04, including Appendix 01, of the service bulletin, dated July 17, 2006, which describes essentially the same actions as those in Revision 03. Revision 04 recommends a shorter repetitive interval for inspecting the upper THSA attachment. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition. The EASA mandated the service information and issued airworthiness directive 2006–0223, dated July 21, 2006, to ensure the continued airworthiness of these airplanes in the European Union.

FAA's Determination and Requirements of the Proposed AD

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. As described in FAA Order 8100.14A, ''Interim Procedures for Working with the European Community on Airworthiness Certification and Continued Airworthiness,'' dated August 12, 2005, the EASA has kept the FAA informed of the situation described above. We have examined the EASA's findings, evaluated all pertinent information, and determined that we need to issue an AD for airplanes of this type design that are certificated for operation in the United States.

This proposed AD would supersede AD 2006–07–09. This proposed AD would retain the requirements of that AD but with a shorter repetitive interval for inspecting the upper THSA attachment. This proposed AD would also require that reports of positive findings of each inspection be sent to Airbus.

Explanation of Change to Existing AD

The existing AD requires that certain repairs be done using a method approved by either the FAA or the Direction Générale de l'Aviation Civile (DGAC) (or its delegated agent). The EASA has assumed responsibility for the airplane models that would be subject to this proposed AD. Therefore, this proposed AD would require that those repairs be done using a method approved by the FAA, the DGAC (or its delegated agent), or the EASA (or its delegated agent).

Explanation of Change to Applicability

We have revised the applicability of the existing AD to identify model designations consistent with the parallel EASA airworthiness directive.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this proposed AD, per inspection cycle.

ESTIMATED COSTS

Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
1	$80	None	$80	700	$56,000

Authority for This Rulemaking

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

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

Regulatory Findings

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

responsibilities among the various levels of government.

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

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The Federal Aviation Administration (FAA) amends § 39.13 by removing amendment 39–14536 (71 FR 16203, March 31, 2006) and adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA–2006–26516; Directorate Identifier 2006–NM–173–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by January 8, 2007.

Affected ADs

(b) This AD supersedes AD 2006–07–09.

Applicability

(c) This AD applies to all Airbus Model A318, A319, A320, and A321 airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from a report indicating that, during lab testing to verify the performance of the secondary load path of the trimmable horizontal stabilizer actuator (THSA) with a simulated failure of the THSA's primary load path, the secondary load path's nut did not jam (as it was supposed to do). We are issuing this AD to detect and correct failure of the THSA's primary load path, which could result in latent (undetected) loading and eventual failure of the THSA's secondary load path and consequent uncontrolled movement of the horizontal stabilizer and loss of control of the airplane.

Compliance

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

Note 1: For the purposes of this AD, a detailed inspection is: ''An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.''

Repetitive Inspections: Lower THSA Attachment

(f) Within 20 months since first flight, or within 600 flight hours after May 5, 2006 (the effective date of AD 2006–07–09), whichever occurs later: Do detailed inspections of the lower THSA attachments for proper clearances, and do related corrective actions as applicable, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1164, Revision 03, including Appendix 01, dated August 24, 2005; or Revision 04, including Appendix 01, dated July 17, 2006. After the effective date of this AD, only Revision 04 of the service bulletin may be used. Do corrective actions before further flight. Repeat the inspection thereafter at intervals not to exceed 20 months.

Repetitive Inspections: Upper THSA Attachment

(g) At the earlier of the times specified in paragraphs (g)(1) and (g)(2) of this AD: Do detailed inspections of the upper THSA attachment for cracks, damage, or metallic particles, and do related corrective actions as applicable, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–1164, Revision 04, including Appendix 01, dated July 17, 2006, except as required by paragraph (h) of this AD. Do corrective actions before further flight. Repeat the inspections thereafter at intervals not to exceed 10 months.

(1) At the latest of the times specified in paragraphs (g)(1)(i), (g)(1)(ii), and (g)(1)(iii) of this AD.

(i) Within 10 months since the first flight of the airplane.

(ii) Within 10 months after the most recent inspection of the upper THSA attachment done in accordance with Airbus Service Bulletin A320–27–1164, Revision 02, including Appendix 01, dated March 30, 2005; Revision 03, including Appendix 01, dated August 24, 2005; or Revision 04, including Appendix 01, dated July 17, 2006.

(iii) Within 100 days after the effective date of this AD.

(2) Within 20 months after the most recent inspection of the upper THSA attachment done in accordance with Airbus Service Bulletin A320–27–1164, Revision 02, dated March 30, 2005; Revision 03, dated August 24, 2005; or Revision 04, dated July 17, 2006.

Repair Exceptions

(h) If any metallic particles are detected during any inspection required by paragraph (g) of this AD: Repair the damage before further flight in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; the Direction Générale de l'Aviation Civile (DGAC) (or its delegated agent); or the European Aviation Safety Agency (EASA) (or its delegated agent).

Acceptable Prior Actions

(i) Inspections of the lower THSA attachment done before May 5, 2006, in accordance with Airbus Alert Service Bulletin A320–27A1164, dated September 10, 2004; or Airbus Service Bulletin A320–27–1164, Revision 01, including Appendix 01, dated December 17, 2004; are acceptable for compliance with the inspection requirements of paragraph (f) of this AD.

(j) Actions done before the effective date of this AD in accordance with Airbus Service Bulletin A320–27–1164, Revision 02, including Appendix 01, dated March 30, 2005; or Revision 03, including Appendix 01, dated August 24, 2005; are acceptable for compliance with the corresponding requirements of paragraphs (f) and (g) of this AD.

Inspection Reports

(k) At the applicable time specified in paragraph (k)(1) or (k)(2) of this AD, send a report of the positive findings of all inspections required by paragraphs (f) and (g) of this AD to Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. The report must include the inspection results, a description of any discrepancies found, the airplane serial number, and the number of landings and flight hours on the airplane. Using Appendix 01 of Airbus Service Bulletin A320–27–1164, Revision 02, dated March 30, 2005; Revision 03, dated August 24, 2005; or Revision 04, dated July 17, 2006; is an acceptable method to comply with this paragraph. Under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements contained in this AD and has assigned OMB Control Number 2120–0056.

(1) For any inspection done before the effective date of this AD: Send the report within 30 days after the effective date of this AD.

(2) For any inspection done after the effective date of this AD: Send the report within 30 days after the inspection.

Alternative Methods of Compliance (AMOCs)

(l)(1) The Manager, International Branch, ANM–116, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA

Flight Standards Certificate Holding District Office.

Related Information

(m) EASA airworthiness directive 2006–0223, dated July 21, 2006, also addresses the subject of this AD.

Issued in Renton, Washington, on November 24, 2006.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6–20851 Filed 12–7–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 399

[Docket No. OST–2003–15759]

RIN: 2105–AD25

Actual Control of U.S. Air Carriers

AGENCY: Office of the Secretary, DOT.

ACTION: Withdrawal of certain proposed amendments.

SUMMARY: Current law requires that U.S. citizens actually control each U.S. air carrier, that U.S. citizens own or control at least 75 percent of the shareholders' voting interest, and that the president and two-thirds of the directors and the managing officers must be U.S. citizens. The Department interprets this law in conducting initial and continuing fitness reviews of U.S. air carriers. We are withdrawing a proposal to modify by regulation the standards we apply in those cases where ''actual control'' by U.S. citizens is at issue.

The proposal being withdrawn would have narrowed the scope of our inquiry in such cases to those core matters affecting compliance with U.S. requirements affecting safety, security, national defense and corporate governance. These rationalized standards for deciding whether U.S. citizens maintained ''actual control'' of a carrier would have applied only to proposed transactions involving investors whose countries have an open-skies air services agreement with the United States and offer reciprocal investment opportunities to U.S. citizens. Our interpretation of other aspects of the statutory citizenship requirement would have been unchanged.

Although we are withdrawing the current proposal, we will continue to consider other ways to rationalize and simplify our domestic investment regime. The need for greater certainty and transparency in our requirements and administrative process has become very apparent. Indeed, public comment in this docket has only served to confirm the Department's growing concern that the current regime is so unduly complex and burdensome that it needlessly inhibits the movement of capital that otherwise would flow into the U.S. airline industry and thus interferes with the legitimate needs of U.S. carriers to attract strategic investors from overseas markets. The Department notes that most of the American economy has progressed well beyond the antiquated notions that continue to apply to the airline industry because of our administrative interpretations of the current statute. In a modern, global industry such as aviation, we believe that the United States should not shut its doors to foreign investment by perpetuating archaic and time-consuming administrative practices that serve neither a statutory purpose nor an identifiable policy interest of the United States.

The Department had also proposed amendments to 14 CFR Part 204, the rules governing the data used in fitness determinations, and invited comment on the procedures used in fitness cases. The Department will publish a separate decision on those matters.

FOR FURTHER INFORMATION CONTACT: William M. Bertram, Chief, Air Carrier Fitness Division (X–56), Office of Aviation Analysis, U.S. Department of Transportation, 400 7th Street, SW., Washington, DC 20590; (202) 366–9721.

SUPPLEMENTARY INFORMATION:

Introduction

Under Title 49 of the U.S. Code, only ''citizens'' of the United States may obtain certificate authority to provide air transportation within the United States or operate as a U.S. air carrier on international routes. (49 U.S.C. 41102 or 41103.) The Department proposed to modify its interpretation of ''actual control,'' an element in the statutory definition of a citizen of the United States, 49 U.S.C. 40102(a)(15), because it believes that modernizing its policies so as to allow more foreign investment in U.S. carriers would better reflect the realities of a global aviation industry, strengthen the U.S. air transportation system, and encourage other countries to open their own air services and investment markets.

Our proposal would not have and could not have altered the statutory test for citizenship nor was it an attempt to do so. We stated our intention to continue vigorous enforcement of the statute's express requirements. We did propose, however, to eliminate certain *additional* citizenship restrictions that had been established administratively over the course of decades in individual fitness cases and that in our view are anachronistic, overly complex, and unduly burdensome. Accordingly, the net result of our proposal would have been to end a long-standing, extraneous administrative prohibition against foreign investors having even a ''semblance'' of control over airline commercial decisions; the revised approach would have applied only to investors whose home countries had open-skies agreements with the United States and provided reciprocal investment opportunities for U.S. citizens. The proposal would have maintained the prohibition against foreign citizen control of decisions on corporate governance, safety, security, and participation in the Civil Reserve Air Fleet program and other national defense airlift programs (for simplicity, referred to as ''CRAF'' hereafter). To ensure control by U.S. citizens, as an added measure we would have required that any delegation of authority by U.S. citizens to foreign investors be fully revocable by the shareholders or board of directors.

We provided several opportunities for interested parties to comment on the proposal, including a supplemental notice of proposed rulemaking (SNPRM) that further clarified our proposed modified interpretation of ''actual control.'' 71 FR 26425 (May 5, 2006). In the supplemental notice, we made refinements to our proposal reflecting further consultations with our Federal Aviation Administration (FAA), the Department of Homeland Security (DHS), and the Department of Defense (DOD). We also acknowledged requests by members of Congress, who wanted us to provide time for more public comment on the proposal and for Congressional hearings on the topic.

The additional comments that we received in response to the SNPRM confirmed our earlier determination that the Department's historic interpretation of the actual control requirement did not serve the public interest well.

During the rulemaking we also proposed several technical changes to the rules governing the data for fitness determinations, 14 CFR Part 204. Those proposals were unopposed. We also requested public comment on the procedures used by us in resolving citizenship issues. We will publish our decision on those proposals in a separate rulemaking document.

Background

A firm may not be certificated as an air carrier to operate within the United

States or as a U.S. carrier on international routes unless it is a citizen of the United States. 49 U.S.C. 40102(a). We examine carrier citizenship primarily in two situations. First, when a firm applies for authority to operate as a U.S. carrier, we conduct an initial fitness review, which necessarily includes a review of the carrier's citizenship. We conduct initial fitness reviews through adjudicatory proceedings for which a public record is maintained in our docket. Second, we conduct a continuing fitness review if a carrier undergoes a substantial change in ownership, operations, or management. We usually conduct continuing fitness investigations without a public proceeding and thus without a public record or an opportunity for public comment. In some continuing fitness cases, we may decide to use procedures that are more public so that there will be a public record and an opportunity for public comment. We may amend, modify, suspend, or revoke the carrier's license, or begin an enforcement action if a carrier no longer meets the citizenship test. See 71 FR 26426–26427. The statute defines the requirements for United States citizenship. 49 U.S.C. 40102(a)(15)(C). For many years that statute required only that the president and at least two-thirds of the board of directors and other managing officers be citizens of the United States, and that at least 75 percent of the voting interest be owned or controlled [1] by persons that are citizens of the United States. Our predecessor agency in administering this statute, the Civil Aeronautics Board (the Board), created an additional requirement not then required by the text of the statute: the requirement that U.S. citizens must ''actually control'' each U.S. carrier. *Willye Peter Daetwyler, d.b.a. Interamerican Air Freight Co., Foreign Permit,* 58 CAB 118, 120–121 (1971).

In order to determine citizenship to verify compliance with the actual control requirement, both the Department and the Board have employed a fact-specific method of inquiry. *See* 71 FR 26437, citing 68 FR 44675, 44676 (July 30, 2003). Each decision considered the ''totality of circumstances'' of the airline's organization, including its capital structure, management, and contractual relationships, in determining whether U.S. citizens actually control a carrier. We developed our policies on interpreting the actual control requirement through our decisions in individual cases, based on the facts and circumstances of each case, and did not establish a specific definition of ''actual control'' through any rulemaking. We have continually modified our interpretation over time in light of changing conditions. *See* 71 FR 27437, citing *Northwest Airlines Acquisition by Wings Holdings,* Order 91–1–41 (January 23, 1991), and a more recent decision enabling Hawaiian Airlines to complete its reorganization with some foreign investment.

Neither the Department nor the Board has administered the actual control requirement in a way that barred U.S. carriers from having substantial commercial relationships with foreign carriers and other foreign firms. For instance, we have held that a U.S. airline continued to satisfy the actual control requirement when it had an alliance relationship with a foreign airline that necessarily enabled the foreign partner airline to influence the U.S. airline's commercial decisions. *Acquisition of Northwest Airlines by Wings Holdings, Inc.,* Order 92–11–27 (November 16, 1992), at 16–17.

Nonetheless, the Department's and the Board's interpretations of ''actual control,'' by effectively prohibiting foreign investors from enjoying any meaningful participation in the decision-making of U.S. airlines, has left foreign investors with a very limited ability to protect their interests as minority investors. We at times implemented the ''actual control'' requirement as barring foreign investors from having any ''semblance'' of control, which effectively relegated them to being passive investors, unable to participate in carrier commercial decisions that affected the value of their own investment.

Three years ago Congress amended the citizenship definition by expressly adding an actual control requirement to the statute. As a result, the statute provides that a corporation can only be a citizen of the United States if it is ''under the actual control of citizens of the United States.'' Vision 100—Century of Aviation Reauthorization Act, P.L. 108–176, § 807, 117 Stat. 2490 (2004). Congress chose not to define ''actual control.''

Notice of Proposed Rulemaking

We proposed our modified interpretation of ''actual control'' in order to facilitate efforts by U.S. airlines to remain competitive in the global airline industry. We grounded our proposal on three premises: *first,* that in view of the changes taking place in the global economy, U.S. air carriers should have the broadest access to the global capital markets permitted by law; *second,* that our historical interpretation of the term ''actual control'' has failed to keep pace with the changes in the global economy; and *third,* that in order to provide U.S. carriers with more flexibility to compete in the global economy, we should not maintain an interpretation of ''actual control'' that is more restrictive than necessary to meet statutory requirements. 71 FR 26427–26429; 70 FR 67393–67394. In sum, we acted on the policy that we should remove unnecessary restrictions on U.S. carriers seeking access to global capital markets.

In 2003, we issued an Advance Notice of Proposed Rulemaking (ANPRM) that sought comment on our standards and procedures for determining whether U.S. citizens actually control a carrier. 68 FR 44675 (July 30, 2003). After considering the comments, we issued a Notice of Proposed Rulemaking (NPRM) concerning our interpretation of ''actual control'' and use of informal procedures in most continuing fitness reviews. 70 FR 67389 (November 7, 2005). The Department proposed to update our interpretation of ''actual control'' so as to end restrictions on foreign involvement that, in our view, needlessly interfere with the ability of U.S. carriers to access international capital markets and thus to compete effectively in the global marketplace. Under our proposal, U.S. citizens would remain in control of the carrier through their authority over corporate governance and those areas of airline operations subject to significant government regulation: Safety, security, and CRAF participation. This modification would apply only if the foreign investors' home country had an open-skies air services agreement with the United States and, further, provided investment reciprocity for U.S. citizens wishing to invest in that country's airlines, or where the United States' international obligations otherwise required the same approach.

Supplemental Notice of Proposed Rulemaking

We issued a Supplemental Notice of Proposed Rulemaking (SNPRM) to address comments received on the NPRM, and to propose additional refinements to the proposal in order to definitively clarify that U.S. citizens would still retain actual control of U.S. carriers under the Department's proposal. 71 FR 26425 (May 5, 2006).

The SNPRM retained our proposal to allow carriers to delegate decision-making responsibilities to foreign citizens (except for organizational documents, safety, security, and CRAF

[1] We and the Board have always interpreted this part of the statute as ''owned and controlled.''

participation matters). However, we added language to make clear that such delegations would have to be revocable by the board of directors or shareholders—whose votes would be controlled by U.S. citizens. The right to revoke delegations of management authority, we felt, was intrinsic to the requirement that U.S. citizens maintain actual control of the carrier. We further proposed in the SNPRM to broaden the scope of decision-making in the areas of safety, security, and CRAF participation that must remain under the actual control of U.S. citizens. The proposed revisions would unequivocally ensure that safety and security decisions generally, not just those related to FAA and TSA safety and security requirements, as well as all decisions on national defense airlift commitments, not just CRAF commitments, remained firmly under the actual control of U.S. citizens. Our refinement of our proposals on safety, security, and CRAF participation reflected as well our discussions with the FAA, DHS, TSA, and DOD.

We determined that we have the authority to interpret the statutory definition of ''actual control,'' because we are responsible for administering it; that authority enables us to modify our interpretations when changing industry conditions and policies require doing so; and our proposed modified interpretation would be consistent with the language and purpose of the statute. We further stated that we should change our interpretation when the past interpretation has become inconsistent with commercial developments and the public policy goals set by our statute, 49 U.S.C. 40101(a). Finally, we noted that neither the statute nor its legislative history indicated that Congress had intended to freeze our earlier interpretations of ''actual control.'' 71 FR 26436–26439.

After we issued the SNPRM, the Aviation Subcommittee of the Senate Committee on Commerce, Science, and Transportation held a hearing on our proposal on May 9, 2006. The Aviation Subcommittee of the House Transportation and Infrastructure Committee had held a hearing on our proposal on February 8, 2006, based on the NPRM. Jeffrey N. Shane, the Department's Under Secretary for Policy, testified at both hearings.

Several members of Congress have written letters to the Secretary that contend that our proposal is unwise and a significant departure from what they perceive as existing precedent. These concerns were also raised at hearings and in proposed legislation.

Summary of Comments

We invited comments on the proposal as refined by our SNPRM. We received 21 comments on the SNPRM from carriers, labor parties, and industry associations, and three comments from individuals.

The majority of commenters supported the policy change as a way to strengthen the U.S. airline industry and encourage the liberalization of international aviation. The Department received general support for its proposed changes from Airports Council International— Europe (ACI), Airports Council International— North America (ACI–NA), Association of European Airlines (AEA), bmi, Delta Air Lines (Delta), DePaul University College of Law International Aviation Law Institute (DePaul), Federal Express (FedEx), Hawaiian Airlines (Hawaiian), International Air Transport Association (IATA), United Air Lines (United), United Parcel Service (UPS), United States Airports for Better International Air Service (USA–BIAS), U.S. Airways, and the Washington Airports Task Force (WATF).

Other commenters—notably the Aircraft Mechanics Fraternal Association (AMFA), Air Line Pilots Association (ALPA), British Airways, Continental Airlines (Continental), Independent Pilots Association (IPA), Transportation Trades Department AFL–CIO (TTD), and Virgin Atlantic Airways (Virgin Atlantic)—opposed our proposal, claiming that the proposed rule would be unlawful, impracticable, ineffective in achieving the desired result, or harmful to the airline industry and its unionized employees.

Both supporters and opponents of our proposal asserted that the rule, as proposed, provided inadequate guidance to carriers and potential foreign investors and that our final decision should provide examples of the kind of business relationships that would or would not be permitted by a final rule. *See, e.g.*, AEA Comments at 4; British Airways Comments at 3–4; IATA Comments at 6; Virgin Atlantic Comments at 5–6; ACI Comments at 2. Other commenters asserted that it was not clear whether our proposed revocability requirement—the requirement that a U.S. carrier have the practicable ability to revoke any delegation of decision-making authority to a foreign investor—would be consistent with standard commercial practices in other industries, which make a firm's ability to revoke a contract with its investors subject to conditions limiting the ability to revoke in order to protect the investors' legitimate interests. *See, e.g.*, FedEx Comments at 7–9; ACI–NA Comments at 4; DePaul Comments at 4; US–BIAS Comments. Some commenters contended that our proposals were too restrictive; Delta, for example, asserted that the revocation requirement was ''flatly inconsistent'' with our goal of encouraging foreign investment. Delta Comments at 6–7.

Our Final Decision

We have decided to withdraw the proposal on interpretation of ''actual control.'' We still believe there are significant benefits to be realized by liberalizing and rationalizing our domestic investment regime for U.S. air carriers. Nonetheless, our policy could gain from additional public insight into the practical advantages and drawbacks of particular administrative reforms.

We maintain that our past administration of the ''actual control'' requirement is obsolete and the notion has needlessly precluded foreign investment in the U.S. airline industry to its detriment. In the Department's view, retention of the anachronistic administrative standard for determining actual control serves no discernible policy interest of the United States. Instead, it has prevented U.S. carriers from entering into sound and desirable business relationships with foreign allies ''relationships that U.S. corporate management concluded would benefit their carrier, their employees and shareholders. *See, e.g.*, FedEx Comments at 2; Atlas & Polar Comments on NPRM at 3; United Comments at 3. We continue to believe we need a way to enable strategic investors ''interested in long-term gain, not short-term arbitrage—to participate more meaningfully in the decision-making at U.S. carriers, as such investors would ''more likely be concerned about a U.S. airline's product quality, market strategy, and its capital reinvestment plans than short-term investors who view airlines merely as trading vehicles.'' 71 FR 26428. An up-to-date approach towards administering the ''actual control'' requirement that takes into account the realities of modern capital markets would permit our carriers to catch up with increasingly competitive and financially stronger foreign airlines in terms of integrating their operations and services with those of marketing partners. It would also enable investments abroad by U.S. air carriers and the formation of durable business relationships with foreign carriers, such as Continental, for example, enjoys with COPA, a leading Latin American airline. Continental Airlines, SEC Report on Form 10–Q (July 21, 2006) at 34. In our view, we

should encourage additional foreign investment in the U.S. airline industry, give U.S. carriers freedom in developing beneficial business relationships across borders and eliminate outdated restrictions on business conduct.

Our proposal has become controversial, as to both the questions of whether our interpretation of ''actual control'' should be changed and whether our specific proposal will effectively accomplish our objectives. In addition, as noted, letters sent by members of Congress have urged the Department not to adopt the proposal without further discussion. In this particular instance, we have concluded that the expressions of concern support the concept that more public discussion of the underlying issues is warranted. By withdrawing the proposal, we will be free to engage in broad-ranging dialogue without the constraints of a specific rulemaking proposal.

Rulemaking Analyses and Notices

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires federal agencies, as part of each rule, to consider regulatory alternatives that minimize the impact on small entities while achieving the objectives of the rulemaking. Because we are withdrawing our proposal, we are not adopting any final rule requiring a regulatory flexibility analysis.

Trade Impact Assessments

The Trade Agreement Act of 1979 prohibits federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that U.S. standards be compatible. The Department has assessed the potential effect of this withdrawal of the proposed rule and has determined that it will have no effect on any trade-sensitive activity.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is the Department's policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The Department has determined that there are no ICAO Standards and Recommended Practices that correspond to this withdrawal notice.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1955 (the Act) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' This withdrawal notice is not a final or proposed rule. The requirements of Title II of the Act, therefore, do not apply.

Executive Order 13132, Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, dated August 4, 1999 (64 FR 43255). This withdrawal notice does not have a substantial direct effect on, or significant federalism implications for the States, nor would it limit the policymaking discretion of the States.

It will not directly preempt any State law or regulation, or impose burdens on the States. This action will have not a significant effect on the States' ability to execute traditional State governmental functions. The agency has therefore determined that this withdrawal notice does not have sufficient federalism implications to warrant either the preparation of a federalism summary impact statement or consultations with State and local governments.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.) requires federal agencies to obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulation. Because this is a withdrawal notice, it will not impose any additional requirements. Thus, there is no change in the paperwork collection, as it currently exists.

Issued in Washington, DC on December 5, 2006.

Andrew B. Steinberg,

Assistant Secretary for Aviation and International Affairs.

[FR Doc. 06–9603 Filed 12–5–06; 12:39 pm]

BILLING CODE 4910–62–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34–54863; File No. S7–19–06]

RIN 3235–AJ41

Proposed Amendments to Municipal Securities Disclosure

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Proposed rule.

SUMMARY: The Commission is publishing for comment proposed amendments to a rule under the Securities Exchange Act of 1934 (''Exchange Act'') relating to municipal securities disclosure which would delete references to the Municipal Securities Rulemaking Board (''MSRB'') as a recipient of material event notices filed by or on behalf of issuers of municipal securities or other obligated persons.

DATES: Comments should be received on or before January 8, 2007.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/proposed.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File No. S7–19–06 on the subject line; or
- Use the Federal eRulemaking Portal (*http://www.regulations.gov*). Follow the instructions for submitting comments.

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 No. S7–19–06. This file number should be included on the subject line if e-mail is used. To help us 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/proposed.shtml*). Comments are also available for public inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Martha Mahan Haines, Chief, Office of Municipal Securities, at (202) 551–5681; Mary N. Simpkins, Senior Special Counsel, at (202) 551–5683; or David Liu, Special Counsel, at (202) 551–5645, Division of Market Regulation, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–6628.

SUPPLEMENTARY INFORMATION: The Commission is requesting public comment on proposed amendments to Rule 15c2–12 [17 CFR 240.15c2–12] under the Exchange Act.

Table of Contents

I. Background
A. 1994 Amendments to Rule 15c2–12
B. CDI System and CDINet
II. MSRB Petition
III. Discussion
IV. Request for Comment
V. Paperwork Reduction Act
VI. Costs and Benefits of Proposed Amendments to Rule 15c2–12
A. Benefits
B. Costs
VII. Consideration of Burden and Promotion of Efficiency, Competition, and Capital Formation
VIII. Consideration of Impact on the Economy
IX. Regulatory Flexibility Act Certification
X. Statutory Authority

I. Background

A. 1994 Amendments to Rule 15c2–12

On November 10, 1994, the Commission adopted amendments (''1994 Amendments'') to Rule 15c2–12 (''Rule'') under the Exchange Act [1] to provide, among other things, enhanced ongoing disclosure to the market for municipal securities.[2] Pursuant to subsection (b)(5)(i) of the Rule,[3] the Commission requires brokers, dealers, and municipal securities dealers (''Participating Underwriters''), prior to underwriting a primary offering of municipal securities of $1,000,000 or more, to reasonably determine that the issuer or obligated person for whom financial or operating data is presented in the final official statement (''Issuer''), has undertaken, in a written agreement or contract for the benefit of bondholders, to provide certain continuing disclosure information. Among other things, the Issuer must undertake to send to each nationally recognized municipal securities information repository (''NRMSIR'') or the MSRB, and to the appropriate state information depository (''SID''), if any, certain material event notices designated in subsection (b)(5)(i)(C) of the Rule.[4] In addition, subsection (b)(5)(i)(D) of the Rule requires a Participating Underwriter to reasonably determine that the Issuer has agreed to notify those same repositories if it fails to provide annual financial information by the agreed-upon date.[5]

The Commission included the MSRB in its plan for dissemination of material event notices set forth in the Rule because, at the time of the 1994 Amendments, the MSRB already had a voluntary disclosure system in place for receiving and disseminating certain types of material event notices.[6] As the Commission noted in the 1994 Adopting Release, ''permitting issuers and obligated persons to file such notices either with each NRMSIR or with the MSRB (as well as the appropriate SID) will facilitate prompt and wide disclosure.'' [7] In adopting the 1994 Amendments, the Commission also stated that inclusion of the MSRB as a filing option reflected the preference expressed by some commenters to file the required notices in one central place, rather than having to file with multiple NRMSIRs.[8] Under the Rule, the use of the MSRB filing alternative is optional, as the material event notice obligation can be satisfied by sending notice to each of the NRMSIRs rather than to the MSRB.

B. CDI System and CDINet

The MSRB's original system for receiving material event notices, the Continuing Disclosure Information (''CDI'') System, was approved by the Commission in April 1992 and commenced operation in January 1993.[9] On March 24, 1997, the MSRB implemented certain improvements to its dissemination process and replaced its earlier CDI System with CDINet. CDINet was approved by the Commission in December 1996 [10] and, among other things, is designed to accept and disseminate material event notices submitted as a result of the Rule. Once a document has been accepted and processed by CDINet, it is broadcast to subscribers [11] and made available in the MSRB's public access facility.[12]

II. MSRB Petition

In a recent letter to the Commission,[13] the MSRB petitioned the Commission to remove the MSRB as a recipient of material event notices under the Rule.[14] According to the MSRB petition, CDINet was designed to permit Issuers to satisfy their material event undertakings through a single submission to the MSRB, rather than through separate filings to each of the NRMSIRs. However, the MSRB states that relatively few Issuers have opted to use CDINet and, in recent years, usage of CDINet has diminished. According to the MSRB, in 1997, CDINet received over 10,000 material event notices. Since that time, submissions to the MSRB have dropped considerably, ranging from 1,000 to 2,500 annually.[15]

A review conducted by the MSRB of the material event notices received by CDINet in the first half of 2004 showed that, of the 1,104 notices received in that time period, 504 were bond calls, 213 were defeasances, and 145 were rating changes.[16] The MSRB also

---

[1] 17 CFR 240.15c2–12.

[2] Securities Exchange Act Release No. 34961 (November 10, 1994), 59 FR 59590 (November 17, 1994) (''1994 Adopting Release'').

[3] 17 CFR 240.15c2–12(b)(5)(i).

[4] 17 CFR 240.15c2–12(b)(5)(i)(C). Subsection (b)(5)(i)(C) lists the following events which, if material, require notice: (1) Principal and interest payment delinquencies; (2) non-payment related defaults; (3) unscheduled draws on debt service reserves reflecting financial difficulties; (4) unscheduled draws on credit enhancements reflecting financial difficulties; (5) substitution of credit or liquidity providers, or their failure to perform; (6) adverse tax opinions or events affecting the tax-exempt status of the security; (7) modifications to rights of security holders; (8) bond calls; (9) defeasances; (10) release, substitution, or sale of property securing repayment of the securities; and (11) rating changes.

In addition, in Rule 15c2–12(d)(2), the small issuer exemption is conditioned on an issuer or obligated person undertaking a limited disclosure obligation, including sending certain material event notices to each NRMSIR or the MSRB, as well as the appropriate SID. 17 CFR 240.15c2–12(d)(2).

[5] 17 CFR 240.15c2–12(b)(5)(i)(D).

[6] *See* Securities Exchange Act Release No. 30556 (April 6, 1992), 57 FR 12534 (April 10, 1992) (''CDI System Approval Order''). *See also* Securities Exchange Act Release No. 33742 (March 9, 1994), 59 FR 12759 (March 17, 1994) (''1994 Proposing Release'') at 12764, note 25.

[7] *See* 1994 Adopting Release at 59605.

[8] *See* 1994 Adopting Release at 59605.

[9] CDI System Approval Order.

[10] Securities Exchange Act Release No. 38066 (December 19, 1996), 61 FR 68322 (December 27, 1996) (''CDINet Approval Order'').

[11] The MSRB has represented to the Commission that CDINet has only two subscribers. *See infra* notes 18 and 19.

[12] The MSRB has represented to the Commission that, as of September 2005, no one has requested CDINet information at the MSRB's public access facility for at least the last five years.

[13] Letter from Diane G. Klinke, General Counsel, MSRB, to Jonathan G. Katz, Secretary, Commission, dated September 8, 2005 (''MSRB Petition'').

[14] 17 CFR 240.15c2–12.

[15] MSRB Petition at 2.

[16] The remaining notices included the following categories: Failure to File Annual Report (70 notices); Information not specifically required under SEC Rule 15c2–12 (70); Bond Calls and Defeasances (56); Annual Report and CAFR Related Information (13); Various multiple categories indicated (10); Release, Substitution, or Sale of Property Securing Repayment of Securities (5); Principal and Interest Payment Delinquencies (4); Substitution of Credit or Liquidity Providers, or Their Failure to Perform (4); Non-Payment Related Defaults (3); Adverse Tax Opinions or Events Affecting the Tax-Exempt Status of the Security (3); Unscheduled Draws on Debt Service Reserves Reflecting Financial Difficulties (2); Unscheduled

recently reviewed a sample of 100 material event notices received by CDINet in June 2005.[17] The MSRB believes that most of the material event notices received by CDINet also are provided to, or otherwise obtained by, the NRMSIRs.[18] In its petition, the MSRB also expressed concern that the notices filed exclusively with the MSRB may not be reaching the broader market as intended by the Rule because not all NRMSIRs subscribe to CDINet and the information may not otherwise be widely distributed.[19]

In addition, the MSRB believes that the need for CDINet has also been lessened because an alternative document delivery system has become available to Issuers and dissemination agents who prefer to send their filings to a single location for delivery to all of the NRMSIRs and any appropriate SID.[20] In its petition to the Commission, the MSRB stated that it believes that the number of documents submitted to CDINet will further decrease and that the continued operation of CDINet would provide minimal continuing benefit to the marketplace.[21] Finally, because of the age of the CDINet system, the MSRB states that upgrades at an estimated cost of $500,000 to $1 million would be necessary to keep the system operational.[22]

III. Discussion

The Commission proposes to amend Rule 15c2–12 [23] to delete references to the MSRB as an alternative recipient of material event notices filed by Issuers. Under the proposal, Issuers and their dissemination agents instead would undertake to send material event notices to each NRMSIR and the appropriate SID, if any. The Commission believes that, given the limited usage of the MSRB's CDINet system and the MSRB's petition for rulemaking, the proposed elimination of the option of filing material event notices with the MSRB is warranted. The relatively small number of filings made with CDINet indicates that there is little demand for the MSRB filing option. The Commission believes that requiring Issuers to send their material event notices only to each of the NRMSIRs and any appropriate SIDs would simplify the Rule and compliance by Issuers with their undertakings, because Issuers would be required to file material event notices at the same locations that annual financial information is required to be filed pursuant to undertakings in accordance with subsection (b)(5)(i)(A) of the Rule.[24] In addition, the Commission believes that eliminating the MSRB filing option would better assure that material event notices are widely disseminated to the market, since it appears that CDINet data may not be broadly distributed.[25] Requiring that each NRMSIR and the appropriate SID, if any, receives all material event notices should help assure the completeness and consistency of information available from those repositories.

Finally, the Commission notes the MSRB's statement that the upgrading of CDINet required to maintain the system would cost approximately $500,000 to $1 million.[26] In light of the current alternative options under Rule 15c2–12 for Issuers to file with NRMSIRs and SIDs and the lack of demand for the MSRB filing alternative—both by Issuers and information users—the Commission believes that the MSRB's proposal to cease CDINet's operations is reasonable. The Commission notes that the MSRB has committed to forward material event notices to the NRMSIRs and applicable SIDs for a period of one year from the date CDINet ceases operations.[27] The MSRB has also agreed to alert senders of such notices of the fact that CDINet is ceasing operations, and ask that such senders comply with their undertakings by sending future material event notices to the NRMSIRs and applicable SIDs.

IV. Request for Comment

The Commission seeks comment on the proposed amendments to the Rule. Specifically, comment is requested on whether, in light of the alternative filing options available to Issuers and dissemination agents, there is still a need for the MSRB to be a recipient of material event notices. The Commission also requests comment on whether there exist any applicable continuing disclosure agreements which require issuers or other obligated persons to file material event notices solely with the MSRB that might require modification were the Commission to amend the Rule as proposed. It is the staff's understanding that such agreements often contain a requirement to file notices with both the (1) NRMSIRs and applicable SIDs and (2) MSRB. The Commission seeks comment on whether any such agreements require filings solely with the MSRB.

In addition, the Commission seeks comment on whether the proposed amendment would in fact simplify compliance with undertakings in accordance with the Rule, and better assure widespread dissemination of material event notices.

V. Paperwork Reduction Act

The proposed amendment to the Rule, contains no new ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[28] The title of the current information collection as required and under the Rule is Municipal Securities Disclosure (17 CFR 240.15c2–12) (OMB Control No. 3235–0372).

VI. Costs and Benefits of Proposed Amendments to Rule 15c2–12

The Rule currently requires Participating Underwriters to reasonably determine that Issuers have undertaken to submit material event notices to (1) each NRMSIR or the MSRB and (2) the appropriate SID, if any. The proposed amendments would remove the MSRB as an option for the filing of such notices, thereby requiring submission, pursuant to the undertakings, to each NRMSIR and the appropriate SID, if any.

A. Benefits

The Commission preliminarily believes that the proposed amendments to the Rule should improve the disclosure of material event information to the municipal securities marketplace. Because the MSRB's CDINet system currently only has two subscribers, it is

Draws Credit Enhancements Reflecting Financial Difficulties (1); and Modifications to the Rights of Security Holders (1). *See* Attachment to MSRB Petition.

[17] MSRB Petition at 2–3.

[18] Definitive information on 90 of the June 2005 notices was found by the MSRB in a review of information available from NRMSIRs that do not subscribe to CDINet. CDINet only has two NRMSIR subscribers: Kenny S&P and Thomson Financial Services. MSRB Petition at 2, note 7. The MSRB presumed that the remaining ten notices were not provided directly to all the NRMSIRs. These notices included six notices regarding failure to provide an annual financial statement, two bond calls, one rating change and one relating to ''other information.'' The MSRB believes that there is some evidence, however, that at least one NRMSIR may have received some of the notices of failure to provide an annual financial statement but subsequently superseded such information with the annual financial statements themselves once these were received. MSRB Petition at 3, note 8.

[19] MSRB Petition at 3.

[20] The Commission understands that there may be other entities that have developed or are developing services related to Rule 15c2–12.

[21] MSRB Petition at 3.

[22] MSRB Petition at 3.

[23] 17 CFR 240.15c2–12.

[24] 17 CFR 240.15c2–12(b)(5)(i)(A).

[25] As the MSRB's recent review showed, a portion of the notices received by the MSRB may not have been fully disseminated to the wider market, since there are only two subscribers to the MSRB's CDINet. *See supra* notes 18 and 19.

[26] MSRB Petition at 3.

[27] MSRB Petition at 4; Letter from Diane G. Klinke, General Counsel, MSRB, to Martha Mahan Haines, Chief, Office of Municipal Securities, Commission, dated April 20, 2006.

[28] 44 U.S.C. 3501 *et seq.*

not clear that all material event notices submitted to the MSRB are fully distributed to the marketplace. Requiring that each NRMSIR and the appropriate SID, if any, receives all material event notices should help assure the completeness and consistency of information available from those repositories. The Commission also preliminarily believes that the elimination of the MSRB as a filing option would simplify compliance by Issuers with their undertakings in accordance with the Rule. If the proposed amendments are adopted, Issuers would be required to file, pursuant to their undertakings, material event notices at the same locations—each NRMSIR and the appropriate SID, if any—that annual financial information is required to be filed. Finally, the Commission preliminarily concludes that the proposed amendments could save the MSRB substantial funds, represented by the MSRB to be approximately $500,000 to $1 million,[29] by not requiring it to perform certain upgrades to its CDINet system which would otherwise be required in order for the system to be maintained. As the costs of the MSRB are paid primarily from fees paid by brokers, dealers and municipal securities dealers, those parties and their customers would benefit from this savings.

B. Costs

The Commission preliminarily believes that the proposed amendments to the Rule should only minimally increase compliance costs for a few Issuers and may decrease overall compliance costs. Because some Issuers may currently be sending their material event notices only to the MSRB, the proposed amendments would require them to send such notices to each of the (currently four) NRMSIRs. However, the Commission believes that the cost of sending such notices to three additional locales would be minimal because such notices are generally short in length and would only encompass the additional costs of copying several pages, as well as the minor additional mailing costs. In addition, the MSRB has indicated that there is an alternative free document delivery system available to Issuers and dissemination agents who prefer to send their filings to a single location for delivery to all of the NRMSIRS and appropriate SIDs.[30] We request comment on whether this would result in any increased costs to issuers. Finally, the Commission preliminarily believes that those Issuers that currently send to their material event notices to each NRMSIR as well as the MSRB would reduce their costs because the proposed amendments would require those Issuers to send their material event notices to one fewer location.

To assist the Commission in evaluating the costs and benefits that may result from the proposed amendments to the Rule, the Commission requests comments on the potential costs and benefits identified in the release, as well as any other costs or benefits that may result from the proposed amendments to the Rule. In addition, the commenters should provide analysis and data to support their views on the costs and benefits.

VII. Consideration of Burden and Promotion of Efficiency, Competition, and Capital Formation

Section 3(f) of the Exchange Act [31] requires the Commission, whenever it engages in rulemaking and is required to consider or determine whether an action is necessary or appropriate in the public interest, to consider whether the action would promote efficiency, competition, and capital formation. In addition, Section 23(a)(2) of the Exchange Act [32] requires the Commission, when making rules under the Exchange Act, to consider the impact of such rules on competition. Section 23(a)(2) also prohibits the Commission from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.

The Commission preliminarily believes that the proposed amendments to the Rule would not impose any burdens on efficiency, capital formation, and competition not necessary or appropriate in furtherance of the purposes of the Exchange Act. The proposed amendments are expected to simplify the material event notice delivery requirements for Issuers, in accordance with their undertakings, by eliminating the MSRB as an alternative. In doing so, the Commission preliminarily believes that municipal securities disclosure would be enhanced, as all Issuers would be required to send all NRMSIRs (and appropriate SIDs) such notices. Under the current disclosure system, Issuers may choose to send such notices to the MSRB. However, there is some evidence [33] that some of the notices sent to the MSRB are not fully disseminated to the entire marketplace. By requiring delivery of such notices to all NRMSIRs and appropriate SIDs, if any, the Commission preliminarily believes that the completeness and consistency of information from these repositories would be improved, thereby promoting efficiency and having no adverse impacts on competition or capital formation. In fact, competition to establish alternative delivery systems in the private sector may be enhanced by the elimination of the MSRB as a single filing location.

The Commission requests comment on all aspects of this analysis and, in particular, on whether the proposed amendments to the Rule would place a burden on competition, as well as the effect of the proposed amendments on efficiency, competition, and capital formation.

VIII. Consideration of Impact on the Economy

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996, or ''SBREFA,'' [34] we must advise the Office of Management and Budget as to whether the proposed regulation constitutes a ''major'' rule. Under SBREFA, a rule is considered ''major'' where, if adopted, it results or is likely to result in: (1) An annual effect on the economy of $100 million or more (either in the form of an increase or a decrease); (2) a major increase in costs or prices for consumers or individual industries; or (3) significant adverse effect on competition, investment or innovation. The Commission preliminarily believes that this proposed amendment is not a major rule.

If a rule is ''major,'' its effectiveness will generally be delayed for 60 days pending Congressional review. We request comment on the potential impact of the proposed rule on the economy on an annual basis. Commenters are requested to provide empirical data and other factual support for their view to the extent possible.

IX. Regulatory Flexibility Act Certification

Pursuant to Section 605(b) of the Regulatory Flexibility Act (''RFA''), the Commission hereby certifies that the proposed amendments to the Rule, would not, if adopted, have a significant economic impact on a substantial number of small entities. Under the RFA, the term ''small entity'' shall have the same meaning as the RFA defined

[29] MSRB Petition at 3.

[30] The Commission understands that there may be other entities that have developed or are developing services related to Rule 15c2–12.

[31] 15 U.S.C. 78c(f).

[32] 15 U.S.C. 78w(a)(2).

[33] MSRB Petition at 3.

[34] Pub. L. No. 104–121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C., 15 U.S.C. and as a note to 5 U.S.C. 601).

terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' According to Section 601(3) of the RFA, ''the term ''small business'' has the same meaning as the term ''small business concern'' under Section 3 of the Small Business Act (15 U.S.C. 632), unless an agency, after consultation with the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.'' If the agency has not defined the term for a particular purpose, the Small Business Act states that ''a small business concern * * * shall be deemed to be one which is independently owned and operated and which is not dominant in its field of operation.'' The Section 601(4) of the RFA defines a ''small organization'' to include ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' A ''small governmental jurisdiction'' is defined by Section 601(5) of the RFA to include ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.''

It is likely that a substantial number of the Issuers required to submit material event notices are small governmental jurisdictions included in the RFA's definition of small entities. However, in this regard, the proposed amendments to the Rule would either not require any additional work for such small entities if they do not currently send material event notices to the MSRB, or would simply require them to send such notices to each of the (currently four) NRMSIRs. However, the Commission believes that the cost of sending such notices to three additional locales would be minimal because such notices are generally short in length and would only encompass the additional costs of copying several pages, as well as the minor additional mailing costs. Finally, the Commission preliminarily believes that those Issuers that currently send their material event notices to each NRMSIR as well as the MSRB would reduce their costs because, under the proposed amendments, the MSRB would no longer be available as a location to send such notices. Thus, while the proposed amendments may impact a small entity, such impact would likely not be significant.

For the above reasons, the Commission certifies that the proposed amendments to the Rule would not have a significant economic impact on a substantial number of small entities. The Commission requests comments regarding this certification. The Commission requests that commenters describe the nature of any impact on small businesses and provide empirical data to support the extent of the impact.

X. Statutory Authority

Pursuant to the Exchange Act, and particularly Sections 3(b), 15(c), 15B and 23(a)(1) the Commission is proposing the amendments to § 240.15c2–12 of Title 17 of the *Code of Federal Regulations* in the manner set forth below.

Text of Proposed Rule

List of Subjects in 17 CFR Part 240

Brokers, Reporting and recordkeeping requirements, Securities.

For the reasons set out in the preamble, Title 17, Chapter II, of the Code of Federal Regulations is proposed to be amended as follows.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The general authority citation for part 240 is revised to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78l, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78ll, 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

2. Section 240.15c2–12 is amended by revising the introductory text of paragraph (b)(5)(i)(C) and paragraphs (b)(5)(i)(D) and (d)(2)(ii)(B) to read as follows:

§ 240.15c2–12 Municipal securities disclosure.

* * * * *

(b) * * *

(5) * * *

(i) * * *

(C) In a timely manner, to each nationally recognized municipal securities information repository and to the appropriate state information depository, if any, notice of any of the following events with respect to the securities being offered in the Offering, if material:

* * * * *

(D) In a timely manner, to each nationally recognized municipal securities information repository and to the appropriate state information depository, if any, notice of a failure of any person specified in paragraph (b)(5)(i)(A) of this section to provide required annual financial information on or before the date specified in the written agreement or contract.

* * * * *

(d) * * *

(2) * * *

(ii) * * *

(B) In a timely manner, to each nationally recognized municipal securities information repository and to the appropriate state information depository, if any, notice of events specified in paragraph (b)(5)(i)(C) of this section with respect to the securities that are the subject of the Offering, if material; and

* * * * *

By the Commission.

Dated: December 4, 2006.

Nancy M. Morris,

Secretary.

[FR Doc. E6–20829 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

INTERNATIONAL TRADE COMMISSION

19 CFR Part 210

[MISC–022]

Adjudication and Enforcement

AGENCY: U.S. International Trade Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission proposes to amend some of its rules for investigations and related proceedings under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) to do the following: (1) Provide for service of certain Commission documents by overnight delivery; and (2) provide one additional day to respond to Commission documents served by overnight delivery. The current manner of service of Commission documents is not effective according to recent agency studies. These rules will ensure effective service of Commission documents on private parties in section 337 investigations and related proceedings.

DATES: Submit comments on or before February 6, 2007.

ADDRESSES: You may submit comments, identified by docket number MISC–022 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Agency Web Site: http://www.usitc.gov.* Follow the instructions for submitting comments. See *http://www.usitc.gov/secretary/edis.htm.*
- *Mail:* For paper submission. U.S. International Trade Commission, 500 E

Street, SW., Room 112, Washington, DC 20436.

• *Hand Delivery/Courier:* U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436. From the hours of 8:45 a.m. to 5:15 p.m.

For detailed instructions on submitting comments, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Clint A. Gerdine, Esq., telephone 202–708–2310, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). Hearing-impaired persons are advised that information on the proposed rulemaking can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION:

Public Participation

Instructions: All submissions received must include the agency name and docket number (MISC–022) or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.usitc.gov,* including any personal information provided. For paper copies, a signed original and 14 copies of each set of comments, along with a cover letter stating the nature of the commenter's interest in the proposed rulemaking, should be submitted to Marilyn R. Abbott, Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436. Comments, along with a cover letter, may be submitted electronically to the extent provided by section 201.8 of the Commission's rules. This rule may refer commenters to the Handbook for Electronic Filing Procedures (see *http://www.usitc.gov/secretary/edis.htm*). For those submitting comments by mail, it is advisable to mail in comments in advance of the due date since Commission mail will be delayed due to necessary security screening.

Docket: For access to the docket to read comments received, go to *http://www.usitc.gov* or U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436.

The preamble below is designed to assist readers in understanding these proposed amendments to the Commission's rules. The preamble includes a discussion of the background leading up to these proposed amendments, a regulatory analysis addressing government-wide statutes and issuances on rulemaking, and a description of the proposed amendments to the rules. The Commission encourages members of the public to comment—in addition to any other comments they wish to make on the proposed amendments—on whether the proposed language is sufficiently clear for users of the rules to understand.

If the Commission decides to proceed with this rulemaking after reviewing the comments filed in response to this notice, the proposed rule revisions will be promulgated in accordance with the Administrative Procedure Act (5 U.S.C. 553), and will be codified in 19 CFR part 210.

Background

Currently, service of Commission documents in investigations and related proceedings under section 337 of the Tariff Act is effected under section 210.7 of the Commission's rules in part 210 (19 CFR 210.7) which refers back to the general service provisions of § 201.16 of the Commission's rules in part 201 (19 CFR 201.16). Also, the computation of time to respond to Commission documents in section 337 investigations and related proceedings is governed by § 210.6 of the Commission's rules in part 210 (19 CFR 210.6) which refers back to the general computation of time presented in § 201.16(d) of the Commission's rules in part 201 (19 CFR 201.16(d)). Currently, the Commission rules governing service of Commission documents in section 337 investigations and related proceedings allow for service by mail or hand delivery.

The Commission is considering changing the manner in which it serves certain documents in section 337 investigations and related proceedings to: (1) Eliminate gamesmanship between parties served by different manners of service in responding to Commission documents; and (2) streamline service of Commission documents. The Commission proposes that certain Commission documents, which are identified below, be served by overnight delivery on private parties. For these documents hand pickup will not be permitted. Parties served by overnight delivery will be given one additional day to respond. The Commission is considering providing the Commission Investigative Attorney (''IA'') with sufficient time to allow filing contemporaneously with the private parties.

Regulatory Analysis of Proposed Amendments to 19 CFR Part 210

The Commission has determined that the proposed rules do not meet the criteria described in Section 3(f) of Executive Order 12866 (58 FR 51735, Oct. 4, 1993) and thus do not constitute a significant regulatory action for purposes of the Executive Order.

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is inapplicable to this rulemaking because it is not one for which a notice of proposed rulemaking is required under 5 U.S.C. 553(b) or any other statute. Although the Commission has chosen to publish a notice of proposed rulemaking, these proposed regulations are ''agency rules of procedure and practice,'' and thus are exempt from the notice requirement imposed by 5 U.S.C. 553(b).

These proposed rules do not contain federalism implications warranting the preparation of a federalism summary impact statement pursuant to Executive Order 13132 (64 FR 43255, Aug. 4, 1999).

No actions are necessary under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*) because the proposed rules will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments.

The proposed rules are not major rules as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). Moreover, they are exempt from the reporting requirements of the Contract With America Advancement Act of 1996 (Pub. L. 104–121) because they concern rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.

The amendments are not subject to section 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), since they do not contain any new information collection requirements.

Explanation of the Proposed Amendments to 19 CFR Part 210

The Commission proposes to amend part 210 in the manner described below.

Section 210.6

Section 210.6 governs the computation of response time when a party is served with a document that requires a response. The Commission proposes to amend that rule by adding provisions concerning when to respond to Commission documents that are served by overnight delivery.

The Commission proposes to revise the text of § 210.6 by dividing the current text and designating the portions as paragraphs (a) and (b) of the amended rule. Also, the Commission proposes to add a new paragraph (c) which provides that a party shall be given one additional day to respond to a Commission document when served by overnight delivery, and add another new paragraph (d) which defines ''overnight delivery''.

Section 210.7

Paragraph (a) of § 210.7 governs the service of process of Commission documents. The Commission proposes to amend that rule by adding provisions concerning service of certain documents by overnight delivery on private parties (for these documents hand pickup will not be permitted).

The Commission proposes to revise and redesignate current paragraph (a) as paragraph (a)(1), and then add new paragraph (a)(2) which provides that certain Commission documents shall be served by overnight delivery.

List of Subjects in 19 CFR Part 210

Administration practice and procedure, Business and industry, Customs duties and inspection, Imports, Investigations.

For the reasons discussed in the preamble, the United States International Trade Commission proposes to amend 19 CFR part 210 as follows:

PART 210—ADJUDICATION AND ENFORCEMENT

1. The authority citation for part 210 will continue to read as follows:

Authority: 19 U.S.C. 1333, 1335, and 1337.

2. Revise § 210.6 to read as follows:

§ 210.6 Computation of time, additional hearings, postponements, continuances, and extensions of time.

(a) Unless the Commission, the administrative law judge, or this or another section of this part specifically provides otherwise, the computation of time and the granting of additional hearings, postponements, continuances, and extensions of time shall be in accordance with §§ 201.14 and 201.16(d) of this chapter.

(b) Whenever a party has the right or is required to perform some act or to take some action within a prescribed period after service of a document upon it, and the document was served by mail, the deadline shall be computed by adding to the end of the prescribed period the additional time allotted under § 201.16(d), unless the Commission, the administrative law judge, or another section of this part specifically provides otherwise.

(c) Whenever a party has the right or is required to perform some act or to take some action within a prescribed period after service of a Commission document upon it, and the document was served by overnight delivery, the deadline shall be computed by adding one day to the end of the prescribed period, unless the Commission, the administrative law judge, or another section of this part specifically provides otherwise.

(d) ''Overnight delivery'' is defined as delivery by the next business day.

3. Amend § 210.7 by revising paragraph (a) to read as follows:

§ 210.7 Service of process and other documents; publication of notices.

(a) *Manner of service.* (1) The service of process and all documents issued by or on behalf of the Commission or the administrative law judge—and the service of all documents issued by parties under §§ 210.27 through 210.34 of this part—shall be in accordance with § 201.16 of this chapter, unless the Commission, the administrative law judge, or this or another section of this part specifically provides otherwise.

(2) The service of all initial determinations as defined in § 210.42 and all documents containing confidential business information—issued by or on behalf of the Commission or the administrative law judge—on a private party shall be effected by serving a copy of the document by overnight delivery—as defined in § 210.6(d)—on the person to be served, on a member of the partnership to be served, on the president, secretary, other executive officer, or member of the board of directors of the corporation, association, or other organization to be served, or, if an attorney represents any of the above before the Commission, by serving a copy by overnight delivery on such attorney.

* * * * *

Issued: December 4, 2006.

By Order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E6–20766 Filed 12–7–06; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Parts 502, 546, and 547

Class II Definitions and Gaming Standards and Technical Standards

AGENCY: National Indian Gaming Commission, Interior

ACTION: Notice of reopening of comment period.

SUMMARY: This notice reopens the period for comments on proposed Class II definitions and game classification standards published in the **Federal Register** on May 25, 2006 (71 FR 30232, 71 FR 30238). This notice also reopens the period for comments on proposed Class II technical standards published in the **Federal Register** on August 11, 2006 (71 FR 46336).

DATES: The comment period for the proposed classification, definition, and technical regulations is being reopened from November 15, 2006, to December 15, 2006.

FOR FURTHER INFORMATION CONTACT: Penny Coleman, John Hay, or Michael Gross at 202/632–7003; fax 202/632–7066 (these are not toll-free numbers).

SUPPLEMENTARY INFORMATION: Congress established the National Indian Gaming Commission (NIGC or Commission) under the Indian Gaming Regulatory Act of 1988 (25 U.S.C. 2701 *et seq.*) (IGRA) to regulate gaming on Indian lands. On May 25, 2006, proposed Class II definitions and game classification standards were published in the **Federal Register** (71 FR 30232, 71 FR 30238). On August 11, 2006, proposed Class II technical standards were published in the **Federal Register** (71 FR 46336).

Dated: December 4, 2006.

Philip N. Hogen,

Chairman, National Indian Gaming Commission.

Cloyce V. Choney,

Commissioner, National Indian Gaming Commission.

[FR Doc. E6–20843 Filed 12–7–06; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–121509–00]

RIN 1545–AY54

Exclusion From Gross Income of Previously Taxed Earnings and Profits and Adjustments to Basis of Stock in Controlled Foreign Corporations and of Other Property; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document corrects notice of proposed rulemaking (REG–121509–00) that was published in the **Federal Register** on Tuesday, August 29, 2006 (71 FR 51155). The document contains proposed regulations that provide guidance relating to the exclusion from gross income of previously taxed earnings and profits under section 959 of the Internal Revenue Code (Code) and related basis adjustments under section 961 of the Code.

FOR FURTHER INFORMATION CONTACT: Ethan Atticks, (202) 622–3840 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking (REG–121509–00) that is the subject of these corrections is under sections 959 and 961 of the Internal Revenue Code.

Need for Correction

As published, REG–121509–00 contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the notice of proposed rulemaking (REG–121509–00), that was the subject of FR Doc. 06–7195, is corrected as follows:

1. On page 51155, column 1, in the preamble, under the paragraph heading ''Background'', the last paragraph of the column, third line, the language, ''sections 959 and 961. Section 959(a)(1)'' is corrected to read ''sections 959, 961, and 1502. Section 959(a)(1)''.

2. On page 51156, column 1, in the preamble, the last paragraph of the column, fifth line from bottom, the language ''109–222), which provides for look-'' is corrected to read ''109–222), which generally provides for look-''.

3. On page 51156, column 3, in the preamble, under paragraph heading ''2. Shareholder PTI Accounts'', sixth line, the language ''directly, or indirectly under section'' is corrected to read ''directly or indirectly under section''.

4. On page 51157, column 1, in the preamble, under paragraph heading ''3. Successors in Interest'', second paragraph, sixteenth line, the language ''corporation from a person that is not a'' is corrected to read ''corporation from any person, including a person that is not a''.

5. On page 51157, column 1, in the preamble, under paragraph heading ''*B. CFC-Level Exclusion Under Section 959(b)*'' first line of first paragraph, the language ''The earnings and profits of a CFC'' is corrected to read ''Section 959(b) provides an exclusion pursuant to which the earnings and profits of a CFC''.

6. On page 51157, column 1, in the preamble, under paragraph heading ''*B. CFC-Level Exclusion Under Section 959(b)*'', first paragraph, third line from the bottom of the paragraph, the language ''rules regarding cross-chain sales of'' is corrected to read ''to provide guidance regarding cross-chain sales of''.

7. On page 51157, column 2, in the preamble, first paragraph of the column, ninth line, the language ''section 951(a)) and a $100 of non-'' is corrected to read ''section 951(a)) and $100x of non-''.

8. On page 51157, column 2, in the preamble, first paragraph of the column, last line, the language ''$91x ((70% × $30) + (70% × $100)).'' is corrected to read ''$91x ((70% × $30x) + (70% × $100x)).''.

9. On page 51157, column 2, in the preamble, second paragraph of the column, third line, the language ''accordingly, provides that, the amount'' is corrected to read ''accordingly, provides that the amount''.

10. On page 51157, column 2, in the preamble, second paragraph of the column, eleventh line, the language ''of section 958(a)) in the lower-tier and'' is corrected to read ''of section 958(a)) in the lower-and''.

11. On page 51157, column 2, in the preamble, fourth paragraph of the column, seventh line, the language ''CFC from a person who was not taxed'' is corrected to read ''CFC from a person that was not taxed''.

12. On page 51157, column 3, in the preamble, first paragraph of the column, eighth line, the language ''inclusion is still $100. In contrast, Prop.'' is corrected to read ''inclusion is still $100x. In contrast, Prop.''.

13. On page 51157, column 3, in the preamble, under the paragraph heading ''1. Shareholder-Level Accounting of PTI'', last line of the column, the language ''shareholder who owns the stock or by'' is corrected to read ''shareholder that owns the stock or by''.

14. On page 51158, column 2, in the preamble, under the paragraph heading ''a. Dollar Basis Pooling Election'', first paragraph of the column, ninth to fifteenth lines, the language ''to a distribution of PTI. Notice 88–71 (1988–2 C.B. 374) makes this pooled approach available to taxpayers for purposes of section 986(c) at the taxpayer's election, but it does not provide guidance as to how this election is made. The proposed regulations'' is corrected to read ''to a distribution of PTI. The proposed regulations make this pooled approach available to taxpayers for purposes of section 986(c) at the taxpayer's election. The proposed regulations''.

15. On page 51158, column 3, in the preamble, under paragraph heading ''4. Adjustment of Shareholder PTI Accounts'', second paragraph, tenth line, the language ''corporation. Next, a shareholder's PTI'' is corrected to read ''corporation. Second, a shareholder's PTI''.

16. On page 51160, column 1, in the preamble, under paragraph heading ''b. Shareholder That Is a Member of a Consolidated Group'', first paragraph, seventh line from the bottom of the first paragraph, the language ''consolidated group who own stock in'' is corrected to read ''consolidated group that own stock in''.

17. On page 51160, column 1, in the preamble, second paragraph, eleventh line, the language ''taxable year who own stock in the'' is corrected to read ''taxable year that own stock in the''.

18. On page 51161, column 3, in the preamble, under paragraph heading ''*A. Coordination of Shareholder-Level and Corporate-Level Accounts*'', ninth line, the language ''PTI information is to be shared between'' is corrected to read ''PTI information is to be shared among''.

19. On page 51161, column 3, in the preamble, thirteenth line, the language ''are necessary, and if so, how they'' is corrected to read ''are necessary and, if so, how they''.

20. On page 51162, column 3, in the preamble, under paragraph heading ''*F. Section 961(c) Basis Adjustments*'', first line of the paragraph, the language ''Section 961(c) is by its terms only'' is corrected to read ''Section 961(c) is only''.

§ 1.959–1 [Corrected]

21. On page 51163, column 3, § 1.959–1(a), second line of the column, the language ''except that such

distributions shall'' is corrected to read ''except that such distribution shall''.

22. On page 51164, column 1, § 1.959–1(b)(2), first paragraph of the column, fifth and sixth lines, the language ''any) that are attributable to section 951(a) inclusions.'' is corrected to read ''any).''.

23. On page 51164, column 1, § 1.959–1(b)(3), second paragraph of the column, third line, the language ''income with respect to the previously'' is corrected to read ''a United States shareholder's income with respect to the previously''.

24. On page 51164, column 1, § 1.959–1(b)(4)(iii), second line from the bottom of the paragraph, the language ''corporations are members of the same'' is corrected to read ''if both the first mentioned corporation and the covered shareholder are members of the same''.

25. On page 51165, column 1, § 1.959–1(d)(3), second paragraph of the column, first line, the language ''The application of this paragraph'' is corrected to read ''*Examples.* The application of this paragraph''.

26. On page 51165, column 1, § 1.959–1(d)(3), *Example 1.*, paragraph heading, the language ''*Shareholder previously taxed earnings and profits account.*'' is corrected to read ''*Shareholder's previously taxed earnings and profits account.*''.

27. On page 51165, column 1, § 1.959–1(d)(3)(i), eighth and ninth lines, the language ''currency. FC earns $100x of subpart F income in year 1 and $100x of non-subpart'' is corrected to read ''currency. In year 1, FC earns $100x of subpart F income and $100x of non-subpart F''.

§ 1.959–2 [Corrected]

28. On page 51165, column 2, § 1.959–2(a)(1), fourth line from the bottom of the paragraph, the language ''income of such distributee CFC also'' is corrected to read ''income of such upper-tier CFC also''.

29. On page 51165, column 3, § 1.959–2(a)(2), paragraph (i) of *Example 2.*, second line from the bottom of the paragraph, the language ''2, and FC had no earnings for year 2 other'' is corrected to read ''2, and FC had no earnings and profits for year 2 other''.

30. On page 51165, column 3, § 1.959–2(a)(2), paragraph (ii) of *Example 3.*, eighth and ninth lines, the language ''DP's pro rata share of the remaining $50, or $35 ($50 × 70%), is included in DP's gross'' is corrected to read ''DP's pro rata share of the remaining $50x, or $35x ($50x × 70%), is included in DP's gross''.

31. On page 51166, column 1, § 1.959–2(a)(2), paragraph (ii) of *Example 3.*, first paragraph of the column, first line, the language ''reduced to $0, however, as a result of the'' is corrected to read ''reduced to $0, as a result of the''.

32. On page 51166, column 1, § 1.959–2(b)(2), third paragraph of the column, first line, the language ''The application of this paragraph'' is corrected to read ''*Example.* The application of this paragraph''.

§ 1.959–3 [Corrected]

33. On page 51166, column 3, § 1.959–3(b)(3)(i), third paragraph of the column, fifth through twelfth lines, the language ''earnings and profits in the year in which such amounts are included in gross income of a United States shareholder under section 951(a) and are reclassified as to category of earnings and profits in the year in which such amounts would be so included but for the provisions of'' is corrected to read ''earnings and profits in the taxable year of the foreign corporation in which such amounts are included in the gross income of a United States shareholder under section 951(a) and are reclassified as to category of earnings and profits in the taxable year of the foreign corporation in which such amounts would be so included in the gross income of a United States shareholder under section 951(a) but for the provisions of''.

34. On page 51167, column 2, § 1.959–3(c)(1), third paragraph of the column, fourth line, the language ''are distributed by a foreign corporation'' is corrected to read ''are distributed by a foreign corporation to another foreign corporation''.

35. On page 51167, column 2, § 1.959–3(c)(1), fourteenth line, the language ''included in the foreign corporation's'' is corrected to read ''included in the distributee foreign corporation's''.

36. On page 51167, column 2, § 1.959–3(c)(2), fourth paragraph of the column, first line, the language ''The application of this paragraph'' is corrected to read ''*Example.* The application of this paragraph''.

37. On page 51172, column 3, § 1.959–3(g)(4), paragraph (i) of *Example 1.*, first paragraph of the column, fourth line from the bottom of the paragraph, the language ''earnings and profits on its stock Class A'' is corrected to read ''earnings and profits on its Class A''.

38. On page 51173, column 3, § 1.959–3(g)(4), paragraph (i) of *Example 5.*, third line, the language ''on its stock Class A stock consisting of a'' is corrected to read '' on its Class A stock consisting of a''.

39. On page 51174, column 3, § 1.959–3(h)(3)(i), third paragraph of the column, fourth line from the bottom of the paragraph, the language ''§§ 1.959–1 and this section shall apply'' is corrected to read ''§ 1.959–1 and this section shall apply''.

40. On page 51175, column 1, § 1.959–3(h)(4)(i), fourth paragraph of the column, fifth line from the bottom of the paragraph, the language ''§§ 1.959–1 and this section shall'' is corrected to read ''§ 1.959–1 and this section shall''.

41. On page 51175, column 1, § 1.959–3(h)(4)(ii), fifth paragraph of the column, first line, the language ''The application of this paragraph'' is corrected to read ''*Example.* The application of this paragraph''.

§ 1.961–2 [Corrected]

42. On page 51177, column 1, § 1.961–2(d), paragraph (i) of *Example 3.*, third paragraph of the column, third line from the bottom of the paragraph, the language ''December 31, of year 1. In year 2, DP has a'' is corrected to read ''December 31 of year 1. In year 2, DP has a''.

§ 1.961–3 [Corrected]

43. On page 51177, column 2, § 1.961–3(a)(1), first paragraph of the column, second line from the bottom of the paragraph, the language ''shareholders gross income under'' is corrected to read ''shareholder's gross income under''.

44. On page 51177, column 3, § 1.961–3(b)(1), third paragraph of the column, twelfth line, the language ''than wholly owned by a single United'' is corrected to read ''than wholly indirectly owned by a single United''.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. E6–20798 Filed 12–7–06; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF EDUCATION

34 CFR Parts 674, 682, and 685

Office of Postsecondary Education; Notice of Intent To Establish Negotiated Rulemaking Committees Under Title IV of the Higher Education Act of 1965, as Amended

AGENCY: Department of Education.

ACTION: Notice of negotiated rulemaking.

SUMMARY: The Secretary of Education (Secretary) announces the establishment of a negotiated rulemaking committee to

develop proposed regulations related to the Federal student loan programs authorized by Title IV, Parts B, D, and E of the Higher Education Act of 1965, as amended (HEA). The Secretary is also announcing that she will establish a negotiating committee that will begin meeting in January to address issues related to the Academic Competitiveness Grant (ACG) and the National Science and Mathematics Access to Retain Talent (National SMART) Grant programs. The Secretary is still considering whether to establish additional committees to address accreditation issues and/or other Title IV programmatic, institutional eligibility and general provisions issues.

The Secretary also is announcing that she is reopening our request for nominations of individual negotiators to serve on the ACG and National SMART Grant programs committee and any additional negotiating committees that may be formed to address accreditation issues and other Title IV programmatic, institutional eligibility, and general provisions issues.

DATES: The dates for the negotiation sessions are listed in the **SUPPLEMENTARY INFORMATION** section of this notice. We must receive your nominations for negotiators to serve on the ACG and National SMART Grant programs committee and on any additional committees that may be established to address accreditation issues and other Title IV programmatic, institutional eligibility, and general provisions issues on or before December 22, 2006.

FOR FURTHER INFORMATION CONTACT: Wendy Macias, U.S. Department of Education, 1990 K Street, NW., room 8017, Washington, DC 20006. Telephone: (202) 502–7526. E-mail: *Wendy.Macias@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed in this section.

SUPPLEMENTARY INFORMATION: On August 18, 2006, we published a notice in the **Federal Register** (71 FR 47756) announcing our intent to establish up to four negotiated rulemaking committees to prepare regulations under Title IV of the HEA. The notice also announced a series of four regional hearings where interested parties could suggest issues for consideration for action by the negotiating committees. We also invited parties to submit issues for consideration in writing. In the notice, we requested nominations for individual negotiators who represent key stakeholder constituencies that are involved in the student financial assistance programs authorized under Title IV of the HEA to serve on these committees.

After consideration of the information received at the regional hearings and in writing, we have decided to establish a negotiating committee (''Loans Committee'') that will begin meeting in December 2006 to address issues related to the Federal student loan programs authorized by Title IV, Parts B, D, and E of the HEA. We list the topics the Loans Committee is likely to address, the members of the committee, and the meeting schedule for the committee elsewhere in this notice under *Loans Committee Topics, Members, and Meeting Schedule.*

We will also establish a negotiating committee that will begin meeting in January 2007 to address issues related to the ACG and the National SMART Grant programs. We are still considering whether to establish additional committees to address accreditation issues and other Title IV programmatic, institutional eligibility and general provisions issues.

We are reopening our request for nominations for individual negotiators who represent key stakeholder constituencies to serve on the ACG and National SMART Grant programs committee and any additional negotiating committees that may be formed to address accreditation issues and Title IV programmatic, institutional eligibility, and general provisions issues (see *Invitation for Additional Nominations for the ACG and National SMART Grant Program Committees and Possible Additional Committees* elsewhere in this notice). We will announce the members of the ACG and National SMART Grant programs committee, the issues this committee will likely address, and the meeting schedule for this committee in the **Federal Register** at a later date. We will announce the formation of any additional negotiating committees in the **Federal Register** in early 2007.

Loans Committee Topics, Members, and Meeting Schedule

The topics the Loans Committee is likely to address are:

- Entrance Counseling for Graduate and Professional Student PLUS Loan borrowers.
- Discharge of student loans based on identity theft of the borrower.
- Eligible lender trustee relationships between Federal Family Education Loan (FFEL) lenders and schools or school-affiliated organizations.
- Use of lists of FFEL preferred lenders.
- Prohibited inducements in the FFEL program.
- FFEL loan certification and Direct Loan origination for non-standard term programs.
- Modifications to the Economic Hardship Deferment provisions and Income Contingent Repayment Formula to improve consideration of family size.
- Retention of disbursement records supporting Title IV, HEA loan program Master Promissory Notes (MPNs).
- Documentation of E-Signature standards on Title IV Loan Program MPNs Assigned to ED.
- Use of true and exact copies of death certificates for discharges of student loans based on death.
- The impact of retroactive conditional disability periods on total and permanent disability loan discharges.
- National Student Loan Data System reporting timeframes for lenders.
- Assignment of defaulted Perkins Loans.
- Eligibility requirements for the Perkins Loan Program Child & Family Service Cancellation
- Definition of ''reasonable and affordable'' collection costs in the Perkins Loan Program.
- Technical corrections.

This list of topics is tentative. Topics may be added as the process continues.

In selecting individuals from the submitted nominations, the Department sought to assemble a balanced and complementary representation of the interests affected by the subject matter, consistent with section 492 of the HEA. We believe the individuals selected will bring valuable knowledge and expertise to the table, and will work as a cohesive unit to assist us in developing proposed regulations that are both reasonable and effective. Individuals that were not selected as members of the committees will be able to attend the meetings and have access to the negotiators. The committee meetings will be open to the public.

The members of the Loans Committee are:

Students: Jennifer Pae, United States Student Association

Alternate: Luke Swarthout, State Public Interest Research Groups

Legal assistance organizations that represent students: Deanne Loonin, National Consumer Law Center.

Public 2-Year Institutions of higher education: Darrel Hammon, Laramie Community College.

Alternate: Kenneth L. Whitehurst, North Carolina Community Colleges.

Public 4-Year Institutions of higher education: Pamela W. Fowler, University of Michigan.
Alternate: Patricia McClug, University of Wyoming.
Private, non-profit Institutions of higher education: Elizabeth Hicks, Massachusetts Institute of Technology.
Alternate: Ellen Frishberg, Johns Hopkins University.
Private, for-profit postsecondary education institution: Jeff Arthur, ECPI College of Technology.
Alternate: Robert Collins, Apollo Group, Inc.
Historically Black Colleges and Universities: Shari Crittendon, United Negro College Fund.
Alternate: Dr. N. Joyce Payne, National Association of State and Land Grant Colleges and Universities.
Guaranty agencies: Scott Giles, Vermont Student Assistance Corporation.
Alternate: Rachael Lohman, Pennsylvania Higher Education Assistance Agency.
FFEL Program Lenders: Tom Levandowski, Wachovia Corporation.
Alternate: Lee Woods, Chase Education Finance.
Secondary markets: Phil Van Horn, Wyoming Student Loan Corporation.
Alternate: Robert L. Zier, Indiana Secondary Market for Education Loan Program, Inc.
Loan servicers: Robert Sommer, Sallie Mae.
Alternate: Wanda Hall, EDFinancial Services.
Guaranty agency servicers: Richard George, Great Lakes Education Guaranty Corporation.
Alternate: Gene Hutchins, New Jersey Higher Education Assistance Authority.
Institutions of higher education that participate in the Federal Direct Loan Program: Eileen O'Leary, Stonehill College.
Alternate: Christine W. McGuire, Boston University.
Institutions of higher education that participate in the Perkins Loan Program: Alisa Abadinsky, University of Illinois at Chicago.
Alternate: Karen Fooks, University of Florida.

We will hold a total of three meetings, all of which will be held in the metropolitan Washington, DC area. The following is the schedule for negotiations. This schedule is subject to change.

- Session 1: December 12–14.
- Session 2: January 29–February 1.
- Session 3: February 26–February 28.

The December 12–14 negotiating session is scheduled from 1 to 5 p.m. on December 12th; 9 a.m. to 5 p.m. on December 13th; and 9 a.m. to 4 p.m. on December 14th. The Committee will convene at the Marriott Crystal Gateway at 1700 Jefferson Davis Highway, Arlington, Virginia.

We will post information about the January and February negotiating sessions, including information on the meeting sites and any schedule changes, at *http://www.ed.gov/policy/highered/reg/hearulemaking/2007/nr.html.*

Participation in the rulemaking process is not limited to members of the committee or those who work with the committee. Following the negotiated rulemaking process, we will publish proposed regulations in the **Federal Register** for public comment. The target date for publication of proposed regulations developed by this committee is May 2007.

Invitation for Additional Nominations for the ACG and National SMART Grant Programs Committee and Possible Additional Committees

We are reopening our request for nominations for individual negotiators who represent key stakeholder constituencies that are involved in the student financial assistance programs authorized under Title IV of the HEA to serve on the ACG and National SMART Grant programs committee and any committee that may be formed to address accreditation issues (Title IV, Part H of the HEA) or other programmatic, institutional eligibility, and general provisions issues related to Title IV, Parts A (except for ACG and National SMART Grant programs), C, G, and H (except subpart 2) of the HEA, as well as Title II, Section 208(b)(2) of the HEA. Nominations must be received on or before December 22, 2006.

The Secretary has identified the following constituencies as having interests that are significantly affected by the subject matter of the negotiating committee for the ACG and National SMART Grant Programs and the committees that may be established to negotiate changes to the other regulations. These constituencies are:

- Students.
- Legal assistance organizations that represent students.
- Financial aid administrators at institutions of higher education.
- Business officers and bursars at institutions of higher education.
- Institutional servicers (including collection agencies).
- Trustees.
- State higher education executive officers.
- Business and industry.
- Institutions of higher education eligible to receive Federal assistance under Title III, Parts A and B, and Title V of the HEA, which includes Historically Black Colleges and Universities, Hispanic-Serving Institutions, American Indian Tribally Controlled Colleges and Universities, Alaska Native and Native Hawaiian-Serving Institutions, and other institutions with a substantial enrollment of needy students as defined in Title III of the HEA.
- Two-year public institutions of higher education.
- Four-year public institutions of higher education.
- Private, non-profit institutions of higher education.
- Private, for-profit institutions of higher education.
- Guaranty agencies and guaranty agency servicers (including collection agencies).
- Lenders, secondary markets, and loan servicers.
- Accrediting agencies.
- K–12 public schools, including charter schools.
- State Governors.
- Private schools and home schooled students.
- Admissions officers at postsecondary education institutions.
- Parent organizations.
- Organizations related to National SMART Grant majors.

Individuals who were nominated for these committees in response to our earlier notice do not need to be renominated.

Electronic Access to This Document

You may view this document 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 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.*

Program Authority: 20 U.S.C. 1098a.

Dated: December 5, 2006.

James F. Manning,

Delegated the Authority of Assistant Secretary for Postsecondary Education.

[FR Doc. E6–20931 Filed 12–7–06; 8:45 am]

BILLING CODE 4000–01–P

Notices

Federal Register
Vol. 71, No. 236
Friday, December 8, 2006

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Thorn Fire Salvage Recovery Project, Malheur National Forest, Grant County, OR

AGENCY: Forest Service, USDA.

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

SUMMARY: The USDA Forest Service will prepare an environmental impact statement (EIS) to disclose environmental effects on a proposed action to recover the economic value of dead and dying tees damaged in the Shake Table Fire Complex, and remove potential hazard trees from open forest travel routes within the Todd, Duncan, Fields Creek and Dry Creek subwatersheds. Shake Table Fire Complex, located approximately 20 miles southwest of John Day, Oregon, burned approximately 14,527 acres across mixed ownership in August 2006, of that approximately 13,536 acres were on National Forest System Lands administered by the Blue Mountain Ranger District, Malheur National Forest. The proposed action is the Thorn Fire Salvage Recovery Project.

DATES: Comments concerning the scope of the analysis must be received by January 8, 2007. The draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and be available to the public for review by April 2007. The Final EIS is scheduled to be completed by June 2007.

ADDRESSES: Send written comments to the Responsible Official, Gary L. ''Stan'' Benes, Forest Supervisor, Malheur National Forest, 431 Patterson Bridge Road, P.O. Box 909, John Day, Oregon 97845. send electronic comments to: *comments-pacificnorthwest-malheur@fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Jerry Hensley, Project Manager, Malheur National Forest, 431 Patterson Bridge Road, P.O. Box 909, John Day, Oregon, telephone 541–575–3167, e-mail *jhensley@fs.fed.us.*

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The purpose and need of the Thorn Fire Salvage Recovery Project includes: (1) Recovery of the economic value of a portion of the dead and dying trees consistent with protection of other resource values; and (2) Improving public safety within the fire area by removing potentional hazard trees for public safety along open forest travel routes.

Proposed Action

This action includes salvage of fire killed trees from approximately 4,480 acres and removal of potential hazard trees for public safety along open forest travel routes. Salvage harvest methods would include ground-based and helicopter logging systems. Approximately 80 percent of the harvest area would be salvaged by helicopter. No commercial harvest or road construction is proposed within Appendix C Inventoried Dry Cabin, Cedar Grove and Shake Table Roadless Areas. Road activities associated with salvage and restoration will be limited to reconstruction, opening and re-closing existing roads, and maintenance. No new roads would be built. Following site preparation, approximately 4,480 acres would be planted with conifer seedlings. Forest Plan amendments would be included as needed.

Possible Alternatives

Alternatives will include the proposed action, no action, and additional alternatives that respond to issues generated during the scoping process. The agency will give notice of the full environmental analysis and decision-making process to interested and affected people may participate and contribute to the final decision.

Responsible Official and Nature of Decision To Be Made

The Responsible Official is Gary L. ''Stan'' Benes, Forest Supervisor of the Malheur National Forest, 431 Patterson Bridge Road, P.O. Box 909, John Day, OR 97845. The Responsible Official will decide if the proposed project will be implemented and will document the decision and reasons for the decision in a Record of Decision. That decision will be subject to Forest Service Appeal Regulations. The responsibility for preparing the DEIS and FEIS has been delegated to Brooks Smith, Acting District Ranger, Blue Mountain Ranger District.

Scoping Process

Public participation will be especially important at several points during the analysis, beginning with the scoping process (40 CFR 1501.7). Initial scoping began with the project listed in the 2006 Fall Edition of the Malheur National Forest's Schedule of Proposed Actions. A Public meeting has been planned for January 2007 to discuss the project. Other meetings will be scheduled as needed. Also, correspondence with tribes, government agencies, organizations, and individuals who have indicated their interested will be conducted.

Preliminary Issues

Preliminary issues identified include the potential effect of the proposed action on: Soils, water quality and fish habitat, snags and down wood, disturbance to cultural resources, potential for noxious weed expansion, threatened, endangered and sensitive aquatic, terrestrial and plant species, potential loss of economic value of trees damaged by wildfire, and the safety and use of the area by public and land managers.

Comment

Public comments about this proposal are requested to identify issues and alternatives to the proposed action and to focus the scope of the analysis. Comments received in response to solicitation, including names and addresses of those who comment, will be considered part of the public record on this proposed action, and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments will not have standing to appeal the subsequent decisions under 36 CFR Parts 215 or 217. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of

Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that under the FOIA, confidentiality may be granted in only very limited circumstances such as to protect trade secrets. The Forest Service will inform the requester of the agency's decisions regarding the request for confidentiality, and where the request is denied; the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within a specified number of days.

Early Notice of Importance of Public Participation in Subsequent Environmental Review

A draft environmental impact statement will be prepared for comment. The comment period on the draft environmental impact statement will be 45 days from the date the Environmental Protection agency publishes the notice of availability in the **Federal Register**. The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon v. Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act of 40 CFR 1503.3 in addressing these points.

Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal and will be available for public inspection.

(Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21)

Dated: December 4, 2006.

Gay L. Benes,

Forest Supervisor.

[FR Doc. 06–9593 Filed 12–7–06; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Chrome Fire Salvage Recovery Project, Malheur National Forest, Grant County, OR

AGENCY: Forest Service, USDA.

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

SUMMARY: The USDA Forest Service will prepare an environmental impact statement (EIS) to disclose environmental effects on a proposed action to recover the economic value of dead and dying trees damaged in the Shake Table Fire Complex, and remove potential hazard trees from open forest travel routes within the Todd, Duncan, Fields Creek and Dry Creek subwatersheds. The Shake Table Fire Complex, located approximately 20 miles south west of John Day, Oregon, burned approximately 14,527 acres across mixed ownership in August 2006, of that approximately 13,536 acres were on National Forest System Lands administered by the Blue Mountain Ranger District, Malheur National Forest. The proposed action is the Chrome Fire Salvage Recovery Project.

DATES: Comments concerning the scope of the analysis must be received by January 8, 2007. The Draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and be available to the public for review by July 2007. The Final EIS is scheduled to be completed by September 2007.

ADDRESSES: Send written comments to the Responsible Official, Gary L. ''Stan'' Benes, Forest Supervisor, Malheur National Forest, 431 Patterson Bridge Road, P.O. Box 909, John Day, Oregon 97845. Send electronic comments to: *comments-pacificnorthwest-malheur@fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Jerry Hensley, Project Manager, Malheur National Forest, 431 Patterson Bridge Road, P.O. Box 909, John Day, Oregon, telephone 541–575–3167, e-mail *jhensley@fs.fed.us.*

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The purpose and need of the Chrome Fire Salvage Recovery Project includes: (1) Recovery of the economic value of a portion of the dead and dying trees consistent with protection of other resource values; and (2) Improving public safety within the fire area by removing potential hazard trees for public safety along open forest travel routes.

Proposed Action

This action includes salvage of dead and dying trees from approximately 3,472 acres and removal of potential hazard trees for public safety along open forest travel routes. Salvage harvest methods would include ground-based and helicopter logging systems. Approximately 70 percent of the harvest area would be salvaged by helicopter. No commercial harvest or road construction is proposed within Appendix C Inventoried Dry Cabin, Cedar Grove and Shake Table Roadless Areas. Road activities associated with salvage and restoration will be limited to reconstruction, opening and re-closing existing roads, and maintenance. No new roads would be built. Following site preparation, approximately 3,472 acres would be planted with conifer seedlings. Forest Plan amendments, related to old growth replacement, snag levels, visuals, timber harvest within Semi-Primitive Non-Motorized Recreation Areas, etc. would be included as needed.

Possible Alternatives

Alternatives will include the proposed action, no action, and additional alternatives that respond to issues generated during the scoping process. The agency will give notice of the full environmental analysis and decision-making process to interested and affected people may participate and contribute to the final decision.

Responsible Official and Nature of Decision To Be Made

The Responsible Official is Gary L. ''Stan'' Benes, Forest Supervisor of the Malheur National Forest, 431 Patterson

Bridge Road, P.O. Box 909, John Day, OR 97845. The Responsible Official will decide if the proposed project will be implemented and will document the decision and reasons for the decision in a Record of Decision. That decision will be subject to Forest Service Appeal Regulations. The responsibility for preparing the DEIS and FEIS has been delegated to Brooks Smith, Acting District Ranger, Blue Mountain Ranger District.

Scoping Process

Public participation will be especially important at several points during the analysis, beginning with the scoping process (40 CFR 1501.7). Initial scoping began with the project listed in the 2006 Fall Edition of the Malheur National Forest's Schedule of Proposed Actions. A Public meeting has been planned for January 2007 to discuss the project. Other meetings will be scheduled as needed. Also, correspondence with tribes, government agencies, organizations, and individuals who have indicated their interest will be conducted.

Preliminary Issues

Preliminary issues identified include the potential effect of the proposed action on: soils, water quality and fish habitat, snags and down wood, disturbance to cultural resources, potential for noxious weed expansion, threatened, endangered and sensitive aquatic, terrestrial and plant species, potential loss of economic value of trees damaged by wildfire, and the safety and use of the area by public and land managers.

Comment

Public comments about this proposal are requested to identify issues and alternatives to the proposed action and to focus the scope of the analysis. Comments received in response to this solicitation, including names and addresses of those who comment, will be considered part of the public record on this proposed action, and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments will not have standing to appeal the subsequent decisions under 36 CFR Parts 215 or 217. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that under the FOIA, confidentiality may be granted in only very limited circumstances such as to protect trade secrets. The Forest Service will information the requester of the agency's decision regarding the request for confidentiality, and where the request is denied; the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within a specified number of days.

Early Notice of Importance of Public Participation in Subsequent Environmental Review

A draft environmental impact statement will be prepared for comment. The comment period on the draft environmental impact statement will be 45 days from the date the Environmental Protection agency publishes the notice of availability in the **Federal Register.** The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the council on Environmental Quality Regulations for implementing the procedural provisions of the National environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received, including the names and addresses of those who comment, will be considered part of the public record on this proposal and will be available for public inspection.

(Authority: 40 CFR 1501.7 and 1508.22; Forest Service Handbook 1909.15, Section 21)

Dated: December 4, 2006.

Gary L. Benes,

Forest Supervisor.

[FR Doc. 06–9594 Filed 12–07–06; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Opportunity for Designation in the Muncie (IN), Fremont (NE), Savage (MN), and West Lafayette (IN) Areas, and Request for Comments on the Official Agencies Serving These Areas

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice.

SUMMARY: The designations of the official agencies listed below will end on June 30, 2007. We are asking persons interested in providing official services in the areas served by these agencies to submit an application for designation. We are also asking for comments on the quality of services provided by these currently designated agencies: East Indiana Grain Inspection, Inc. (East Indiana); Fremont Grain Inspection Department, Inc. (Fremont); State Grain Inspection, Inc. (State Grain); and Titus Grain Inspection, Inc. (Titus).

DATES: Applications and comments must be received on or before January 8, 2007.

ADDRESSES: We invite you to submit applications and comments on this notice. You may submit applications and comments by any of the following methods:

* *Hand Delivery or Courier:* Deliver to Karen Guagliardo, Review Branch Chief, Compliance Division, GIPSA, USDA, Room 1647–S, 1400 Independence Avenue, SW., Washington, DC 20250.

* *Fax:* Send by facsimile transmission to (202) 690–2755, attention: Karen Guagliardo.

* *E-mail:* Send via electronic mail to *Karen.W.Guagliardo@usda.gov.*

* *Mail:* Send hardcopy to Karen Guagliardo, Review Branch Chief,

Compliance Division, GIPSA, USDA, STOP 3604, 1400 Independence Avenue, SW., Washington, DC 20250–3604.

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

Read Applications and Comments: All applications and comments will be available for public inspection at the office above during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Karen Guagliardo at 202–720–7312, e-mail *Karen.W.Guagliardo@usda.gov.*

SUPPLEMENTARY INFORMATION: Section 7(f)(1) of the United States Grain Standards Act, as amended (USGSA), authorizes GIPSA's Administrator to designate a qualified applicant to provide official services in a specified area after determining that the applicant is better able than any other applicant to provide such official services (7 U.S.C. 79(f)(1)).

Section 7(g)(1) of USGSA provides that designations of official agencies will terminate not later than three years and may be renewed according to the criteria and procedures prescribed in Section 7(f) of USGSA.

CURRENT DESIGNATIONS BEING ANNOUNCED FOR RENEWAL

Official agency	Main office	Designation start	Designation end
East Indiana	West Sacramento, CA	07/01/2004	06/30/2007
Fremont	Frankfort, IN	07/01/2004	06/30/2007
State Grain	Savage, MN	07/01/2004	06/30/2007
Titus	West Lafayette, IN	07/01/2004	06/30/2007

East Indiana

In accordance with Section 7(f)(2) of USGSA (7 U.S.C. 79(f)(2)) the following geographic area, in the States of Indiana and Ohio, is assigned to East Indiana:

* Bounded on the North by the northern and eastern Grant County lines; the northern Blackford, and Jay County lines;

* Bounded on the East by the eastern Jay, Randolph, Wayne, and Union County lines;

* Bounded on the South by the southern Union and Fayette County lines; the eastern Rush County line south to State Route 244; State Route 244 west to the Rush County line; and

* Bounded on the West by the western Rush and Henry County lines; the southern Madison County line west to State Route 13; State Route 13 north to State Route 132; State Route 132 northwest to Madison County; the western and northern Madison County lines; the northern Delaware County line; the western Blackford County line north to State Route 18; State Route 18 west to County Highway 900E; County Highway 900E north to the northern Grant County line. Darke County, Ohio.

Fremont

In accordance with Section 7(f)(2) of USGSA (7 U.S.C. 79(f)(2)), the following geographic area, in the States of Iowa and Nebraska, is assigned to Fremont:

In Iowa

* Carroll (west of U.S. Route 71); Clay (west of U.S. Route 71); Crawford; Dickinson (west of U. S. Route 71); Harrison (east of State Route 183); O'Brien (north of B24 and east of U.S. Route 59); Osceola (east of U.S. Route 59); and Shelby Counties, Iowa.

In Nebraska

* Bounded on the North by U.S. Route 20 east to the Pierce County line; the eastern Pierce County line; the northern Wayne, Cuming, and Burt County lines east to the Missouri River;

* Bounded on the East by the Missouri River south-southeast to State Route 91; State Route 91 west to the Dodge County line; the eastern and southern Dodge County lines west to U.S. Route 77; U.S. Route 77 south to the Saunders County line;

* Bounded on the South by the southern Saunders, Butler, and Polk County lines; and

* Bounded on the West by the western Polk County line north to the Platte River; the Platte River northeast to the western Platte County line; the western and northern Platte County lines east to U.S. Route 81; U.S. Route 81 north to U.S. Route 20.

The following grain elevators, located outside of the above contiguous geographic area, are part of this geographic area assignment: Farmers Cooperative, and Krumel Grain and Storage, both in Wahoo, Saunders County, Nebraska (located inside Omaha Grain Inspection Service, Inc.'s, area).

Fremont's assigned geographic area does not include the following grain elevators inside Fremont's area which have been and will continue to be serviced by the following official agencies:

1. Hastings Grain Inspection, Inc.: Huskers Cooperative Grain Company, Columbus, Platte County, Nebraska; and

2. Omaha Grain Inspection Service, Inc.: United Farmers Coop, Rising City, Butler County, Nebraska; and United Farmers Coop (2 elevators), Shelby, Polk County, Nebraska.

State Grain

In accordance with Section 7(f)(2) of USGSA (7 U.S.C. 79(f)(2)), the following geographic area, in the State of Minnesota, is assigned to State Grain:

* Hennepin, Ramsey, Washington, Carver, Scott, Dakota, Brown, Nicollet, Le Sueur, Rice, Goodhue, Watonwan, Blue Earth, Waseca, Steele, Dodge, McLeod, and Sibley Counties.

Titus

In accordance with Section 7(f)(2) of USGSA (7 U.S.C. 79(f)(2)) the Act, the following geographic area, in the State of Indiana, is assigned to Titus:

* Bounded on the North by the northern Pulaski County line;

* Bounded on the East by the eastern and southern Pulaski County lines; the eastern White County line; the eastern Carroll County line south to State Route 25; State Route 25 southwest to Tippecanoe County; the eastern Tippecanoe County line;

* Bounded on the South by the southern Tippecanoe County line; the eastern and southern Fountain County lines west to U.S. Route 41; and

* Bounded on the West by U.S. Route 41 north to the northern Benton County line; the northern Benton County line east to State Route 55; State Route 55 north to U.S. Route 24; U.S. Route 24 east to the White County line; the western White and Pulaski County lines.

* The following grain elevators, located outside of the above contiguous geographic area, are part of this geographic area assignment: Boswell Chase Grain, Boswell, Benton County; ADM, Dunn, Benton County; ADM, Raub, Benton County (located inside Champaign-Danville Grain Inspection Departments, Inc.'s, area); and The

Andersons, Delphi, Carroll County; Frick Services, Inc., Leiters Ford, Fulton County; and Cargill, Inc., Linden, Montgomery County (located inside Frankfort Grain Inspection, Inc.'s, area).

Opportunity for Designation

Interested persons, including East Indiana, Fremont, State Grain, and Titus, may apply for designation to provide official services in the geographic areas specified above under the provisions of Section 7(f) of USGSA (7 U.S.C. 79(f)(2)), and 9 CFR 800.196(d) regulations. Designation in the specified geographic areas is for the period beginning July 1, 2007, and ending June 30, 2010. To apply for designation, contact the Compliance Division at the address listed above for forms and information, or obtain applications at the GIPSA Web site, *http://www.gipsa.usda.gov.*

Request for Comments

We are also publishing this notice to provide interested persons the opportunity to present comments on the quality of services provided by the East Indiana, Fremont, State Grain, and Titus official agencies. In the designation process, we will consider substantive comments citing reasons and pertinent data for support or objection to the designation of the applicants. Submit all comments to the Compliance Division at the above address.

In determining which applicant will be designated, we will consider applications, comments, and other available information.

Authority: 7 U.S.C. 71 *et seq.*

James E. Link,

Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. E6–20905 Filed 12–7–06; 8:45 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Designation for the Sacramento (CA), Frankfort (IN), Indianapolis (IN), and Virginia Areas

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice.

SUMMARY: We are announcing designation of the following organizations to provide official services under the United States Grain Standards Act, as amended (USGSA): California Agri Inspection Company, Ltd. (California Agri); Frankfort Grain Inspection, Inc. (Frankfort); Indianapolis Grain Inspection & Weighing Service, Inc. (Indianapolis); and Virginia Department of Agriculture and Consumer Services (Virginia).

EFFECTIVE DATE: January 1, 2007.

FOR FURTHER INFORMATION CONTACT: Karen Guagliardo at 202–720–7312, e-mail *Karen.W.Guagliardo@usda.gov.*

SUPPLEMENTARY INFORMATION: In the June 16, 2006, **Federal Register** (71 FR 34882–34883), we requested applications for designation to provide official services in the geographic areas assigned to the official agencies named above. Applications were due by July 14, 2006.

There were two applicants for the Sacramento area: California Agri and Mid-Iowa Grain Inspection, Inc. (Mid-Iowa); both are currently designated official agencies. Mid-Iowa withdrew its application. Frankfort, Indianapolis, and Virginia were the sole applicants for designation to provide official services in the entire area currently assigned to them, so GIPSA did not ask for additional comments on them.

We evaluated all available information regarding the designation criteria in Section 7(f)(l)(A) of USGSA (7 U.S.C. 79(f)) and, according to Section 7(f)(l)(B), determined that California Agri, Frankfort, Indianapolis, and Virginia are able to provide official services in the geographic areas specified in the June 16, 2006, **Federal Register**, for which they applied. You may obtain official services by calling the telephone numbers listed below.

Official agency	Headquarters location and telephone	Designation start—end
California Agri ...	West Sacramento, CA, (916) 375–5809.	1/01/2007–12/31/2009
Frankfort	Frankfort, IN, (765) 258–3624.	1/01/2007–12/31/2009
Indianapolis	Indianapolis, IN, (317) 899–2337.	1/01/2007–12/31/2009
Virginia	Richmond, VA, (757) 494–2464.	1/01/2007–12/31/2009

Authority: 7 U.S.C. 71 *et seq.*

James E. Link,

Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. E6–20906 Filed 12–7–06; 8:45 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Inviting Applications for Rural Business Opportunity Grants

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Business-Cooperative Service (RBS), an Agency within the Rural Development mission area, announces the availability of grants of up to $50,000 per application from the Rural Business Opportunity Grant (RBOG) program for fiscal year (FY) 2007, to be competitively awarded. For multi-State projects, grant funds of up to $150,000 will be available on a competitive basis. The awards are being capped due to limited funding. This notice is being issued prior to passage of a final appropriations bill, which may or may not provide for funding this program, to allow applicants sufficient time to leverage financing, submit applications, and give the Agency time to process applications within the current fiscal year. The Agency will publish a subsequent notice identifying the amount received in the appropriations, if any.

DATES: The deadline for the receipt of non-earmarked applications in the Rural Development State Office is March 30, 2007. If the RBOG appropriation provides earmarks for Native American, Empowerment Zones, Enterprise Communities, and Rural Economic Area Partnerships, then those applications must be received in the Rural Development State Office by January 31, 2007. The Agency reserves the right to extend this application deadline. If no earmark is provided in the appropriations, applications from these applicants will compete in the March 30, 2007, competition. Any applications received at a Rural Development State Office after these dates would not be considered for FY 2007 funding.

FOR FURTHER INFORMATION CONTACT: Cindy Mason, Loan Specialist, USDA Rural Development, STOP 3225, Room 6866, 1400 Independence Avenue, SW., Washington, DC 20250–3225. Telephone: (202) 690–1433.

ADDRESSES: For further information, entities wishing to apply for assistance should contact a Rural Development State Office to receive copies of the application package. Potential applicants located in the District of Columbia must send their applications to the National Office at:

District of Columbia

USDA Rural Development, Specialty Lenders Division, 1400 Independence Avenue, SW., Room 6867, STOP 3225, Washington, DC 20250–3225, (202) 720–1400.

A list of Rural Development State Offices follows:

Alabama

USDA Rural Development State Office, Sterling Centre, Suite 601, 4121 Carmichael Road, Montgomery, AL 36106–3683, (334) 279–3400/TDD (334) 279–3495.

Alaska

USDA Rural Development State Office, 800 West Evergreen, Suite 201, Palmer, AK 99645–6539, (907) 761–7705/TDD (907) 761–8905.

Arizona

USDA Rural Development State Office, 230 N. 1st Ave., Suite 206, Phoenix, AZ 85003, (602) 280–8701/TDD (602) 280–8705.

Arkansas

USDA Rural Development State Office, 700 West Capitol Avenue, Room 3416, Little Rock, AR 72201–3225, (501) 301–3200/TDD (501) 301–3279.

California

USDA Rural Development State Office, 430 G Street, #4169, Davis, CA 95616–4169, (530) 792–5800/TDD (530) 792–5848.

Colorado

USDA Rural Development State Office, 655 Parfet Street, Room E100, Lakewood, CO 80215, (720) 544–2903/TDD (720) 544–2976.

Delaware-Maryland

USDA Rural Development State Office, 1221 College Park Drive, Suite 200, Dover, DE 19904, (302) 857–3580/TDD (302) 857–3585.

Florida/Virgin Islands

USDA Rural Development State Office, 4440 NW 25th Place, P.O. Box 147010, Gainesville, FL 32614–7010, (352) 338–3400/TDD (352) 338–3499.

Georgia

USDA Rural Development State Office, Stephens Federal Building, 355 E. Hancock Avenue, Athens, GA 30601–2768, (706) 546–2162/TDD (706) 546–2034.

Hawaii

USDA Rural Development State Office, Federal Building, Room 311, 154 Waianuenue Avenue, Hilo, HI 96720, (808) 933–8380/TDD (808) 933–8321.

Idaho

USDA Rural Development State Office, 9173 West Barnes Drive, Suite A1, Boise, ID 83709, (208) 378–5600/TDD (208) 378–5644.

Illinois

USDA Rural Development State Office, 2118 W. Park Court, Suite A, Champaign, IL 61821, (217) 403–6200/TDD (217) 403–6240.

Indiana

USDA Rural Development State Office, 5975 Lakeside Boulevard, Indianapolis, IN 46278, (317) 290–3100/TDD (317) 290–3343.

Iowa

USDA Rural Development State Office, Federal Building, Room 873, 210 Walnut Street, Des Moines, IA 50309, (515) 284–4663/TDD (515) 284–4858.

Kansas

USDA Rural Development State Office, 1303 S.W. First American Place, Suite 100, Topeka, KS 66604–4040, (785) 271–2700/TDD (785) 271–2767.

Kentucky

USDA Rural Development State Office, 771 Corporate Drive, Suite 200, Lexington, KY 40503, (859) 224–7300/TDD (859) 224–7422.

Louisiana

USDA Rural Development State Office, 3727 Government Street, Alexandria, LA 71302, (318) 473–7921/TDD (318) 473–7655.

Maine

USDA Rural Development State Office, 967 Illinois Avenue, Suite 4, P.O. Box 405, Bangor, ME 04402–0405, (207) 990–9160/TDD (207) 942–7331.

Massachusetts/Rhode Island/Connecticut

USDA Rural Development State Office, 451 West Street, Suite 2, Amherst, MA 01002–2999, (413) 253–4300/TDD (413) 253–4590.

Michigan

USDA Rural Development State Office, 3001 Coolidge Road, Suite 200, East Lansing, MI 48823, (517) 324–5190/TDD (517) 324–5169,

Minnesota

USDA Rural Development State Office, 375 Jackson Street, Suite 410, St. Paul, MN 55101–1853, (651) 602–7800/TDD (651) 602–3799.

Mississippi

USDA Rural Development State Office, Federal Building, Suite 831, 100 West Capitol Street, Jackson, MS 39269, (601) 965–4316/TDD (601) 965–5850.

Missouri

USDA Rural Development State Office, 601 Business Loop 70 West, Parkade Center, Suite 235, Columbia, MO 65203, (573) 876–0976/TDD (573) 876–9480.

Montana

USDA Rural Development State Office, 900 Technology Boulevard, Suite B, P.O. Box 850, Bozeman, MT 59771, (406) 585–2580/TDD (406) 585–2562.

Nebraska

USDA Rural Development State Office, Federal Building, Room 152, 100 Centennial Mall North, Lincoln, NE 68508, (402) 437–5551/TDD (402) 437–5093.

Nevada

USDA Rural Development State Office, 1390 South Curry Street, Carson City, NV 89703–5146, (775) 887–1222/TDD (775) 885–0633.

New Jersey

USDA Rural Development State Office, 8000 Midlantic Drive, 5th Floor North, Suite 500, Mt. Laurel, NJ 08054, (856) 787–7700/TDD (856) 787–7784.

New Mexico

USDA Rural Development State Office, 6200 Jefferson Street NE, Room 255, Albuquerque, NM 87109, (505) 761–4950/TDD (505) 761–4938.

New York

USDA Rural Development State Office, The Galleries of Syracuse, 441 South Salina Street, Suite 357, Syracuse, NY 13202–2541, (315) 477–6400/TDD (315) 477–6447.

North Carolina

USDA Rural Development State Office, 4405 Bland Road, Suite 260, Raleigh, NC 27609, (919) 873–2000/TDD (919) 873–2003.

North Dakota

USDA Rural Development State Office, Federal Building, Room 208, 220 East Rosser, P.O. Box 1737, Bismarck, ND 58502–1737, (701) 530–2037/TDD (701) 530–2113.

Ohio

USDA Rural Development State Office, Federal Building, Room 507, 200 North High Street, Columbus, OH 43215–2418, (614) 255–2400/TDD (614) 255–2554.

Oklahoma

USDA Rural Development State Office, 100 USDA, Suite 108, Stillwater, OK 74074–2654, (405) 742–1000/TDD (405) 742–1007.

Oregon

USDA Rural Development State Office, 1201 NE Lloyd Blvd., Suite 801, Portland, OR 97232, (503) 414–3300/TDD (503) 414–3387.

Pennsylvania

USDA Rural Development State Office, One Credit Union Place, Suite 330, Harrisburg, PA 17110–2996, (717) 237–2299/TDD (717) 237–2261.

Puerto Rico

USDA Rural Development State Office, IBM Building, Suite 601, 654 Munos Rivera Avenue, San Juan, PR 00918–6106, (787) 766–5095/TDD (787) 766–5332.

South Carolina

USDA Rural Development State Office, Strom Thurmond Federal Building, 1835 Assembly Street, Room 1007, Columbia, SC 29201, (803) 765–5163/TDD (803) 765–5697.

South Dakota

USDA Rural Development State Office, Federal Building, Room 210, 200 Fourth Street, SW., Huron, SD 57350, (605) 352–1100/TDD (605) 352–1147.

Tennessee

USDA Rural Development State Office, 3322 West End Avenue, Suite 300, Nashville, TN 37203–1084, (615) 783–1300.

Texas

USDA Rural Development State Office, Federal Building, Suite 102, 101 South Main, Temple, TX 76501, (254) 742–9700/TDD (254) 742–9712.

Utah

USDA Rural Development State Office, Wallace F. Bennett Federal Building, 125 South State Street, Room 4311, Salt Lake City, UT 84147–0350, (801) 524–4320/TDD (801) 524–3309.

Vermont/New Hampshire

USDA Rural Development State Office, City Center, 3rd Floor, 89 Main Street, Montpelier, VT 05602, (802) 828–6000/TDD (802) 223–6365.

Virginia

USDA Rural Development State Office, 1606 Santa Rosa Road, Suite 238, Richmond, VA 23229–5014, (804) 287–1550/TDD (804) 287–1753.

Washington

USDA Rural Development State Office, 1835 Black Lake Boulevard SW., Suite B, Olympia, WA 98512–5715, (360) 704–7740/TDD (360) 704–7760.

West Virginia

USDA Rural Development State Office, Federal Building, 75 High Street, Room 320, Morgantown, WV 26505–7500, (304) 284–4860/TDD (304) 284–4836.

Wisconsin

USDA Rural Development State Office, 4949 Kirschling Court, Stevens Point, WI 54481, (715) 345–7600/TDD (715) 345–7614.

Wyoming

USDA Rural Development State Office, 100 East B, Federal Building, Room 1005, P.O. Box 11005, Casper, WY 82602–5006, (307) 233–6700/TDD (307) 233–6733.

SUPPLEMENTARY INFORMATION: The RBOG program is authorized under section 306 of the Consolidated Farm and Rural Development Act (CONACT) (7 U.S.C. 1926(a)(11)). The Rural Development State Offices administer the RBOG program on behalf of USDA Rural Development at the State level. The primary objective of the program is to improve the economic conditions of rural areas. Assistance provided to rural areas under this program may include technical assistance for business development and economic development planning. To ensure that a broad range of communities have the opportunity to benefit from the program, no grant will exceed $50,000, unless it is a multi-State project where funds may not exceed $150,000. There is no project dollar amount limitation on applications for earmarked funds. Awards are made on a competitive basis using specific selection criteria contained in 7 CFR part 4284, subpart G. Information required to be in the application package are contained in 7 CFR part 4284, subpart G. The State Director may assign up to 15 discretionary points to an application, and the Agency Administrator may assign up to 20 additional discretionary points for projects funded from the national office reserve. Discretionary points awarded by the State Director or Administrator must be based on geographic distribution of funds, special importance for implementation of a strategic plan in partnership with other organizations, or extraordinary potential for success due to superior project plans or qualifications of the grantee. Applications will be tentatively scored by the State Offices and submitted to the National Office for final review and selection.

The National Office will review the scores based on the grant selection criteria and weights contained in 7 CFR part 4284, subpart G. All applicants will be notified by RBS of the Agency's decision on the awards.

Application Requirements

Applicants are encouraged to submit applications through the Grants.gov Web site at: *http://www.grants.gov.* Applications may be submitted in either electronic or paper format. Users of Grants.gov will be able to download a copy of the application package, complete it off line, and then upload and submit the application via the Grants.gov site. Applications may not be submitted by electronic mail.

- 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. USDA Rural Development strongly recommends that you do not wait until the application deadline date to begin the application process through Grants.gov. To use Grants.gov, applicants must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number which can be obtained at no cost via a toll-free request line at 1–866–705–5711.
- You may submit all documents electronically through the Web site, including all information typically included on the application for RBOGs and all necessary assurances and certifications.
- After electronically submitting an application through the Web site, the applicant will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number.
- USDA Rural Development may request that the applicant provide original signatures on forms at a later date.
- If applicants experience technical difficulties on the closing date and are unable to meet the deadline, you may submit a paper copy of your application to your respective Rural Development State Office. Paper applications submitted to a Rural Development State Office must meet the closing date and local time deadline.

Please note that applicants must locate the downloadable application package for this program by the Catalog of Federal Domestic Assistance Number or FedGrants Funding Opportunity Number, which can be found at *http://www.fedgrants.gov.*

In accordance with the Paperwork Reduction Act of 1995, the information

collection requirement contained in this Notice is approved by the Office of Management and Budget (OMB) under OMB Control Number 0570–0024.

Nondiscrimination Statement

''The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, SW., Washington, DC 20250–9410, or call (800) 795–3272 (voice), or (202) 720–6382 (TDD). ''USDA is an equal opportunity provider, employer, and lender.''

Dated: December 1, 2006.

William F. Hagy III,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. E6–20875 Filed 12–7–06; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Maximum Dollar Amount on Awards Under the Rural Economic Development Loan and Grant Program for Fiscal Year 2007

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Business-Cooperative Service, an Agency within the Rural Development mission area, hereby announces the maximum dollar amount on loan and grant awards under the Rural Economic Development Loan and Grant (REDLG) program for fiscal year (FY) 2007. This notice is being issued prior to passage of a final appropriations bill, which may or may not provide funding for these programs, to allow applicants sufficient time to leverage financing, submit applications, and give the Agency time to process applications within the current fiscal year. The awards made as a result of this notice are effective for loans and grants made during the fiscal year beginning October 1, 2006, and ending September 30, 2007. REDLG loans and grants are available to any electric or telecommunications cooperative (borrower) under the Rural Electrification Act that does not have any delinquent debt with the Federal Government that has not been resolved pursuant to 31 CFR 285.13. REDLG loans and grants are to assist in economically developing rural areas.

FOR FURTHER INFORMATION CONTACT: Todd S. Hubbell, Loan Specialist, USDA Rural Development, STOP 3225, Room 6866, 1400 Independence Avenue, SW., Washington, DC 20250–3225. Telephone: (202) 690–2516, FAX: (202) 720–2213.

ADDRESSES: For further information, entities wishing to apply for assistance should contact a Rural Development State Office to receive further information and copies of the application package. A list of Rural Development State Offices follows:

District of Columbia

USDA Rural Development, Specialty Lenders Division, 1400 Independence Avenue, SW., STOP 3225, Room 6867, Washington, DC 20250–3225, (202) 720–1400.

Alabama

USDA Rural Development State Office, Sterling Centre, Suite 601, 4121 Carmichael Road, Montgomery, AL 36106–3683, (334) 279–3400/TDD (334) 279–3495.

Alaska

USDA Rural Development State Office, 800 West Evergreen, Suite 201, Palmer, AK 99645–6539, (907) 761–7705/TDD (907) 761–8905.

Arizona

USDA Rural Development State Office, 230 N. 1st First Ave., Suite 206, Phoenix, AZ 85003, (602) 280–8701/TDD (602) 280–8705.

Arkansas

USDA Rural Development State Office, 700 West Capitol Avenue, Room 3416, Little Rock, AR 72201–3225, (501) 301–3200/TDD (501) 301–3279.

California

USDA Rural Development State Office, 430 G Street, # 4169, Davis, CA 95616–4169, (530) 792–5800/TDD (530) 792–5848.

Colorado

USDA Rural Development State Office, 655 Parfet Street, Room E100, Lakewood, CO 80215, (720) 544–2903/TDD (720) 544–2976.

Delaware-Maryland

USDA Rural Development State Office, 1221 College Park Drive, Suite 200, Dover, DE 19904, (302) 857–3580/TDD (302) 857–3585.

Florida/Virgin Islands

USDA Rural Development State Office, 4440 NW 25th Place, P.O. Box 147010, Gainesville, FL 32614–7010, (352) 338–3400/TDD (352) 338–3499.

Georgia

USDA Rural Development State Office, Stephens Federal Building, 355 E. Hancock Avenue, Athens, GA 30601–2768, (706) 546–2162/TDD (706) 546–2034.

Hawaii

USDA Rural Development State Office, Federal Building, Room 311, 154 Waianuenue Avenue, Hilo, HI 96720, (808) 933–8380/TDD (808) 933–8321.

Idaho

USDA Rural Development State Office, 9173 West Barnes Dr., Suite A1, Boise, ID 83709, (208) 378–5600/TDD (208) 378–5644.

Illinois

USDA Rural Development State Office, 2118 W. Park Court, Suite A, Champaign, IL 61821, (217) 403–6200/TDD (217) 403–6240.

Indiana

USDA Rural Development State Office, 5975 Lakeside Boulevard, Indianapolis, IN 46278, (317) 290–3100/TDD (317) 290–3343.

Iowa

USDA Rural Development State Office, Federal Building, Room 873, 210 Walnut Street, Des Moines, IA 50309, (515) 284–4663/TDD (515) 284–4858.

Kansas

USDA Rural Development State Office, 1303 S.W. First American Place, Suite 100, Topeka, KS 66604–4040, (785) 271–2700/TDD (785) 271–2767.

Kentucky

USDA Rural Development State Office, 771 Corporate Drive, Suite 200, Lexington, KY 40503, (859) 224–7300/TDD (859) 224–7422.

Louisiana

USDA Rural Development State Office, 3727 Government Street, Alexandria, LA 71302, (318) 473–7921/TDD (318) 473–7655.

Maine

USDA Rural Development State Office, 967 Illinois Avenue, Suite 4, P.O. Box 405, Bangor, ME 04402–0405, (207) 990–9160/TDD (207) 942–7331.

Massachusetts/Rhode Island/ Connecticut

USDA Rural Development State Office, 451 West Street, Suite 2, Amherst, MA 01002–2999, (413) 253–4300/TDD (413) 253–4590.

Michigan

USDA Rural Development State Office, 3001 Coolidge Road, Suite 200, East Lansing, MI 48823, (517) 324–5190/ TDD (517) 324–5169.

Minnesota

USDA Rural Development State Office, 375 Jackson Street, Suite 410, St. Paul, MN 55101–1853, (651) 602–7800/TDD (651) 602–3799.

Mississippi

USDA Rural Development State Office, Federal Building, Suite 831, 100 W. Capitol Street, Jackson, MS 39269, (601) 965–4316/TDD (601) 965–5850.

Missouri

USDA Rural Development State Office, 601 Business Loop 70 West, Parkade Center, Suite 235, Columbia, MO 65203, (573) 876–0976/TDD (573) 876–9480.

Montana

USDA Rural Development State Office, 900 Technology Boulevard, Suite B, P.O. Box 850, Bozeman, MT 59771, (406) 585–2580/TDD (406) 585–2562.

Nebraska

USDA Rural Development State Office, Federal Building, Room 152, 100 Centennial Mall North, Lincoln, NE 68508, (402) 437–5551/TDD (402) 437–5093.

Nevada

USDA Rural Development State Office, 1390 South Curry Street, Carson City, NV 89703–5146, (775) 887–1222/TDD (775) 885–0633.

New Jersey

USDA Rural Development State Office, 8000 Midlantic Drive, 5th Floor North, Suite 500, Mt. Laurel, NJ 08054, (856) 787–7700/TDD (856) 787–7784.

New Mexico

USDA Rural Development State Office, 6200 Jefferson Street, NE, Room 255, Albuquerque, NM 87109, (505) 761–4950/TDD (505) 761–4938.

New York

USDA Rural Development State Office, The Galleries of Syracuse, 441 South Salina Street, Suite 357, Syracuse, NY 13202–2541, (315) 477–6400/TDD (315) 477–6447.

North Carolina

USDA Rural Development State Office, 4405 Bland Road, Suite 260, Raleigh, NC 27609, (919) 873–2000/TDD (919) 873–2003.

North Dakota

USDA Rural Development State Office, Federal Building, Room 208, 220 East Rosser, P.O. Box 1737, Bismarck, ND 58502–1737, (701) 530–2037/TDD (701) 530–2113.

Ohio

USDA Rural Development State Office, Federal Building, Room 507, 200 North High Street, Columbus, OH 43215–2418, (614) 255–2400/TDD (614) 255–2554.

Oklahoma

USDA Rural Development State Office, 100 USDA, Suite 108, Stillwater, OK 74074–2654, (405) 742–1000/TDD (405) 742–1007.

Oregon

USDA Rural Development State Office, 1201 NE Lloyd Blvd., Suite 801, Portland, OR 97232, (503) 414–3300/ TDD (503) 414–3387.

Pennsylvania

USDA Rural Development State Office, One Credit Union Place, Suite 330, Harrisburg, PA 17110–2996, (717) 237–2299/TDD (717) 237–2261.

Puerto Rico

USDA Rural Development State Office, IBM Building, Suite 601, 654 Munos Rivera Avenue, San Juan, PR 00918–6106, (787) 766–5095/TDD (787) 766–5332.

South Carolina

USDA Rural Development State Office, Strom Thurmond Federal Building, 1835 Assembly Street, Room 1007, Columbia, SC 29201, (803) 765–5163/ TDD (803) 765–5697.

South Dakota

USDA Rural Development State Office, Federal Building, Room 210, 200 Fourth Street, SW., Huron, SD 57350, (605) 352–1100/TDD (605) 352–1147.

Tennessee

USDA Rural Development State Office, 3322 West End Avenue, Suite 300, Nashville, TN 37203–1084, (615) 783–1300.

Texas

USDA Rural Development State Office, Federal Building, Suite 102, 101 South Main, Temple, TX 76501, (254) 742–9700/TDD (254) 742–9712.

Utah

USDA Rural Development State Office, Wallace F. Bennett Federal Building, 125 South State Street, Room 4311, Salt Lake City, UT 84147–0350, (801) 524–4320/TDD (801) 524–3309.

Vermont/New Hampshire

USDA Rural Development State Office, City Center, 3rd Floor, 89 Main Street, Montpelier, VT 05602, (802) 828–6000/TDD (802) 223–6365.

Virginia

USDA Rural Development State Office, 1606 Santa Rosa Road, Suite 238, Richmond, VA 23229–5014, (804) 287–1550/TDD (804) 287–1753.

Washington

USDA Rural Development State Office, 1835 Black Lake Boulevard SW., Suite B, Olympia, WA 98512–5715, (360) 704–7740/TDD (360) 704–7760.

West Virginia

USDA Rural Development State Office, Federal Building, 75 High Street, Room 320, Morgantown, WV 26505–7500, (304) 284–4860/TDD (304) 284–4836.

Wisconsin

USDA Rural Development State Office, 4949 Kirschling Court, Stevens Point, WI 54481, (715) 345–7600/TDD (715) 345–7614.

Wyoming

USDA Rural Development State Office, 100 East B, Federal Building, Room 1005, P.O. Box 11005, Casper, WY 82602–5006, (307) 233–6700/TDD (307) 233–6733.

SUPPLEMENTARY INFORMATION: The Regulations for these programs are at 7 CFR part 1703, subpart B. The maximum loan and grant awards are determined in accordance with 7 CFR 1703.28. The maximum loan and grant awards are calculated at 3.0 percent of the projected program levels, rounded to the nearest $10,000; however, as specified in 7 CFR 1703.28(b), regardless of the projected total amount that will be available, the maximum size may not be lower than $200,000. The projected program level during FY 2007 for zero-interest loans is $34,652,000, and the projected level for grants is $10,000,000. Applying the 3.0 percent to the program level for loans, rounded to the nearest $10,000, results in a

projected maximum loan award of $1,040,000. Applying the specified 3.0 percent to the program level for grants results in an amount higher than $200,000. Therefore, the projected grant award for FY 2007 is $300,000. This notice will be amended should funding in excess of the projected levels be received.

Nondiscrimination Statement

''The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).''

To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, SW., Washington, DC 20250–9410, or call (800) 795–3272 (voice), or (202) 720–6382 (TDD). ''USDA is an equal opportunity provider, employer, and lender.''

Dated: December 1, 2006.

William F. Hagy III,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. E6–20871 Filed 12–7–06; 8:45 am]

BILLING CODE 3410–XY–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase from People Who are Blind or Severely Disabled.

ACTION: Deletions from Procurement List.

SUMMARY: This action deletes from the Procurement List products previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* January 7, 2007.

ADDRESS: Committee for Purchase From People Who are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

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

SUPPLEMENTARY INFORMATION:

Deletions

On October 13, 2006, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (71 FR 60471) of proposed deletions to the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action may result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

PRODUCT/NSN: Computer Accessories.
NSN: 7045–01–483–7843—Visionguard Plus Anti-Glare Screen.
NSN: 7045–01–483–7836—Quick Keyboard Drawer.
NSN: 7045–01–483–7449—Disk File 100 for 3½'' Disks.
NSN: 7045–01–483–7839—Ergo Gel Keyboard Drawer.
NPA: Wiscraft Inc.—Wisconsin Enterprises for the Blind, Milwaukee, WI.
Contracting Activity: Office Supplies & Paper Products Acquisition Ctr, New York, NY.

PRODUCT/NSN: Drape, Surgical.
NSN: 6530–00–299–9604—Drape, Surgical.
NSN: 6530–00–299–9605—Drape, Surgical.
NSN: 6530–00–299–9607—Drape, Surgical.
NSN: 6530–00–299–9608—Drape, Surgical.
NPA: In-Sight, Warwick, RI.
NPA: Alabama Industries for the Blind, Talladega, AL.
NPA: Mississippi Industries for the Blind, Jackson, MS.
Contracting Activity: Defense Supply Center Philadelphia, Philadelphia, PA.

PRODUCT/NSN: Kit, Suture Removal.
NSN: 6515–01–443–0976—Kit, Suture Removal.
NPA: Washington-Greene County Branch, PAB, Washington, PA.
Contracting Activity: Veterans Affairs National Acquisition Center, Hines, IL.

PRODUCT/NSN: Mask, Surgical.
NSN: 6515–00–982–7493—Mask, Surgical.
NPA: Industries of the Blind, Inc., Greensboro, NC.
NPA: Susquehanna Association for the Blind and Visually Impaired, Lancaster, PA.
NPA: Washington-Greene County Branch, PAB, Washington, PA.
Contracting Activity: Defense Supply Center Philadelphia, Philadelphia, PA.
Contracting Activity: Veterans Affairs National Acquisition Center, Hines, IL.

PRODUCT/NSN: Mat, Floor.
NSN: 7220–00–205–3192—Mat, Floor (For Chairs), 36'x48'.
NSN: 7220–00–205–3182—Mat, Floor (For Chairs), 49'x55'.
NPA: Northeastern Michigan Rehabilitation and Opportunity Center (NEMROC), Alpena, MI.
Contracting Activity: GSA, Southwest Supply Center, Fort Worth, TX.

PRODUCT/NSN: Tape, Electronic Data Processing.
NSN: 7045–01–293–4809—Tape, Electronic Data Processing.
NPA: North Central Sight Services, Inc., Williamsport, PA.
Contracting Activity: Defense Supply Center Columbus, Columbus, OH.

PRODUCT/NSN: Thumbtacks, Maptacks and Pushpins.
NSN: 7510–00–285–5844—Maptacks, Assorted Colors.
NSN: 7510–00–272–3099—Maptacks, White.
NPA: Delaware County Chapter, NYSARC, Inc., Walton, NY.
Contracting Activity: Office Supplies & Paper Products Acquisition Ctr, New York, NY.

PRODUCT/NSN: Tracheotomy Care Kit.
NSN: 6515–01–447–1720—Tracheotomy Care Kit.
NPA: Washington-Greene County Branch, PAB, Washington, PA.
Contracting Activity: Veterans Affairs National Acquisition Center, Hines, IL.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. E6–20879 Filed 12–7–06; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

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

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee is proposing to add to the Procurement List services

to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must Be Received On Or Before: January 14, 2007.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

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

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

If the Committee approves the proposed additions, the entities of the Federal Government identified in the notice for each service will be required to procure the services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Services

Service Type/Location: Custodial Services, 10 W. Jackson Boulevard and 18 W. Jackson, Chicago, IL.
NPA: Bona Fide Conglomerate, Inc., Lakeside, CA.
Contracting Activity: GSA, Public Buildings Service, Region 5, Chicago, IL.
Service Type/Location: Custodial Services, Coast Guard Housing Office, 227 S. Oakwood, Novato, CA.
NPA: North Bay Rehabilitation Services, Inc., Rohnert Park, CA.
Contracting Activity: U.S. Coast Guard—Alameda, Alameda, CA.
Service Type/Location: Facilities Maintenance, Dryden Flight Research Center, Edwards, CA.
NPA: PRIDE Industries, Inc., Roseville, CA.
Contracting Activity: NASA-Dryden Flight Research Center, Edwards, CA.
Service Type/Location: Patient Escort Service, Veterans Affairs Medical Center, 1055 Clermont Drive, Denver, CO.
NPA: Bayaud Industries, Inc., Denver, CO.
Contracting Activity: VISN 19 Eastern Colorado Health Care System, Denver, CO.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. E6–20880 Filed 12–7–06; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Steller Sea Lion Protection Economic Survey.

Form Number(s): None.

OMB Approval Number: None.

Type of Request: Regular submission.

Burden Hours: 1,373.

Number of Respondents: 3,325.

Average Hours per Response: Mail survey, 30 minutes; follow-up telephone survey, 6 minutes.

Needs and Uses: The objective of the survey is to collect data for measuring the preferences, and economic values, that U.S. residents have for protecting Steller sea lions, a listed species under the Endangered Species Act. These preferences are currently not known, but are needed for decision makers to more fully understand the trade-offs involved in choosing among protection alternatives and to complement other information available about the costs, benefits, and impacts of Steller sea lion protection alternatives. The data collection consists of conducting a mail survey of U.S. households.

Affected Public: Individuals or households.

Frequency: One-time only.

Respondent's Obligation: Voluntary.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, FAX number (202) 395–7285, or *David_Rostker@omb.eop.gov*.

Dated: December 4, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–20793 Filed 12–7–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Evaluation of the NOAA Coastal Management Fellowship Program.

Form Number(s): None.

OMB Approval Number: None.

Type of Request: Regular submission.

Burden Hours: 75.

Number of Respondents: 127.

Average Hours per Response: Current and past fellow surveys, 35 minutes; current and past mentor surveys, 40 minutes; and Coastal Services Center Partners and Sea Grant Director surveys, 25 minutes.

Needs and Uses: The NOAA National Ocean Service Coastal Services Center will conduct an evaluation of the NOAA Coastal Management Fellowship Program. The evaluation is designed to assess the effectiveness of the fellowship program. Respondents include: Current and past fellows, current and past state coastal zone management program mentors, and Center partners. The results of the evaluation will allow the Center to identify aspects of the program that enhance state coastal zone management

programs and determine how the fellowship impacts a fellow's professional experiences.

Affected Public: Individuals or households; not-for-profit institutions.

Frequency: One-time only.

Respondent's Obligation: Voluntary.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, FAX number (202) 395–7285, or *David_Rostker@omb.eop.gov*.

Dated: December 4, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–20794 Filed 12–7–06; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Southeast Region Logbook Family of Forms.

Form Number(s): None.

OMB Approval Number: 0648–0016.

Type of Request: Regular submission.

Burden Hours: 18,714.

Number of Respondents: 7,389.

Average Hours per Response: Annual fixed-cost reports, 30 minutes; economic cost per trip reports, 10 minutes; headboat and Colombian fishery logbooks, 18 minutes; golden crab, reef fish-mackerel, wreckfish and shrimp logbooks, 10 minutes; live rock and discard logbooks, 18 minutes; no-fishing responses for golden crab, reef fish-makerel and Colombian fisheries, 2 minutes.

Needs and Uses: The catch and effort data are needed for scientific analyses that support critical conservation and management decisions that are made by national and international fishery management agencies. In addition, biologist need data on the amount of fish, marine mammals, and sea turtles are caught or interacted with. This family of forms also includes the collection of cost-earning information and discards reported by fishermen.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: Annually and by trip.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, FAX number (202) 395–7285, or *David_Rostker@omb.eop.gov*.

Dated: December 4, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–20795 Filed 12–7–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 061130319–6319–01]

Annual Surveys in the Manufacturing Area

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of determination.

SUMMARY: The Bureau of the Census (Census Bureau) is conducting the 2006 Annual Surveys in the Manufacturing Area. The 2006 Annual Surveys consist of the Current Industrial Reports surveys, the Annual Survey of Manufactures, the Survey of Industrial Research and Development, the Survey of Plant Capacity Utilization, and the Survey of Pollution Abatement Costs and Expenditures. We have determined that annual data collected from these surveys are needed to aid the efficient performance of essential governmental functions and have significant application to the needs of the public and industry. The data derived from these surveys, most of which have been conducted for many years, are not publicly available from non-governmental or other governmental sources.

ADDRESSES: The Census Bureau will furnish report forms to organizations included in the survey. Additional copies are available upon written request to the Director, U.S. Census Bureau, Washington, DC 20233–0101.

FOR FURTHER INFORMATION CONTACT: Thomas E. Zabelsky, Chief, Manufacturing and Construction Division, at (301) 763–4598.

SUPPLEMENTARY INFORMATION: The Census Bureau may conduct surveys necessary to furnish current data on the subjects covered by the major censuses, as authorized by Title 13, United States Code, Sections 61, 81, 131, 182, 193, 224, and 225.

These surveys will provide continuing and timely national statistical data on manufacturing for the period between economic censuses. The next economic censuses will be conducted for the year 2007. The data collected in these surveys will be within the general scope and nature of those inquiries covered in the economic censuses.

Current Industrial Reports

Most of the following commodity or product surveys provide data on shipments or production, stocks, unfilled orders, orders booked, consumption, etc. Reports will be required of all, or a sample of, establishments engaged in the production of the items covered by the following list of surveys:

	SURVEY TITLE
MA314Q ...	Carpets and Rugs.
MA321T	Lumber Production and Mill Stocks.
MA325F	Paint and Allied Products.
MA325G ...	Pharmaceutical Preparations, except Biologicals.
MA327C	Refractories.
MA327E	Consumer, Scientific, Technical, and Industrial Glassware.
MA331B	Steel Mill Products.
MA332Q ...	Antifriction Bearings.
MA333A	Farm Machinery and Lawn and Garden Equipment.
MA333D	Construction Machinery.
MA333F	Mining Machinery and Mineral Processing Equipment.
MA333M ...	Refrigeration, Air-conditioning, and Warm Air Equipment.
MA333P	Pumps and Compressors.
MA334A	Electromedical Equipment and Analytical Instruments.
MA334C	Control Instruments.
MA334D	Defense, Navigational and Aerospace Electronics.
MA334M ...	Consumer Electronics.

SURVEY TITLE—Continued

MA334Q ...	Semiconductors, Electronic Components, and Semiconductor Manufacturing Equipment.
MA334T	Meters and Test Devices.
MA335E	Electric Housewares and Fans.
MA335F	Major Household Appliances.
MA335J	Insulated Wire and Cable.
MA335K	Wiring Devices and Supplies.

The following list of surveys represent annual counterparts of monthly and quarterly surveys and will cover only those establishments that are not canvassed, or do not report, in the more frequent surveys. Accordingly, there will be no duplication in reporting. The content of these annual reports (listed below) will be identical with that of the monthly and quarterly reports:

SURVEY TITLE

M311H	Animal and Vegetable Fats and Oils (Stocks).
M311J	Oilseeds, Beans, and Nuts (Primary Producers).
M311L	Fats and Oils (Renderers).
M311M	Animal and Vegetable Fats and Oils (Consumption and Stocks).
M311N	Animal and Vegetable Fats and Oils (Production, Consumption, and Stock).
M313P	Consumption on the Cotton System.
M313N	Cotton and Raw Linters in Public Storage.
M327G	Glass Containers.
M336G	Civil Aircraft and Aircraft Engines.
MQ311A	Flour Milling Products.
MQ313A	Textiles.
MQ315A	Apparel.
MQ315B	Socks.
MQ325A	Inorganic Chemicals.
MQ325B	Fertilizer Materials.
MQ327D	Clay Construction Products.
MQ333W	Metalworking Machinery.
MQ334P	Telecommunications.
MQ334R	Computers and Peripheral Equipment.
MQ335C	Fluorescent Lamp Ballasts.

Annual Survey of Manufactures

The Annual Survey of Manufactures collects industry statistics, such as total value of shipments, employment, payroll, workers' hours, capital expenditures, cost of materials consumed, supplemental labor costs, and so forth. This survey, conducted on a sample basis, covers all manufacturing industries, including data on plants under construction but not yet in operation.

Survey of Industrial Research and Development

The Survey of Industrial Research and Development measures spending on research and development activities in private U.S. businesses. The Census Bureau collects and compiles this information in accordance with a joint project agreement between the National Science Foundation (NSF) and the Census Bureau. The NSF publishes the results in its publication series. Five data items in the survey provide interim statistics to those collected in the Census Bureau's economic censuses. These items (total company sales, total employment, total expenditures for research and development conducted within the company, federally-funded expenditures for research and development conducted within the company, and total expenditures and federally-funded expenditures for research and development within the company by state) are collected on a mandatory basis under the authority of Title 13, United States Code. Responses to all other data collected are voluntary.

Survey of Plant Capacity Utilization

The Survey of Plant Capacity Utilization is designed to measure the use of industrial capacity. The survey collects information on actual output and estimates of potential output in terms of value of production. These data are the basis for calculating rates of utilization of full production capability and use of production capability under national emergency conditions.

Survey of Pollution Abatement Costs and Expenditures

Under a joint project agreement with the Environmental Protection Agency (EPA), the Survey of Pollution Abatement Costs and Expenditures is designed to collect from establishments in manufacturing, mining, and electric utilities industries the total expenditures by industry and geographic area to abate pollutant emissions. The survey covers current operating costs and capital expenditures to abate air and water pollution and solid waste. The survey also obtains the costs recovered from abatement activities.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a current, valid Office of Management and Budget (OMB) control number. In accordance with the PRA, 44 U.S.C., Chapter 35, the OMB approved the 2006 Annual Surveys under the following OMB control numbers: Current Industrial Reports—0607–0392, 0607–0395, and 0607–0476; Annual Survey of Manufactures—0607–0449; Survey of Industrial Research and Development—0607–0912; Survey of Plant Capacity Utilization—0607–0175, and Survey of Pollution Abatement Costs and Expenditures—0607–0176.

Based upon the foregoing, I have directed that the Annual Surveys in the Manufacturing Area be conducted for the purpose of collecting these data.

Dated: December 5, 2006.

Charles Louis Kincannon,

Director, Bureau of the Census.

[FR Doc. E6–20870 Filed 12–7–06; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

Government Trade Information Request

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burdens, invites the general public and other Federal agencies to take this opportunity to comment on the continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before February 6, 2007.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 1401 Constitution Ave., NW., Washington, DC 20230, or e-mail *dHynek@doc.gov.*

FOR FURTHER INFORMATION CONTACT: Request for additional information or copies of the information collection instrument and instructions should be directed to: Jessica Sanderson, The Advocacy Center, Room 3814A, Department of Commerce, 1401 Constitution Ave., NW., Washington, DC 20230; Phone number: (202) 482–2429, and fax number: (202) 482–3508.

SUPPLEMENTARY INFORMATION:

I. Abstract

The U.S. Department of Commerce invites the general public and other Federal Agencies to comment on the

proposed extension of the use of the U.S. Government (USG) Trade Information Request Form by the Trade Promotion Coordination Committee's (TPCC) Advocacy Network. The form is used to evaluate requests for USG advocacy in connection with overseas commercial bids, offers, and proposals directed at foreign governments. The International Trade Administration's (ITA) Advocacy Center marshals federal resources to assist U.S. commercial interests competing for foreign government commercial projects, procurements, investments, and business ventures worldwide. The mission of the Advocacy Center is to coordinate USG commercial advocacy in order to promote U.S. exports and trade, which both creates and sustains U.S. employment. The Advocacy Center works with and coordinates activities within the TPCC, which is chaired by the Secretary of Commerce and includes 19 federal agencies involved in export promotion.

The purpose of the Trade Information Request is to collect the information necessary to evaluate whether it would be in the U.S. national interest to provide advocacy on a specific case. USG advocacy guidelines exist to assist USG personnel in determining whether and to what extent USG advocacy is appropriate in connection with a transaction involving U.S. interests. The Trade Information Request Form was developed to collect only the information necessary to help the USG make a national interest determination consistent with the advocacy guidelines. The Advocacy Center, appropriate ITA officials, U.S. Embassy/Consulate officials worldwide, and other federal government agencies (the Advocacy Network) that provide advocacy support, will require firms seeking USG advocacy support to complete the request.

II. Method of Collection

When U.S. commercial interests request USG advocacy assistance, they are either sent Form ITA–4136P or referred to the Advocacy Center's Web site from which Form ITA–4136P may be downloaded, completed, signed, and filed.

III. Data

OMB Number: 0625–0238.
Form Number: ITA–4136P.
Type of Review: Regular Submission.
Affected Public: Commercial Interests seeking USG advocacy.
Estimated Number of Respondents: 200.
Estimated Time per Response: 30 minutes.
Estimated Total Annual Burden Hours: 205.
Estimated Total Annual Costs: $15,300.00 ($9,175.00 for respondents and $6,125.00 for federal government).

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 costs) 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 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: December 5, 2006.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–20881 Filed 12–7–06; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

International Trade Administration

Internet Export Finance Matchmaker; Proposed Collection; Comment Request

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burdens, invites the general public and other Federal agencies to take this opportunity to comment on the continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before February 6, 2007.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 1401 Constitution Ave., NW., Washington, DC 20230, or e-mail *dHynek@doc.gov.*

FOR FURTHER INFORMATION CONTACT: Request for additional information or copies of the information collection instrument and instructions should be directed to: Jessica Sanderson, The Advocacy Center, Room 3814A, Department of Commerce, 1401 Constitution Ave., NW., Washington, DC 20230; Phone number: (202) 482–2429, and fax number; (202) 482–3508.

SUPPLEMENTARY INFORMATION:

I. Abstract

The U.S. Department of Commerce invites the general public and other Federal agencies to comment on the proposed extension of the use of the Internet Export Finance Matchmaker. The program is used to assist U.S. firms in identifying trade finance opportunities and promoting the competitiveness of U.S. financial services in international trade. The mission of the International Trade Administration (ITA) is to coordinate U.S. Government (USG) commercial advocacy in order to promote U.S. exports and trade, which both creates and sustains U.S. employment. The ITA interacts with private financial institutions in insurance, banking, leasing, factoring, bartering, and counter-trade; U.S. financing agencies, such as the Export-Import Bank and the Overseas Private Investment Corporation; multilateral development banks, such as the World Bank, Asian Development Bank, and others.

To facilitate contact between exporters and financial institutions, the Office of Finance has developed an interactive Internet trade finance matchmaking program to link exporters seeking trade finance with banks and other financial institutions. The information collected from financial institutions regarding the trade finance products and services they offer is compiled into a database. An exporter is able to electronically submit a one-page form identifying the potential export transaction and type of financing requested. This information is electronically matched with the financial institution(s) that meet the requirements of the exporter. After a match has been made, a message is electronically sent to both the exporter and the financial institution containing information about the match, and contact information for either party to initiate communication. This program is designed to implement the Department of Commerce's goal of improving access to trade financing for small business exporters.

II. Method of Collection

Electronic submission to the International Trade Administration.

III. Data

OMB Number: 0625–0232.
Form Number: ITA–4146P.
Type of Review: Regular Submission.
Affected Public: Business or other For-Profit Organizations.
Estimated Number of Respondents: 500.
Estimated Time per Response: Exporters: 10 Minutes.
Financial Institutions: 30 Minutes.
Estimated Total Annual Burden Hours: 90.
Estimated Total Annual Costs: $3,150.

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 costs) 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 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: December 5, 2006.

Madeleine Clayton,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–20883 Filed 12–7–06; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

International Trade Administration

Export Trade Certificate of Review

ACTION: Notice of Application to Amend an Export Trade Certificate of Review.

SUMMARY: Export Trading Company Affairs (''ETCA''), International Trade Administration, Department of Commerce, has received an application to amend an Export Trade Certificate of Review (''Certificate''). This notice summarizes the proposed amendment and requests comments relevant to whether the Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Jeffrey Anspacher, Director, Export Trading Company Affairs, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or e-mail at *oetca@ita.doc.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from state and federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Export Trading Company Act of 1982 and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register** identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether an amended Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked privileged or confidential business information will be deemed to be nonconfidential. An original and five (5) copies, plus two (2) copies of the nonconfidential version, should be submitted no later than 20 days after the date of this notice to: Export Trading Company Affairs, International Trade Administration, U.S. Department of Commerce, Room 7021–B H, Washington, DC 20230. Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the Certificate. Comments should refer to this application as ''Export Trade Certificate of Review, application number 05–2A001.'' A summary of the application for an amendment follows.

Summary of the Application

Applicant: Central America Poultry Export Quota, Inc. (''CA–PEQ''), 901 New York Avenue, NW., Third Floor, Washington, DC 20001–4413.

Contact: Kyd D. Brenner, Partner, DTB Associates, LLP, Telephone: (202) 661–7098.

Application No.: 05–2A001.
Date Deemed Submitted: November 28, 2006.

The original CA–PEQ Certificate was issued on January 30, 2006 (71 FR 6753, February 9, 2006) and last amended on July 11, 2006 (71 FR 40076, July 14, 2006).

Proposed Amendment

1. CA–PEQ seeks to amend the Export Trade Activities and Methods of Operation section of its certificate at part 2 (Implementation), F (Contents of Bid), first sentence, (ii) *from:* the quantity of poultry bid, in an amount that is a multiple of 25 metric tons *to:* the quantity of poultry bid, with a minimum bid of one metric ton.

2. CA–PEQ seeks to allow for the public disclosure of the following two additional pieces of information regarding the result of its public tender process: (a) The average bid price for all successful bids; and (b) the names of the successful bidders. This change would be reflected by amending the Export Trade Activities and Methods of Operation section of its certificate at part 2 (Implementation), H (Confidentiality of Information) *from:* The Administrator shall treat all bids and their contents as confidential. The Administrator shall disclose any such information only to another neutral third party or authorized government official of the United States, El Salvador, Guatemala, Honduras or Nicaragua, signatories to the DR–CAFTA, and only where necessary to ensure the effective operation of the TRQ System or where required by law (including appropriate disclosure in connection with the arbitration of a dispute). However, after the issuance of all TRQ Certificates from an open-tender process, the Administrator shall notify all bidders and shall disclose publicly (i) the total tonnage for which TRQ Certificates were awarded, and (ii) the lowest price per metric ton of all successful bids *to:* The Administrator shall treat all bids and their contents as confidential. The Administrator shall disclose any such information only to another neutral third party or authorized government official of the United States, El Salvador, Guatemala, Honduras or Nicaragua, signatories to the DR–CAFTA, and only where necessary to ensure the effective operation of the TRQ System or where required by law (including appropriate disclosure in connection with the arbitration of a dispute). However, after close of each open-tender process the Administrator shall notify all bidders and shall disclose publicly (i) the total tonnage for which TRQ certificates were awarded, (ii) the lowest price per metric

ton of all successful bids, (iii) the average price per metric tons for all successful bids, and (iv) the names of the winning bidders.

Dated: December 4, 2006.

Jeffrey Anspacher,

Director, Export Trading Company Affairs.

[FR Doc. E6–20904 Filed 12–7–06; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Regional Economic Data Collection Program for Gulf Coast Alaska

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before February 6, 2007.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Chang Seung, (206) 526–4250 or *Chang.Seung@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The regional or community economic analysis of proposed fishery management policies is required by the Magnuson-Stevens Fishery Conservation and Management Act (MSA), National Environmental Policy Act (NEPA), and Executive Order 12866, among others. To satisfy these mandates and inform policymakers and the public of the likely regional economic impacts associated with fishery management policies, appropriate economic models and the data to implement these models are needed.

Much of the data required for regional economic analysis associated with Gulf Coast Alaska fisheries are either unavailable or unreliable. The accurate fishery-level data on employment, labor income, and expenditures in the Gulf Coast Alaska fishery and related industries are not currently available but are needed to estimate the effects of fisheries on the economy of Gulf Coast Alaska. In this survey effort, data on these important regional economic variables will be collected and used to develop models that will provide more reliable estimates and significantly improve policy-makers' ability to assess policy effects on fishery-dependent communities in Gulf Coast Alaska. The survey will be a one-time survey.

Mail surveys will be used to collect data on employment and labor income from a random sample of 530 vessel owners whose boats delivered fish to Gulf Coast Alaska processors. In-person interviews and telephone calls (130) with businesses involved in the fishery and related industries will be used to obtain (a) Vessel expenditure/cost data; (b) regional economic data for non-fishery industries; and (c) regional economic data for the fish processing sector.

II. Method of Collection

Mail surveys, in-person interviews, and telephone surveys will be used as described above.

III. Data

OMB Number: None.

Form Number: None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 660.

Estimated Time per Response: Mail survey: 10 minutes; phone call or local interview with fish processors: 30 minutes; phone calls with local small businesses: 10 minutes.

Estimated Total Annual Burden Hours: 132 hours.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: December 4. 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–20802 Filed 12–7–06; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Confidential Conflict of Interest Disclosure for Prospective Non-Federal Government Peer Reviewers of Government Science Documents

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Department of 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 February 6, 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 e-mail at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Tom Gleason, (301) 713–2367 x 158, *Tom.Gleason@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Office of Management and Budget (OMB) issued government-wide guidance to enhance the practice of peer review of government science documents. OMB's Final Information Quality Bulletin for Peer Review (''Peer Review Bulletin'' or PRB) (available at

http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf) establishes minimum peer review standards for influential scientific information that Federal agencies intend to disseminate. The Peer Review Bulletin also directs Federal agencies to adopt or adapt the National Academy of Sciences (NAS) policy for evaluating conflicts of interest when selecting peer reviewers who are not Federal government employees (federal employees are subject to Federal ethics requirements). For peer review purposes, the term ''conflicts of interest'' means any financial or other interest which conflicts with the service of the individual because it could: (1) Significantly impair the individual's objectivity; or (2) create an unfair competitive advantage for any person or organization.

NOAA has adapted the NAS policy and developed two confidential conflict disclosure forms which the agency will use to examine prospective reviewers' potential financial conflicts and other interests that could impair objectivity or create an unfair advantage. One form is for peer reviewers of studies related to government regulation and the other form is for all other influential scientific information subject to the Peer Review Bulletin. The forms include questions about employment as well as investment and property interests and research funding. Both forms also require the submission of *curriculum vitae.*

NOAA is seeking to collect this information from potential peer reviewers who are not government employees when conducting a peer review pursuant to the PRB. The number of peer reviews conducted pursuant to the PRB each year will vary, but for illustrative purposes, NOAA currently has thirty-nine peer review plans posted on the Department of Commerce Peer Review Agenda, indicating that for a six-month period in FY 2006, thirty-nine agency reports had recently been completed, were presently undergoing, or were planning to begin peer review. The information collected in the conflict of interest disclosure is essential to NOAA's compliance with the OMB PRB, and helps to ensure that government studies are reviewed by independent, impartial peer reviewers.

II. Method of Collection

Forms may be downloaded from the Internet and are fillable and signable electronically or manually. They may be submitted, along with the Curriculum Vitae, via e-mail or regular mail.

III. Data

OMB Number: None.
Form Number: None.
Type of Review: Regular submission.
Affected Public: Individuals or households.
Estimated Number of Respondents: 300.
Estimated Time per Response: 30 minutes.
Estimated Total Annual Burden Hours: 150.
Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: December 5, 2006.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E6–20882 Filed 12–7–06; 8:45 am]

BILLING CODE 3510–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 101706E]

Incidental Takes of Marine Mammals During Specified Activities; Black Abalone Research Surveys at San Nicolas Island, Ventura County, CA

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA) regulations, notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to Dr. Glenn VanBlaricom (Dr. VanBlaricom) for the take of marine mammals, by Level B harassment only, incidental to the assessment of black abalone populations at San Nicolas Island (SNI), CA.

DATES: Effective from December 1, 2006, through November 30, 2007.

ADDRESSES: A copy of the IHA and the application are available by writing to Michael Payne, Chief, Permits, Conservation, and Education Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3225, or by telephoning the contact listed here. A copy of the application containing a list of references used in this document may be obtained by writing to this address, by telephoning the contact listed here (**FOR FURTHER INFORMATION CONTACT**) or online at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm*. Documents cited in this notice may be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Jolie Harrison, Office of Protected Resources, NMFS, (301) 713–2289, ext. 166.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses, and that the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''...an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by

which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as:

any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Section 101(a)(5)(D) establishes a 45–day time limit for NMFS review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

Summary of Request

On August 10, 2006, NMFS received a letter from Dr. VanBlaricom, of the Washington Cooperative Fish and Wildlife Research Unit, requesting renewal of an IHA that was first issued to him on September 23, 2003 (68 FR 57427, October 3, 2003), and was last reissued on November 30, 2005 (70 FR 73732, December 13, 2005). The proposed 2006/2007 IHA was published, and comments solicited, on October 23, 2006 (71 FR 62087). This final IHA will authorize the take, by harassment, of small numbers of California sea lions (*Zalophus californianus*), Pacific harbor seals (*Phoca vitulina*), and northern elephant seals (*Mirounga angustirostris*) incidental to research surveys performed for the purpose of assessing trends in black abalone (*Haliotis cracherodii*) populations at SNI, Ventura County, California. The research consists of 2 researchers, on foot, counting abalone at nine permanent sites (1 m2 each) on SNI twice a year, with one brief additional visit to each site for maintenance.

Population trend data for black abalone populations have become important in a conservation context because of: (a) the reintroduction of sea otters to SNI in 1987, raising the possibility of conflict between otter conservation and abalone populations (abalones are often significant prey for sea otters); (b) the appearance of a novel exotic disease, abalone withering syndrome, at SNI in 1992, resulting in dramatically increased rates of abalone mortality at the Island; and, (c) the recent designation of California populations of black abalones as a species of concern in the context of listing pursuant to the Endangered Species Act (ESA). Research is done under the auspices of the Washington Cooperative Fish and Wildlife Research Unit, the University of Washington, and the U.S. Navy (owner of SNI), with additional logistical support from the University of California, Santa Cruz. Since the abalone are not handled or removed in the course of the research, neither a state nor federal permit is needed.

Additional information on the research is contained in the application and is available upon request (see **ADDRESSES**).

Project Description

Nine permanent abalone research study areas are located in rocky intertidal habitats on SNI in Ventura County, CA. The applicant has made 106 separate field trips to SNI from September 1979 through March 2006, participating in abalone survey work on 564 different days at nine permanent study sites. Under the 2005/2006 authorization, Dr. VanBlaricom made five different visits and conducted work for 30 total days in the one year period.

Quantitative abalone surveys on SNI began in 1981, at which point permanent research sites were chosen based on the presence of dense patches of abalone in order to monitor changes over time in dense abalone aggregations. Research is conducted by counting black abalone in plots of 1 m2 (3.3 ft2) along permanent transect lines in rocky intertidal habitats at each of the nine study sites on the island. Permanent transect lines are demarcated by stainless steel eyebolts embedded in the rock substrata and secured with marine epoxy compound. Lines are placed temporarily between bolts during surveys and are removed once surveys are completed. Survey work is done by two field biologists working on foot (sites are accessed by hiking to water from vehicle parked inland) and monitoring of black abalone populations at SNI can be done only during periods of extreme low tides. The exact date of a visit to any given site is difficult to predict because variation in surf height and sea conditions can influence the safety of field biologists as well as the quality of data collected. In most years survey work is done during the months of January, February, March, July, November, and December because of optimal availability of low tides. All work is done during daylight hours due to of safety considerations.

During the year, each of the nine permanent study sites at SNI will be visited three times. Abalone surveys, which take no more than 4 hours at each site, are conducted during two of the three visits to each of the nine sites. The third, and final, visit is a maintenance visit, which takes less than half of an hour at each site and is used to take measurements and make necessary repairs to plots and is conducted in a month when smaller numbers of pinnipeds are present.

The affected marine mammal populations at SNI, especially California sea lions and northern elephant seals, have grown substantially since the beginning of abalone research in 1979 and have occupied an expanded distribution on the island due to population growth. Sites previously accessible with no risk of marine mammal harassment are now being utilized by marine mammals at levels such that approach without the possibility of harassment is difficult. An IHA is warranted for this study because of the nine study sites used for the abalone surveys, only two sites can be occupied without the possibility of disturbing at least one species of pinniped.

Description of Habitat and Marine Mammals in the Activity Area

San Nicolas is one of the eight Channel Islands, located in the Santa Barbara Channel off Southern California. Nine miles long (14.5 km) and about 3 1/2 miles (5.6 km) across at its widest point, it is the farthest island from the mainland, more than 60 miles (96.6 km) offshore and about 85 miles (136.8 km) southwest of Los Angeles, California. SNI is owned and operated by the U.S. Navy and is off-limits to civilians without specific permission.

Many of the beaches in the Channel Islands provide resting, molting or breeding places for species of pinnipeds. On SNI, three pinniped species (northern elephant seal, Pacific harbor seal, and California sea lion) can be expected to occur on land in the vicinity of abalone research sites either regularly or in large numbers during certain times of the year. In addition, a single adult male Guadalupe fur seal (*Arctocephalus townsendi*) (federally listed as threatened under the Endangered Species Act) was seen at one abalone research site on two occasions during the summer months in the mid–1980's. However, none have been seen since those original sightings. Further information on the biology and distribution of these species and others in the region can be found in Dr. VanBlaricom's application, which is

available upon request (see **ADDRESSES**), and the Marine Mammal Stock Assessment Reports, which are available online at *http://www.nmfs.noaa.gov/prot__res/PR2/Stock__Assessment__Program/individual__sars.html*.

California Sea Lions

The U.S. stock of California sea lions extends from the U.S./Mexico border north into Canada. Breeding areas of the sea lion are on islands located in southern California, western Baja California, and the Gulf of California and they primarily use the central California area to feed during the non-breeding season. Population estimates for the U.S. stock of California sea lions, which are based on counts conducted in 2001 and extrapolations from the number of pups, range from a minimum of 138,881 to an average of 244,000 animals, with a current growth rate of 5.4 to 6.1 percent per year (Carretta et al., 2005). The California sea lion is not listed under the ESA and the U.S. stock is not considered depleted under the MMPA.

California sea lions haul out at many sites on SNI and are by far the most common pinniped on the island. Over the course of a year, up to 100,000 sea lions may use SNI. Numbers of sea lions at SNI increased by about 21 percent per year between 1983 and 1995 (NMFS, 2003) and sea lions have recently started occupying areas that were not formerly used. Pupping occurs on the beaches of SNI from mid-June to mid-July. Females nurse their pups for about eight days and then begin an alternating pattern of foraging at sea vs. attending and nursing the pup on land, which lasts for about eight months, and sometimes up to a year. California sea lions also haul out at SNI during the molting period in September, and smaller numbers of females and juveniles haul out during most of the year.

Pacific Harbor Seals

Harbor seals are widely distributed in the North Atlantic and North Pacific. In California, approximately 400–500 harbor seal haul-out sites are distributed along the mainland and on offshore islands, including intertidal sandbars, rocky shores and beaches (Hanan, 1996). A complete count of all harbor seals in California is impossible because some are always away from the haul-out sites. A complete pup count (as is done for other pinnipeds in California) is also not possible because harbor seals are precocious, with pups entering the water almost immediately after birth. Based on the most recent harbor seal counts (2004 and 2005) and including a correction factor for the above, the estimated population of harbor seals in California is 34,233 (Caretta et al., 2005), with an estimated minimum population of 31,600 for the California stock of harbor seals. Counts of harbor seals in California showed a rapid increase from 1972 to 1990, but since 1990 there has been no net population growth along the mainland or the Channel Islands. Though no formal determination of Optimal Sustainable Population (OSP) has been made, the decrease in the growth rate may indicate that the population has reached its carrying capacity. The harbor seal is not listed under the ESA and the California stock is not considered depleted under the MMPA.

Harbor seals haul out at various sandy, cobble, and gravel beaches around SNI and pupping occurs on the beaches from late February to early April, with nursing of pups extending into May. Harbor seals may also haul out during molting period in late Spring, and smaller numbers haul out at other times of year. Harbor seal abundance increased at SNI from the 1960s until 1981, but since the average counts have not changed significantly. From 1982 to 1994, numbers of harbor seals have fluctuated between 139 and 700 harbor seals based on both peak ground counts and annual photographic survey photos. The most recent aerial count on SNI was of 457 harbor seals in 1994.

Northern Elephant Seals

Northern elephant seals breed and give birth in California (U.S.) and Baja California primarily on offshore islands, from December to March (Stewart *et al.*, 1994). The California breeding stock, which includes the animals on SNI, is now demographically separated from the Baja California population. Based on trends in pup counts, northern elephant seal colonies appeared to be increasing in California through 2001. The population size of northern elephant seals in California is estimated to be 101,000 animals, with a minimum population estimate of 60,547 (Carretta *et al.*, 2005). A continuous average growth rate (though it has declined a bit in recent years) of 8.3 percent has seen numbers of this species increase from 100 in 1900 to the current population size (Caretta *et al.*, 2005). The northern elephant seal is not listed under the ESA and the California stock is not considered depleted under the MMPA.

Increasing numbers of elephant seals haul out at various sites around SNI. Based on a pup count in 1995 that found 6,575 pups, scientists estimated that over 23,000 elephant seals may use SNI in a year (NMFS, 2003). From 1988 to 1995 the pup counts on SNI increased at an average rate of 15.4 percent per year, however, the growth rate of the population as a whole seems to have declined in recent years (NMFS, 2003). Pupping occurs on the beaches of SNI from January to early February, with nursing of pups extending into March. Northern elephant seals also haul out during the molting periods in the spring and summer, and smaller numbers haul out at other times of the year.

Comments and Responses

On October 23, 2006, NMFS published in the **Federal Register** a notice of a proposed IHA for Dr. VanBlaricom's request to take marine mammals incidental to conducting black abalone research on SNI, and requested comments regarding this proposed IHA (See 71 FR 62087). During the 30–day public comment period, NMFS received one comment from the Marine Mammal Commission recommending NMFS issue the IHA as proposed.

Potential Effects of Activities on Marine Mammals

Variable numbers of sea lions, harbor seals, and elephant seals typically haul out near seven of the nine study sites used for abalone research, with breeding activity occurring at four of these seven sites. Pinnipeds likely to be affected by abalone research activity are those that are hauled out on land at or near study sites.

Incidental harassment may result if hauled animals move away from the abalone researchers. For the purpose of estimating numbers of pinnipeds taken by these activities, NMFS conservatively estimates that pinnipeds that move or change the direction of their movement in response to the presence of researchers are taken by Level B Harassment. Animals that raise their head and look at the researcher are not considered to have been taken. Although marine mammals will not be deliberately approached by abalone survey personnel, approach may be unavoidable if pinnipeds are hauled out directly upon the permanent abalone study plots. In almost all cases, shoreline habitats near the abalone study sites are gently sloping sandy beaches or horizontal sandstone platforms with unimpeded and non-hazardous access to the water. If disturbed, hauled animals may move toward the water without risk of encountering significant hazards. In these circumstances, the risk of serious injury or death to hauled animals is very low.

The risk of marine mammal injury or mortality associated with abalone research increases somewhat if disturbances occur during breeding season, as it is possible that mothers and dependent pups could become separated. If separated pairs don't reunite fairly quickly, risks of mortality to pups (through starvation) may increase. Also, adult northern elephant seals may trample elephant seal pups if disturbed, which could potentially result in the of injury or death of pups. However, the IHA will include time of year restrictions intended to limit the presence of researchers to months that California sea lion and harbor seal dependent pups are not present at the survey sites. Additionally, though elephant seal pups are occasionally present at abalone surveys, risk of pup mortalities are very low because elephant seals are far less reactive to researcher presence than the other two species (an estimated 30 total elephant seals have been disturbed in the last three years out of 1594 present around the study site). Last, researchers use great care approaching sites and pups are on the sand while the permanent study sites are on rocks, which leaves the two always separated by at least 50 m (164 ft). Because of the circumstances and the IHA requirements discussed above, NMFS believes it highly unlikely that the authorized activities would result in the injury or mortality of pinnipeds (and none have been recorded in the 27 years that the researcher has been conducting this research).

The results of Dr. VanBlaricom's monitoring under the previous IHA are summarized in Table 1, which shows the numbers of each species present at Dr. VanBlaricom's survey sites as well as the numbers disturbed during his visits in the last year. As part of the required monitoring, Dr. VanBlaricom records the numbers of disturbed animals that flush into the water, the number that move more than 1 m, but do not enter the water, and the number that become alert and move, but not move more than 1 m (see the application for these numbers). Animals that raised their head and looked at the researcher without moving were not considered disturbed (or harrassed pursuant to the MMPA). For the purposes of estimating take in the IHA, NMFS conservatively estimates take as the total of all three categories of disturbed behavior recorded.

As indicated in Table 1, approximately 25 percent of the total animals harassed by this activity responded by flushing into the water (221 sea lions, 46 harbor seals, and 0 elephant seals) and the rest responded to a lesser degree by moving some distance on land when the researchers approached. Though the researchers have not stayed to find how soon pinnipeds return after flushing (leaving as soon as possible minimizes the effects), increasing numbers at some of the sites and pinniped presence at sites where they were not present before suggest that the research is not having any long-term detrimental effects on the population of any of these three species.

Older, weaned sea lion pups were seen and disturbed at sites 6, 7, and 8, however, none were flushed into the water or injured in any way.

				California Sea Lions		Pacific Harbor Seals		Northern Elephant Seals	
Year	Month	Date	Site #	Present at site	Disturbed	Present at site	Disturbed	Present at site	Disturbed
2006	January	2	1	54	1	0	0	0	0
2006	January	12	1	50	3	0	0	1	0
2006	February	25	1	1	1	0	0	0	0
2006	February	26	1	32	28	0	0	0	0
2005	December	1	2	0	0	0	0	0	0
2005	December	3	2	0	0	0	0	0	0
2006	January	1	2	0	0	0	0	0	0
2006	January	15	2	0	0	0	0	0	0
2006	January	29	2	0	0	0	0	0	0
2006	February	24	2	0	0	0	0	0	0
2005	December	2	3	0	0	0	0	0	0
2006	January	16	3	0	0	0	0	0	0
2006	January	30	3	0	0	0	0	0	0
2006	January	31	3	0	0	0	0	0	0
2006	February	28	3	0	0	0	0	0	0
2005	December	4	4	0	0	0	0	0	0
2006	January	25	4	0	0	0	0	0	0
2006	January	30	4	0	0	0	0	0	0
2006	March	1	4	0	0	0	0	0	0

				California Sea Lions		Pacific Harbor Seals		Northern Elephant Seals	
Year	Month	Date	Site #	Present at site	Disturbed	Present at site	Disturbed	Present at site	Disturbed
2006	January	26	5	27	5	27	25	88	4
2006	January	14	6	86	69	13	13	216	7
2006	January	26	6	97	90	17	12	203	2
2006	January	27	7	610	386	0	0	60	0
2005	December	30	8	226	195	0	0	3	0
2006	January	13	8	241	227	0	0	5	0
2006	January	28	8	140	40	0	0	14	0
2005	December	29	9	0	0	0	0	14	1
2005	December	31	9	0	0	0	0	19	0
Totals				**1564**	**1045**	**57**	**50**	**623**	**14**
# that flushed into water					221 (21%)		46 (92%)		0
# moved >1m, but not into water					680 (65%)		3 (6%)		11 (79%)
# came alert, but did not move >1 m					144 (14%)		1 (2%)		3 (21%)

Table 1. Results from 2006 monitoring. Number of ''disturbed'' animals indicates total of the three categories of recorded reactions, which include: animals that flushed into the water; animals that moved more than 1 m, but did not enter the water; and, animals that moved or changed direction, but did not move more than 1 m.

Mitigation

Several mitigation measures to reduce the potential for harassment from population assessment research surveys will be implemented as part of the SNI abalone research activities. Primarily, mitigation of the risk of disturbance to pinnipeds requires that researchers are judicious in the route of approach to abalone study sites, avoiding close contact with pinnipeds hauled out on shore. In no case will marine mammals be deliberately approached by abalone survey personnel, and in all cases every possible measure will be taken to select a pathway of approach to study sites that minimizes the number of marine mammals harassed. Each visit to a given study site will last for a maximum of 4 hours, after which the site is vacated and can be re-occupied by any hauled marine mammals that may have been disturbed by the presence of abalone researchers.

The potential risk of injury or mortality will be avoided with measures required under the authorization. Disturbances to females with dependent pups (in the cases of California sea lions and Pacific harbor seals) will be mitigated to the greatest extent practicable by avoiding visits to the four black abalone study sites with resident pinnipeds during periods of breeding and lactation from mid-February through the end of October. During this period, abalone research would be confined to the other five sites where pinniped breeding and post-partum nursing does not occur. Limiting visits to the four breeding and lactation sites (5, 6, 7, and 8) to periods when these activities do not occur (November, December, January, and the first half of February) will reduce the possibility of incidental harassment and the potential for serious injury or mortality of dependent California sea lion pups and Pacific harbor seal pups to near zero.

Northern elephant seal pups are present at four sites during winter months. Risks of injury or mortality of elephant seal pups by mother/pup separation or trampling are limited to the period from January through March when pups are born, nursed, and weaned, ending about 30 days post-weaning when pups depart land for foraging areas at sea. However, elephant seals have a much higher tolerance of nearby human activity than sea lions or harbor seals. Also, elephant seal pupping typically occurs on the sandy beaches at SNI, approximately 50 m (164 ft) or more away from the abalone study sites. Possible take of northern elephant seal pups will be minimized by using a very careful approach to the study sites and avoiding the proximity of hauled seals and any seal pups during collection of abalone population data.

One individual Guadalupe fur seal was seen at study site 8 on two separate occasions during the summer months in the mid–1980's. Since the original sightings, no individuals of this species have been seen during abalone research. However, to ensure that Gaudelupe fur seals are not affected by these activities and that authorization is not needed pursuant to the MMPA or the ESA, researchers will only visit site 8 from November through January and work will be immediately suspended and researchers vacated if an individual is seen. Guadalupe fur seals are distinctive in appearance and behavior, and can be readily identified at a distance without any disturbance.

Sea otters, which are federally listed as threatened under the ESA and managed by the U.S. Fish and Wildlife Service, are not expected ashore during the time periods when the research activities would be conducted. However, if sea otters are sighted ashore during the abalone research, Dr. VanBlaricom would follow similar procedures in place for fur seals to avoid impacts, suspending research activities in any areas California sea otters are occupying.

Monitoring

Currently, all biological research activities at SNI are subject to approval and regulation by the Environmental Planning and Management Department (EPMD), U.S. Navy. The U.S. Navy owns SNI and closely regulates all civilian

access to and activity on the island, including biological research. Therefore, monitoring activities will be closely coordinated with Navy marine mammal biologists located on SNI.

In addition, status and trends of pinniped aggregations at SNI are monitored by the NMFS Southwest Fisheries Science Center. Also, long-term studies of pinniped population dynamics, migratory and foraging behavior, and foraging ecology at SNI are conducted by staff at Hubbs-Sea World Research Institute (HSWRI).

Monitoring requirements in relation to Dr. VanBlaricom's abalone research surveys will include observations made by the applicant and his associates. Information recorded will include species counts (with numbers of pups), numbers of observed disturbances, and descriptions of the disturbed behaviors during the abalone surveys. Observations of unusual behaviors, numbers, or distributions of pinnipeds on SNI will be reported to EPMD, NMFS, and HSWRI so that any potential follow-up observations can be conducted by the appropriate personnel. In addition, observations of tag-bearing pinniped carcasses as well as any rare or unusual species of marine mammals will be reported to EPMD and NMFS.

If at any time injury or death of any marine mammal occurs that may be a result of the authorized abalone research, Dr. VanBlaricom will suspend research activities and contact NMFS immediately to determine how best to proceed to ensure that another injury or death does not occur and to ensure that the applicant remains in compliance with the MMPA.

Reporting

A draft final report must be submitted to NMFS within 60 days after the conclusion of the year-long field season. The report will include a summary of the information gathered pursuant to the monitoring requirements set forth in the IHA. A final report must be submitted to the Regional Administrator within 30 days after receiving comments from NMFS on the draft final report. If no comments are received from NMFS, the draft final report will be considered to be the final report.

Dr. VanBlaricom has already submitted the final report required by the current IHA and it may be viewed on the NMFS website (see **ADDRESSES**).

Numbers of Marine Mammals Expected to be Harassed

NMFS has determined that small numbers, relative to population estimates, of California sea lions, Pacific harbor seals, and northern elephant seals may be taken by harassment as a result of this activity (1.3, 0.2, and .04 percent of the minimum population, respectively).

The distribution of pinnipeds hauled out on beaches is not even between sites or at different times of the year. The number of marine mammals disturbed will vary by month and location, and, compared to animals hauled out on the beach farther away from survey activity, only those animals hauled out closest to the actual survey transect plots contained within each research site are likely to be disturbed by the presence of researchers and alter their behavior or attempt to move out of the way.

Table 2 depicts the total numbers of animals encountered and disturbed by Level B Harasssment in Dr. VanBlaricom's 2004, 2005, and 2006 abalone survey field seasons. As discussed earlier, NMFS considers an animal to have been harassed if it moved any distance in response to the researcher's presence or if the animal was already moving and changed direction. Animals that raised their head and looked at the researcher without moving were not considered disturbed. Based on past observations and assuming a maximum level of incidental harassment of marine mammals at each site during periods of visitation, NMFS estimates that the maximum total possible numbers of individuals that will be incidentally harassed during the effective dates of the IHA would be 1770 California sea lions, 75 Pacific harbor seals, and 25 northern elephant seals. Three visits to each site are anticipated during the year-long validity of the IHA.

	California Sea Lions		Pacific Harbor Seals		Northern Elephant Seal	
Year	Present around Site	Est. Harassed	Present around Site	Est. Harassed	Present around Site	Est. Harassed
2004	2239	1472	108	99	562	7
2005	1383	983	99	88	409	9
2006	1564	1045	57	50	623	14

Table 2. Estimated number of each species harassed over the last three years of abalone research. Minimum population estimates for California sea lions, Pacific harbor seals, and Northern elephant seals are 138881, 31600, and 60547,respectively.

Potential Effects of Activities on Marine Mammal Habitat

NMFS anticipates that the action will result in no impacts to marine mammal habitat beyond rendering the areas immediately around each of the nine study sites less desirable as haulout sites for a total of 8.5 hours per year.

ESA

For the reasons already described in this **Federal Register** Notice, NMFS has determined that the described abalone research and the accompanying IHA will have no effect on species or critical habitat protected under the ESA (specifically, the Guadelope fur seal). Therefore, consultation under section 7 of the ESA was not required.

National Environmental Policy Act (NEPA)

NMFS prepared an Environmental Assessment (EA) of the Issuance of an IHA to Take Marine Mammals, by Harassment, During Black Abalone Research at SNI, California, which analyzed the issuance of multiple IHAs over several years for these activities, and subsequently issued a Finding of No Significant Impact on November 21, 2005. A copy of the EA and FONSI are available upon request (see **ADDRESSES**).

Conclusions

Based on Dr. VanBlaricom's application and monitoring reports for previous field seasons, as well as the analysis contained herein, NMFS has determined that the impact of the described abalone research at SNI will result, at most, in a temporary modification in behavior by small numbers of California sea lions, Pacific harbor seals, and northern elephant seals, in the form of head alerts, movement away from the researchers and/or flushing from the beach. In addition, no take by injury or death is anticipated, and take by harassment will be at the lowest level practicable due to

incorporation of the mitigation measures mentioned previously in this document. NMFS has further determined the anticipated takes will have a negligible impact on the affected species.

Authorization

NMFS has issued an IHA to Dr. Glenn R. VanBlaricom for the harassment of California sea lions, Pacific harbor seals, and northern elephant seals incidental to black abalone population trend research, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: December 1, 2006.

James H. Lecky,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E6–20950 Filed 12–7–06; 8:45 am]

BILLING CODE 3510–22–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of an Import Limit for Certain Wool Textile Products Produced or Manufactured in Ukraine

December 4, 2006.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner, Bureau of Customs and Border Protection adjusting a limit.

EFFECTIVE DATE: December 8, 2006.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Bureau of Customs and Border Protection website (http://www.cbp.gov), or call (202) 344-2650. For information on embargoes and quota re-openings, refer to the Office of Textiles and Apparel website at http://otexa.ita.doc.gov.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The Bilateral Textile Agreement of July 22, 1998, as amended and extended by exchange of notes on November 19, 2004, December 31, 2004, and February 7, 2005, between the Governments of the United States and Ukraine (the ''Bilateral Agreement'') establishes limits for certain wool textile products, produced or manufactured in Ukraine and exported during the period beginning on January 1, 2006 and extending through December 31, 2006. On December 2, 2005, the Chairman of CITA directed the Commissioner, Bureau of Customs and Border Protection to reduce the 2006 Category 435 limit for carryforward to be applied to the 2005 limit. See **Federal Register** Notice, 70 FR 72992 (December 8, 2005). Because the carryforward was not fully used in 2005, consistent with paragraph 5.D. of the Bilateral Agreement, the current limit for Category 435 is being increased for the recrediting of unused 2005 carryforward.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (refer to the Office of Textiles and Apparel website at http://otexa.ita.doc.gov). Also see **Federal Register** notice 70 FR 72992, published on December 8, 2005.

Philip J. Martello,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

December 4, 2006.

Commissioner,

Commissioner, Bureau of Customs and Border Protection, Washington, DC 20229

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 2, 2005, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain wool textile products, produced or manufactured in Ukraine and exported during the twelve-month period which began on January 1, 2006 and extends through December 31, 2006.

Effective on December 8, 2006, you are directed to increase the current limit for Category 435 to 110,160 dozen [1], as provided for under the bilateral agreement between the Governments of the United States and Ukraine:

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Philip J. Martello,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. E6–20942 Filed 12–7–06; 8:45 am]

BILLING CODE 3510–DS

[1] The limit has not been adjusted to account for any imports exported after December 31, 2005.

DEPARTMENT OF DEFENSE

Department of the Army

Board of Visitors, United States Military Academy (USMA)

AGENCY: Department of the Army, DoD.

ACTION: Notice of open meeting.

SUMMARY: In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following committee meeting:

Name of Committee: Board of Visitors, United States Military Academy.

Date: Wednesday, January 31, 2007.

Place of Meeting: Veterans Affairs Conference room, Room 418, Senate Russell Building, Washington, DC.

Start Time of Meeting: Approximately 9 a.m.

FOR FURTHER INFORMATION CONTACT: Lieutenant Colonel Shaun T. Wurzbach, United States Military Academy, West Point, NY 10996–5000, (845) 938–4200.

SUPPLEMENTARY INFORMATION: *Proposed Agenda:* Organizational Meeting of the Board of Visitors. Review of the Academic, Military and Physical Programs at the USMA. Elections for Board of Visitor Leadership positions will also be held. All proceedings are open.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 06–9596 Filed 12–07–06; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Availability of Draft Environmental Impact Statement for the Proposed Rio del Oro Specific Plan Project, in the City of Rancho Cordova, Sacramento County, CA

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of availability.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers (USACE), DoD. Sacramento District has prepared a Draft Environmental Impact Statement (DEIS) that analyzes the potential effects of implementing each of five alternative scenarios for a mixed-use development in the approximately 3,828-acre Rio del Oro Specific Plan area, in the City of Rancho Cordova, Sacramento County, CA. The EIS documents the existing

condition of environmental resources in and around areas considered for development, and potential impacts on those resources as a result of implementing the alternatives. The alternatives considered in detail are: (1) Proposed Project/Proposed Action (i.e., Proposed Project Alternative), the Applicants' Preferred Alternative; (2) High Density (Increased Densities Consistent with Sacramento Area Council of Governments Blueprint); (3) Impact Minimization; (4) No Federal Action (No Section 404 of the Clean Water Act Permit); and (5) No Project/No Action (No development).

DATES: All written comments must be postmarked on or before February 5, 2007. A public hearing will be held on a date to be determined following the close of the comment period; notice of this hearing will be sent to all appropriate parties at a later date.

ADDRESSES: Comments may be submitted in writing to: Anna Sutton, U.S. Army Corps of Engineers, Sacramento District, Regulatory Branch, 1325 J Street, Room 1480, Sacramento, CA 95814–2922, or via e-mail to *Anna.M.Sutton@spk01.usace.army. mil.* Oral and written comments may also be submitted at the public hearing described in the **DATES** section.

FOR FURTHER INFORMATION CONTACT: Anna Sutton at (916) 557–7759 or via e-mail at *Anna.M.Sutton@spk01.usace.army.mil.*

SUPPLEMENTARY INFORMATION: Elliott Homes and GenCorp Realty Investments (GenCorp), the project applicant(s), are seeking adoption by the City of Rancho Cordova of the proposed Rio del Oro Specific Plan. Elliott Homes is seeking specific development entitlements (e.g., tentative subdivision maps); GenCorp is seeking overall development entitlements, but has not proposed specific development entitlements necessary for immediate or short-term development. Both Elliott Homes and GenCorp are also seeking authorization from USACE to place dredged or fill material into waters of the United States.

Five alternatives are evaluated in detail in the DEIS. Under the Proposed Project/Proposed Action (Proposed Project Alternative), buildout of the project would be split into five phases and is anticipated to occur over a 25- to 30-year period. The project provides for construction of approximately 11,601 residential dwelling units in three residential land use classifications on 1,920 acres, along with commercial land uses, neighborhood parks and other uses such as a landscape corridor and greenbelt, and several public schools. New utilities and communications infrastructure would be installed and new roadways and on- and off-site infrastructure improvements would be completed. The project designates a 507-acre wetland preserve area and two elderberry preserve areas on the project site. The four alternatives to the Proposed Project/Proposed Action are described briefly below.

(1) The High Density Alternative embraces the concept of ''Smart Growth,'' consistent with the Sacramento Area Council of Governments' Regional Blueprint Project. Under Smart Growth principles, areas planned for development are developed at higher densities. Although these higher densities may result in greater localized impacts on resources, the overall area of disturbance is reduced by concentrating development in particular locations. The total acreage of residential development would be the same under this alternative as under the Proposed Project/Proposed Action, but approximately 3,800 additional residential units would be constructed. The acreage of commercial and industrial development as well as the wetland preserve would be the same.

(2) The Impact Minimization Alternative would reconfigure project components to reduce impacts on waters of the United States, including wetlands and high-quality biological habitat. An additional 485 acres of the project site would be designated as part of the protected wetland preserve; as a result, approximately 25% of the project site would become a part of the wetland preserve. The total acreage of residential development would be reduced by approximately 470 acres and approximately 1,040 fewer residential units would be constructed, although overall density would increase because a greater proportion of residential acreage would be developed with medium and high density. Commercial and industrial development sites would be slightly reduced.

(3) The No Federal Action Alternative was designed to allow some development of the project site while avoiding the placement of dredged or fill material into waters of the United States. Under this alternative, 872 acres of the project site would be designated ''Natural Resources'' under the City of Rancho Cordova General Plan. Land with this use designation is set aside as natural habitat with no urban development; public access into this area would be prohibited. The types of land uses would remain the same as under the Proposed Project/Proposed Action.

(4) The No Project/No Action Alternative would preclude development of the project; under this alternative the majority of the project site would remain under the jurisdiction of the City of Rancho Cordova. This alternative assumes that aggregate mining operations to remove portions of existing dredge tailings at the project site would continue under existing Conditional Use Permits. Aggregate mining operations are not part of the Rio del Oro project.

USACE invites full public participation to promote open communication and better decision-making. All persons and organizations that have an interest in the Rio del Oro Specific Plan Project are urged to participate in the NEPA process. A public hearing will be held as described in the **DATES** section. This hearing will be announced in advance through notices, media news releases, and/or mailings.

Copies of the DEIS may be reviewed at the following locations:

1. U.S. Army Corps of Engineers, Sacramento District Web site: *http://www.spk.usace.army.mil/organizations/cespk-co/regulatory/index.html.*

2. City of Rancho Cordova City Hall, 2729 Prospect Park Drive, Rancho Cordova, CA 95670.

3. City of Rancho Cordova Planning Department Web site: *http://www.cityofranchocordova.org/city_departments/planning_main.html.*

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 06–9597 Filed 12–7–06; 8:45 am]

BILLING CODE 3710–EZ–M

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Prepare an Environmental Impact Statement/ Overseas Environmental Impact Statement for the Virginia Capes Range Complex and Notice of Public Scoping Meetings

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to Section (102)(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as implemented by the Council on Environmental Quality Regulations (40 CFR Parts 1500–1508), and Executive Order 12114, the Department of the Navy (DON) announces its intent to prepare an Environmental Impact Statement (EIS)/Overseas EIS (OEIS) to evaluate the potential environmental

consequences associated with naval training in the Virginia Capes (VACAPES) Range Complex. The DON proposes to support and conduct current and emerging training operations and research, development, testing, and evaluation (RDT&E) operations in the VACAPES Range Complex by: (1) Maintaining baseline operations at current levels; (2) increasing training operations from current levels as necessary to support the Fleet Readiness Training Plan; (3) accommodating mission requirements associated with force structure change; and (4) implementing enhanced range complex capabilities. The EIS/OEIS study area is the VACAPES Range Complex which consists of targets and instrumented areas, airspace, surface and subsurface operations areas (OPAREAs), and land range facilities. Together the VACAPES Range Complex encompasses: 15,143 acres of land area (including 13,600 acres of land area for ranges); 5,158 nm^2 of special use airspace (SUA) associated with land ranges; 27,661 nm^2 of offshore surface and subsurface OPAREA; 9,589 nm^2 of shallow ocean area less than 100 fathoms (600 feet); 18,072 nm^2 of deep ocean areas greater than 100 fathoms; 330 nm^2 of over water danger areas; and 28,672 nm^2 of SUA warning areas. The scope of actions to be analyzed in this EIS/OEIS includes current and proposed future Navy training and RDT&E operations within Navy-controlled operating areas, airspace, and ranges. It also includes proposed Navy-funded range capabilities enhancements, including infrastructure improvements, which support range complex training and RDT&E operations. Training activities that involve the use of active sonar are conducted in the VACAPES Range Complex; however, those potential effects are being analyzed in detail in a separate document, the Atlantic Fleet Active Sonar Training EIS/OEIS. This separate sonar EIS/OEIS addresses active sonar use as a whole by the Atlantic Fleet in the eastern Atlantic Ocean (including waters that are part of the VACAPES Range Complex), and in the Gulf of Mexico. The results of this sonar EIS/OEIS will be incorporated into the VACAPES Range Complex EIS/OEIS to account for active sonar effects that could occur within the geographic area of the VACAPES Range Complex. The DON will request the National Marine Fisheries Service to be a cooperating agency in the preparation of this EIS/OEIS.

Dates and Addresses: Public scoping meetings will be held at the following four sites to receive oral and written comments on environmental concerns that should be addressed in the EIS/OEIS: Salisbury, MD; Chincoteague Island, VA; Virginia Beach, VA; and Nags Head, NC. Public scoping open houses are scheduled below:

1. January 8, 2007, from 5 p.m. to 8 p.m. at James M. Bennett High School, 300 East College Avenue, Salisbury, MD 21804;

2. January 9, 2007 from 5 p.m. to 8 p.m. at the Chincoteague Community Center, 6155 Community Drive, Chincoteague Island, VA 23336;

3. January 10, 2007, from 5 p.m. to 8 p.m. at Lynnhaven Middle School, 1250 Bayne Drive, Virginia Beach, VA 23454; and

4. January 11, 2007 from 5 p.m. to 8 p.m. at the Comfort Inn Oceanfront South, 8031 Old Oregon Inlet Road, Nags Head, NC 27959.

FOR FURTHER INFORMATION CONTACT: Ms. Erin Swiader, Naval Facilities Engineering Command Atlantic, 6506 Hampton Boulevard, Norfolk, VA 23508–1278; telephone 757–322–4960; facsimile 757–322–4894.

SUPPLEMENTARY INFORMATION: Recent world events have placed the U.S. military on heightened alert in the defense of the U.S., and in defense of allied nations. At this time, the U.S. military, and specifically the U.S. Navy, is actively engaged in anti-terrorism efforts around the globe. The Navy's mission is to maintain, train, and equip combat-ready naval forces capable of winning wars, deterring aggression, and maintaining freedom of the seas. For that reason, 10 U.S.C. § 5062 directs the Chief of Naval Operations to train all naval forces for combat. Therefore, naval forces must have access to ranges, OPAREAs and airspace where they can develop and maintain skills for wartime missions and conduct RDT&E of naval weapons systems. As such, Navy ranges, OPAREAs, and airspace must be maintained and/or enhanced to accommodate necessary training and testing activities in support of national security objectives.

The purpose of the proposed action is to: Achieve and maintain Fleet readiness using the VACAPES Range Complex to support and conduct current, emerging, and future training operations, and RDT&E operations; expand warfare missions; and upgrade/modernize existing range capabilities to enhance and sustain Navy and Marine Corps training and testing.

The need for the proposed action is to provide combat capable forces ready to deploy worldwide in accordance with 10 U.S.C. § 5062. Specifically, maintain current levels of military readiness by training in the VACAPES Range Complex; accommodate future increases in operational training tempo in the VACAPES Range Complex and support the rapid deployment of naval units or strike groups; achieve and sustain readiness in ships and squadrons so that the DON can quickly surge significant combat power in the event of a national crisis or contingency operation and consistent with FRTP; support the testing and training needed for new platforms and weapons systems; and maintain the long-term viability of the VACAPES Range Complex while protecting human health and the environment, and enhancing the quality and communication capability and safety of the VACAPES Range Complex.

Three alternatives will be evaluated in the EIS/OEIS including:

(1) The No Action Alternative comprised of baseline operations and support of existing range capabilities;

(2) Alternative 1 comprised of the No Action Alternative plus additional operations and/or expanded warfare missions on upgraded, modernized, or existing ranges; and

(3) Alternative 1 plus a construction and operation of an instrumented minefield training area.

The EIS/OEIS will evaluate the environmental effects associated with: Airspace; noise; range safety; natural land resources; water resources; air quality; biological resources, including threatened and endangered species; land use; socioeconomic resources; infrastructure; and cultural resources. The analysis will include an evaluation of direct and indirect impacts, and will account for cumulative impacts from other DON activities in the VACAPES Range Complex. No decision will be made to implement any alternative until the EIS/OEIS process is completed and a Record of Decision is signed by the Assistant Secretary of the Navy (Installations and Environment).

The DON is initiating the scoping process to identify community concerns and local issues to be addressed in the EIS/OEIS. Federal agencies, state agencies, local agencies, and interested persons are encouraged to provide oral and/or written comments to the DON to identify specific issues or topics of environmental concern that should be addressed in the EIS/OEIS. Written comments must be postmarked by January 23, 2007, and should be mailed to: Naval Facilities Engineering Command, Atlantic, 6506 Hampton Boulevard, Norfolk, VA 23508–1278, Attention: Code EV21JS (Ms. Erin Swiader), telephone 757–322–4960, facsimile 757–322–4894.

Dated: December 4, 2006.

M.A. Harvison,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E6–20846 Filed 12–7–06; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 8, 2007.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Rachel Potter, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503 or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: December 4, 2006.

Dianne M. Novick,

Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services Office of Management.

Institute of Education Sciences

Type of Review: Revision.

Title: Schools and Staffing Survey 2007.

Frequency: Other: one-time.

Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs; Businesses or other for-profit; Not-for-profit institutions.

Reporting and Recordkeeping Hour Burden:

Responses: 124,906.

Burden Hours: 70,775.

Abstract: The Schools and Staffing Survey is a nationally and state representative survey of teachers, principals, schools and school districts. Respondents include public and private school principals, teachers and school and LEA staff persons. Topics covered include characteristics of teachers, principals, schools, school libraries, teacher training opportunities, retention, retirement, hiring, and shortages.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 3191. When you access the information collection, click on ''Download Attachments '' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E6–20887 Filed 12–7–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 6, 2007.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: December 4, 2006.

Dianne M. Novick,

Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services, Office of Management.

Office of Special Education and Rehabilitative Services

Type of Review: Reinstatement.

Title: State Plan for Independent Living and Center for Independent Living Programs (SPIL).

Frequency: Every three years.

Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs; Not-for-profit institutions.

Reporting and Recordkeeping Hour Burden:

Responses: 56.

Burden Hours: 3,360.

Abstract: States wishing to receive funding under the State Independent Living Services (SILS) and Centers for Independent Living (CIL) programs must submit an approvable three-year State Plan for Independent Living (SPIL) to the Rehabilitation Services Administration (RSA). The purpose of these programs is to promote the independent living philosophy—based on consumer control, peer support, self-help, self-determination, equal access and individual and systems advocacy—to maximize the leadership, empowerment, independence and productivity of individuals with significant disabilities and to promote and maximize the integration and full inclusion of individuals with significant disabilities into the mainstream of American society. The SPIL encompasses the activities planned by the State to achieve its specified independent living objectives and reflects the State's commitment to comply with all applicable statutory and regulatory requirements during the three years covered by the Plan.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, by selecting the ''Browse Pending Collections'' link and by clicking on link number 3236. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E6–20888 Filed 12–7–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 8, 2007.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Rachel Potter, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503 or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: December 4, 2006.

Dianne M. Novick,

Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services Office of Management.

Office of Postsecondary Education

Type of Review: Revision.

Title: Annual Performance Report for the Gaining Early Awareness for Undergraduate Programs (GEAR UP) Program.

Frequency: Annually.

Affected Public: Not-for-profit institutions; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 328.

Burden Hours: 11,152.

Abstract: The purpose of this information collection is accountability for program implementation and student outcomes for the Gaining Early Awareness and Readiness for Undergraduate Programs (GEAR UP). The information collected enables the U.S. Department of Education to demonstrate its progress in meeting the GEAR UP performance objectives as reflected in the indicators.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 3194. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E6–20889 Filed 12–7–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 6, 2007.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: December 5, 2006.

Dianne M. Novick,

Acting Leader, Information Policy and Standards Team, Regulatory Information Management Services, Office of Management.

Institute of Education Sciences

Type of Review: New.

Title: Regional Educational Needs Assessment Survey.

Frequency: 1 time Project Year.

Affected Public: Individuals or household; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 2,825.

Burden Hours: 942.

Abstract: In July and August 2006, the Regional Educational Laboratory Northwest (REL–NW) hosted a series of forums with educators in the five states REL–NW serves to discuss the types of evidence educators need to improve student achievement. This project is a follow-up survey with teachers, principals, and district superintendents in Washington, Oregon, Idaho, Montana and Alaska to prioritize the evidentiary needs for improving student learning. Findings from the study will aid in setting the research agenda for REL–NW.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 3237. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E6–20930 Filed 12–7–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER07–74–000]

Caithness Long Island, LLC; Notice of Issuance of Order

November 30, 2006.

Caithness Long Island, LLC (CLI) filed an application for market-based rate authority, with an accompanying rate tariff. The proposed market-based rate tariff provides for the sale of energy, capacity and ancillary services at market-based rates. CLI also requested waivers of various Commission regulations. In particular, CLI requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by CLI.

On November 28, 2006, pursuant to delegated authority, the Director, Division of Tariffs and Market Development—West, granted the request for blanket approval under Part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by CLI should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest is December 28, 2006.

Absent a request to be heard in opposition by the deadline above, CLI is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of CLI, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approvals of CLI's issuance of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20811 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER02–530–000; ER02–530–001]

Duke Energy Marshall, LLC; Notice of Issuance of Order

December 1, 2006.

Duke Energy Marshall County, LLC (Duke Marshall) filed an application for market-based rate authority, with an accompanying rate tariff. The proposed market-based rate tariff provides for the sale of energy, capacity and certain ancillary services at market-based rates and for the reassignment and sale of transmission capacity. Duke Marshall also requested waivers of various Commission regulations. In particular, Duke Marshall requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Duke Marshall.

On April 17, 2002, pursuant to delegated authority, the Director, Division of Tariffs and Rates—West, granted the requests for blanket approval under Part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approvals of issuances of securities or assumptions of liability by Duke Marshall should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211, 385.214 (2006).

Notice is hereby given that the deadline for filing motions to intervene or protest is December 15, 2006.

Absent a request to be heard in opposition by the deadline above, Duke Marshall is authorized to issue securities and assume obligations or liabilities as guarantor, indorser, surety, or otherwise in respect of any security of another person, provided that such issuance or assumption is for some lawful object within the corporate purposes of Duke Marshall, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approvals of Duke Marshall's issuance of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov*, using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the e-Filing link. The Commission strongly encourages electronic filing.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20820 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER02–302–000]

Duke Energy Murray, LLC; Notice of Issuance of Order

December 1, 2006.

Duke Energy Murray, LLC (Duke Murray) filed an application for market-based rate authority, with an accompanying rate tariff and a code of conduct. The proposed market-based rate tariff provides for the sale of capacity, energy and ancillary services at market-based rates and for the reassignment of transmission capacity. Duke Murray also requested waivers of various Commission regulations. In particular, Duke Murray requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Duke Murray.

On January 11, 2002, pursuant to delegated authority, the Director, Division of Tariffs and Rates—East, granted the requests for blanket approval under Part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approvals of issuances of securities or assumptions of liability by Duke Murray should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211, 385.214 (2006).

Notice is hereby given that the deadline for filing motions to intervene or protest is December 15, 2006.

Absent a request to be heard in opposition by the deadline above, Duke Murray is authorized to issue securities and assume obligations or liabilities as guarantor, indorser, surety, or otherwise in respect of any security of another person, provided that such issuance or assumption is for some lawful object within the corporate purposes of Duke Murray, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approvals of Duke Murray's issuance of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov*, using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the e-Filing link. The Commission strongly encourages electronic filing.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20819 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER02–1024–000, ER02–1024–001]

Duke Energy Sandersville, L.L.C.; Notice of Issuance of Order

December 1, 2006.

Duke Energy Sandersville, L.L.C. (Duke Sandersville) filed an application for market-based rate authority, with an accompanying tariff (market-based rate tariff). The proposed market-based rate tariff provides for the sale of capacity, energy, and/or certain ancillary service at market-based rates and the reassignment of transmission capacity. Duke Sandersville also requested waivers of various Commission

regulations. In particular, Duke Sandersville requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Duke Sandersville.

On April 12, 2002, pursuant to delegated authority, the Director, Division of Tariffs and Rates—East, granted the requests for blanket approval under Part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approvals of issuances of securities or assumptions of liability by Duke Sandersville should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211, 385.214 (2006).

Notice is hereby given that the deadline for filing motions to intervene or protest is December 15, 2006.

Absent a request to be heard in opposition by the deadline above, Duke Sandersville is authorized to issue securities and assume obligations or liabilities as guarantor, indorser, surety, or otherwise in respect of any security of another person, provided that such issuance or assumption is for some lawful object within the corporate purposes of Duke Sandersville, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approvals of Duke Sandersville's issuance of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the e-Filing link. The Commission strongly encourages electronic filing.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20818 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER02–583–000]

Duke Energy Southaven, L.L.C.; Notice of Issuance of Order

December 1, 2006.

Duke Energy Southaven, L.L.C. (Duke Southaven) filed an application for market-based rate authority, with an accompanying rate tariff and code of conduct. The proposed market-based rate schedule provides for sales of capacity, energy, and ancillary services at market-based rates, and for the reassignment of transmission capacity. Duke Southaven also requested waivers of various Commission regulations. In particular, Duke Southaven requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Duke Southaven.

On February 13, 2002, pursuant to delegated authority, the Director, Division of Tariffs and Rates—Central, granted the requests for blanket approval under Part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approvals of issuances of securities or assumptions of liability by Duke Southaven should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211, 385.214 (2006).

Notice is hereby given that the deadline for filing motions to intervene or protest is December 15, 2006.

Absent a request to be heard in opposition by the deadline above, Duke Southaven is authorized to issue securities and assume obligations or liabilities as guarantor, indorser, surety, or otherwise in respect of any security of another person, provided that such issuance or assumption is for some lawful object within the corporate purposes of Duke Southaven, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approvals of Duke Southaven's issuance of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the e-Filing link. The Commission strongly encourages electronic filing.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20821 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ID–5112–000]

Notice of Filing; Eason, Carl R.

November 30, 2006.

Take notice that on November 21, 2006, Vernon N. Brinkley filed an application for authority to hold interlocking positions pursuant to section 305(b) of the Federal Power Act, Part 45 of Title 18 of the Code of Federal Regulations and Commission Order No. 664.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on December 21, 2006.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20813 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER07–31–000]

Endeavor Power Partners, LLC; Notice of Issuance of Order

November 30, 2006.

Endeavor Power Partners, LLC (Endeavor) filed an application for market-based rate authority, with an accompanying rate schedule. The proposed market-based rate schedule provides for the sale of energy, capacity and ancillary services at market-based rates. Endeavor also requested waivers of various Commission regulations. In particular, Endeavor requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by Endeavor.

On November 29, 2006, pursuant to delegated authority, the Director, Division of Tariffs and Market Development—West, granted the request for blanket approval under part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Endeavor should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest is December 29, 2006.

Absent a request to be heard in opposition by the deadline above, Endeavor is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of Endeavor, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approvals of Endeavor's issuance of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20810 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER06–1531–000; ER06–1531–001]

Notice of Issuance of Order; Great Lakes Energy LLC

November 30, 2006.

Great Lakes Energy, LLC (Great Lakes) filed an application for market-based rate authority, with an accompanying rate schedule. The proposed market-based rate schedule provides for the sale of energy, capacity and ancillary services at market-based rates. Great Lakes also requested waivers of various Commission regulations. In particular, Great Lakes requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Great Lakes.

On November 29, 2006, pursuant to delegated authority, the Director, Division of Tariffs and Market Development—West, granted the requests for blanket approval under Part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approvals of issuances of securities or assumptions of liability by Great Lakes should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest is December 29, 2006.

Absent a request to be heard in opposition by the deadline above, Great Lakes is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of Great Lakes, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approvals of Great Lakes' issuance of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the

''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20809 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–2641–000]

High Desert Power Project, LLC; Notice of Issuance of Order

November 30, 2006.

High Desert Power Project, LLC (High Desert) filed an application for market-based rate authority, with an accompanying rate tariff. The proposed market-based rate tariff provides for the sale of energy, capacity and certain ancillary services at market-based rates. High Desert also requested waivers of various Commission regulations. In particular, High Desert requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by High Desert.

On September 18, 2001, pursuant to delegated authority, the Director, Division of Tariffs and Rates—West, granted the requests for blanket approval under part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approvals of issuances of securities or assumptions of liability by High Desert should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest is December 13, 2006.

Absent a request to be heard in opposition by the deadline above, High Desert is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person, provided that such issuance or assumption is for some lawful object within the corporate purposes of High Desert, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approvals of High Desert's issuance of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20815 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Filing

November 30, 2006.

	Docket Nos.
House, Wade C	ID–5100–000
Carter, Calvin P	ID–5101–000
Bowman, M. Johnson	ID–5102–000
Andrew, J. William, Jr	ID–5103–000
Frazier, William C	ID–5104–000
Reasor, Jackson E	ID–5105–000
Garber, Fred C	ID–5106–000
Bradshaw, M. Dale	ID–5107–000
Reynolds, James M	ID–5108–000
Leech, William M., Jr	ID–5109–000
Greenlaw, Hunter R., Jr	ID–5110–000
Brinkley, Vernon N	ID–5111–000

Take notice that on November 16, 2006, the above-captioned applicants filed an application for authority to hold interlocking positions pursuant to section 305(b) of the Federal Power Act, Part 45 of Title 18 of the Code of Federal Regulations and Commission Order No. 664.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on December 18, 2006.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20812 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER06–1516–000; ER06–1516–001]

Notice of Issuance of Order; Mac Trading, Inc.

November 30, 2006.

Mac Trading, Inc. (Mac Trading) filed an application for market-based rate authority, with an accompanying rate schedule. The proposed market-based rate schedule provides for the sale of energy and capacity at market-based rates. Mac Trading also requested waivers of various Commission regulations. In particular, Mac Trading requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Mac Trading.

On November 28, 2006, pursuant to delegated authority, the Director, Division of Tariffs and Market

Development—West, granted the requests for blanket approval under Part 34. The Director's order also stated that the Commission would publish a separate notice in the **Federal Register** establishing a period of time for the filing of protests. Accordingly, any person desiring to be heard or to protest the blanket approvals of issuances of securities or assumptions of liability by Mac Trading should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest is December 28, 2006.

Absent a request to be heard in opposition by the deadline above, Mac Trading is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of Mac Trading, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approvals of Mac Trading's issuance of securities or assumptions of liability.

Copies of the full text of the Director's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20808 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP07–25–000]

Questar Pipeline Company; Notice of Filing

December 1, 2006.

Take notice that on November 21, 2006, Questar Pipeline Company (Questar), 180 East 100 South, Salt Lake City, Utah 84111, filed an abbreviated application pursuant to Section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's Rules and Regulations, seeking authority to expand its interstate natural-gas transmission system by constructing and operating 58.6 miles of 24-inch diameter pipeline and related facilities and modifying two existing compressor stations, known as the Southern System Expansion Project II (SSXP II), located in Carbon, Duchesne and Uintah Counties, Utah. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866)208–3676, or for TTY, contact (202) 502–8659.

The proposed project will enable Questar to transport up to an additional 175,000 decatherms of natural gas per day (Dth/d) from various receipt points on Questar's southern interstate transmission system to Questar's Main Line No. 104 (ML 104) which is interconnected with Kern River Gas Transmission Company (Kern River) at Goshen, Utah. Questar has negotiated transportation service agreements for firm transportation service with seven parties for the entire 175,000 Dth/d with terms varying between 10 and 11½ years. Questar states that the total estimated cost of the proposed project is $107,693,000 and the seven contracting shippers have agreed to pay the existing Southern System Expansion Project monthly reservation charge of $7.82712/Dth per month. Questar proposes to complete the proposed project and makes it available for service by November 1, 2007.

Any questions regarding the application are to be directed to L. Bradley Burton, Manager, Federal Regulatory Affairs, Questar Pipeline Company, 180 East 100 South, P.O. Box 45360, Salt Lake City, Utah 84145–0360; phone number (801) 324–2459.

On March 17, 2006, the Commission staff granted Questar's request to utilize the National Environmental Policy Act (NEPA) Pre-Filing Process and assigned Docket No. PF06–18–000 to staff activities involving SSXP II. Now, as of the filing of this application on November 21, 2006, the NEPA Pre-Filing Process for this project has ended. From this time forward, this proceeding will be conducted in Docket No. CP07–25–000, as noted in the caption of this Notice.

Any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the below listed comment date, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

Persons may also wish to comment further only on the environmental review of this project. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents issued by the Commission, and will be notified of meetings associated with the Commission's environmental review process. Those persons, organizations, and agencies who submitted comments during the NEPA Pre-Filing Process in Docket No. PF06–18–000 are already on the Commission staff's environmental mailing list for the proceeding in the above dockets and may file additional comments on or before the below listed comment date. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, environmental commenters are also not parties to the proceeding and will not receive copies of all documents filed by other parties or non-environmental documents issued by the Commission. Further, they will not have the right to seek court review of any final order by Commission in this proceeding.

Motions to intervene, protests and comments may be filed electronically via the Internet in lieu of paper, see, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Comment Date: December 22, 2006.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20817 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IN05–4–003]

Texas Eastern Transmission, LP; Notice of Compliance Filing

November 30, 2006.

Take notice that on September 22, 2006, Texas Eastern Transmission, LP (Texas Eastern) submitted a supplemental compliance filing pursuant to *Texas Eastern Transmission,* LP, 110 FERC ¶ 61,188 (2005), issued on February 28, 2005, in Docket Nos. IN05–4–000 and PA03–14–000.

Texas Eastern states that copies of the filing were served on all affected customers of Texas Eastern and interested state commissions, as well as all parties on the official service list compiled by the Secretary of the Federal Energy Regulatory Commission in the captioned proceedings.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before the date as indicated below. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on December 7, 2006.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20814 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

November 29, 2006.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC07–25–000.

Applicants: Duquesne Light Holdings, Inc.; DQE Financial Corporation; Montauk Energy Capital, LLC; Monmouth Energy, Inc.; Blue Wolf Holdings LLC.

Description: Duquesne Light Holdings, Inc. et al submit an application for authorization under section 206 of the FPA for Disposition of Jurisdictional Facilities.

Filed Date: 11/22/2006.

Accession Number: 20061128–0036.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG07–15–000.

Applicants: Twin Buttes Wind LLC.

Description: Twin Buttes Wind LLC submits a notice of Self-Certification of an Exempt Wholesale Generator Status located in Portland, Oregon.

Filed Date: 11/22/2006.

Accession Number: 20061122–5041.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER02–2189–004.

Applicants: Southern California Edison Company.

Description: Southern Edison Company submits revised sheets, First Revised Service Agreement 53, First Revised Volume 5, Interconnection Facilities Agreement with Whitewater Hill Wind Partners.

Filed Date: 11/24/2006.

Accession Number: 20061128–0288.

Comment Date: 5 p.m. Eastern Time on Friday, December 15, 2006.

Docket Numbers: ER03–739–001.

Applicants: El Dorado Irrigation District.

Description: El Dorado Irrigation District submits an amendment to its updated market power analysis for the Market Based Rate Authorization.

Filed Date: 11/27/2006.

Accession Number: 20061129–0186.

Comment Date: 5 p.m. Eastern Time on Thursday, December 7, 2006.

Docket Numbers: ER04–7–002.

Applicants: Sierra Pacific Energy, LLP.

Description: Sierra Pacific Energy, LLP submits an amendment to its Triennial Market Power Analysis.

Filed Date: 11/20/2006.

Accession Number: 20061122–0099.

Comment Date: 5 p.m. Eastern Time on Monday, December 11, 2006.

Docket Numbers: ER04–734–001.

Applicants: Barclays Bank PLC.

Description: Barclays Bank PLC submits a non-material change in characteristics that the Commission relied upon in granting their market-based rate authorization on 6/2/04.

Filed Date: 11/24/2006.

Accession Number: 20061128–0304.

Comment Date: 5 p.m. Eastern Time on Friday, December 15, 2006.

Docket Numbers: ER05–1179–007.

Applicants: Berkshire Power Company, LLC.

Description: Berkshire Power Co, LLC submits Substitute Original Sheet 25 et al to Rate Schedule FERC 2 to the Amended and Restated RMR Agreement filed on 10/20/06.

Filed Date: 11/21/2006.

Accession Number: 20061128–0298.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 12, 2006.

Docket Numbers: ER06–1309–001.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool Inc. submits revisions to its Network Integration Transmission Service Agreement w/The Empire District Electric Company.

Filed Date: 11/22/2006.

Accession Number: 20061128–0299.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER06–1360–002.

Applicants: California Independent System Operator Corporation.

Description: The California Independent System Operator Corp

submits a compliance filing, revised Transmission Control Agreement, Rate Schedule 7, pursuant to Commission's 11/13/06 Order.

Filed Date: 11/22/2006.

Accession Number: 20061128–0305.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER06–1399–002.

Applicants: Sunbury Generation LP.

Description: Sunbury Generation, LLC submits an amendment to its Notice of Succession in which it adopts and files its own market based rate tariff, FERC Electric Tariff, Original Volume 1.

Filed Date: 11/24/2006.

Accession Number: 20061128–0302.

Comment Date: 5 p.m. Eastern Time on Friday, December 15, 2006.

Docket Numbers: ER06–1412–001.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc submits proposed revisions to section 43.7 of its OAT&EM Tariff, Third Revised Volume No. 1.

Filed Date: 11/22/2006.

Accession Number: 20061128–0291.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER06–1420–001.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc submits revisions to the Midwest Contingency Reserve Sharing Group Agreement in compliance with the Commission's 10/24/06 Order.

Filed Date: 11/22/2006.

Accession Number: 20061128–0294.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER06–1463–002.

Applicants: Empire District Electric Company.

Description: The Empire District Electric Company submits its First Revised Sheet 12 et al to its Electric Tariff, Original Volume 2, pursuant to the Commission's 10/26/06 Order.

Filed Date: 11/22/2006.

Accession Number: 20061128–0290.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER07–238–000.

Applicants: Consolidated Water Power Company.

Description: Consolidated Water Power Co submits a notice of cancellation and revised rate schedule sheet to terminate the Service Agreement for Wholesale Distribution Service.

Filed Date: 11/20/2006.

Accession Number: 20061124–0085.

Comment Date: 5 p.m. Eastern Time on Monday, December 11, 2006.

Docket Numbers: ER07–241–000.

Applicants: Vermont Transco LLC.

Description: Vermont Transco LLC submits an Amended and Restated Three Party Transmission Agreement, designated as FERC Electric Rate Schedule 5.

Filed Date: 11/22/2006.

Accession Number: 20061128–0308.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER07–242–000.

Applicants: MinnDakota Wind LLC.

Description: MinnDakota Wind, LLC submits an application for initial rate schedule rate, Original Volume No. 1, for market-based rate authority under section 205 of the FPA.

Filed Date: 11/22/2006.

Accession Number: 20061128–0306.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER07–243–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits its Revised Executed Service Agreement for Firm Point-to-Point Transmission Service with Southwestern Public Service Co.

Filed Date: 11/22/2006.

Accession Number: 20061128–0307.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER07–244–000.

Applicants: Raven Three, LLC.

Description: Raven Three, LLC submits an Application for Order Authorizing Market-Based Rates, Certain Waivers, and Blanket Authorizations.

Filed Date: 11/22/2006.

Accession Number: 20061128–0300.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER07–245–000.

Applicants: Raven Two, LLC.

Description: Raven Two, LLC submits an application for order authorizing market-based rates, certain waivers, and blanket authorizations.

Filed Date: 11/22/2006.

Accession Number: 20061128–0292.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER07–246–000.

Applicants: American Electric Power Service Corporation.

Description: Appalachian Power Co et al submits revisions to the Annual Transmission Rates—AEP East Operating Companies for Network Integration Transmission Service, Attachment H014 of the PJM Interconnection LLC's OATT.

Filed Date: 11/22/2006.

Accession Number: 20061128–0309.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER07–247–000.

Applicants: Raven One, LLC.

Description: Raven One, LLC submits an order for authorizing market-based rates, certain waivers and blanket authorizations.

Filed Date: 11/22/2006.

Accession Number: 20061128–0293.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: ER07–248–000.

Applicants: Southern Company Services, Inc.

Description: Southern Company Services, Inc on behalf of Alabama Power Company et al submits a rollover service agreement for long-term firm point-to-point transmission service under its OATT.

Filed Date: 11/24/2006.

Accession Number: 20061128–0303.

Comment Date: 5 p.m. Eastern Time on Friday, December 15, 2006.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH07–6–000.

Applicants: GAMCO Investors, Inc.

Description: GAMCO Investors, Inc. submits a Notification of Exemption pursuant to section 366.3 of the PUCHA 2005.

Filed Date: 11/14/2006.

Accession Number: 20061114–5007.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 5, 2006.

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.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20827 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

November 30, 2006.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC07–26–000.

Applicants: Evergreen Wind Power, LLC.

Description: Evergreen Wind Power, LLC submits an application for authorization of transaction under Section 203 of the Federal Power Act.

Filed Date: 11/22/2006.

Accession Number: 20061130–0121.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 13, 2006.

Docket Numbers: EC07–27–000.

Applicants: Cinergy Capital & Trading, Inc.; Caledonia Power I, LLC; Wood Group Power Solutions, Inc.

Description: Cinergy Capital & Trading, Inc *et al.* submit an application for authorization for disposition of jurisdictional assets pursuant to section 203 of the FPA.

Filed Date: 11/24/2006.

Accession Number: 20061130–0126.

Comment Date: 5 p.m. Eastern Time on Friday, December 15, 2006.

Docket Numbers: EC07–28–000.

Applicants: Cleco Midstream Resources LLC; Attala Transmission LLC; Perryville Energy Holdings LLC; Perryville Energy Partners, L.L.C.; Cleco Corporation.

Description: Cleco Midstream Resources LLC, Attala Transmission LLC, Perryville Energy Holding LLC *et al.* submits an application for authorization for internal corporate reorganization.

Filed Date: 11/27/2006.

Accession Number: 20061130–0083.

Comment Date: 5 p.m. Eastern Time on Monday, December 18, 2006.

Docket Numbers: EC07–29–000.

Applicants: PPM Energy, Inc.; PPM Wind Energy LLC; Aeolus Wind Power III LLC; Big Horn Wind Project LLC; Twin Buttes Wind LLC; Atlantic Renewable Projects II, LLC; Flat Rock Windpower II LLC.

Description: PPM Energy, Inc, PPM Wind Energy, LLC *et al.* submit a joint application for authorization to dispose of jurisdictional facilities, pursuant to section 203 of the FPA.

Filed Date: 11/27/2006.

Accession Number: 20061130–0123.

Comment Date: 5 p.m. Eastern Time on Monday, December 18, 2006.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG07–16–000.

Applicants: Telocaset Wind Power Partners, LLC.

Description: Telocaset Wind Power Partners, LLC submits a notice of Self-Certification of Exempt Wholesale Generator Status located in Union County, Oregon.

Filed Date: 11/28/2006.

Accession Number: 20061128–5012.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 19, 2006.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER07–249–000.

Applicants: Red Shield Environmental, L.L.C.

Description: Red Shield Environmental LLC submits a request for expedited consideration and temporary waiver of Definition of Settlement Only Resource Under Market Rule I *et al.*

Filed Date: 11/27/2006.

Accession Number: 20061130–0084.

Comment Date: 5 p.m. Eastern Time on Thursday, December 7, 2006.

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.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20828 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF06–13–000]

Downeast LNG, Inc.; Supplemental Notice of Intent To Prepare an Environmental Impact Statement for the Downeast LNG Project and Request for Comments on Environmental Issues Related to the Potential Expansion of the Maritimes & Northeast Pipeline System

December 1, 2006.

The Federal Energy Regulatory Commission (FERC or Commission) is in the process of evaluating the Downeast Liquefied Natural Gas (LNG) Project planned by Downeast LNG, Inc. (Downeast). The project would consist of an onshore LNG import and storage terminal, located on the south side of Mill Cove in the Town of Robbinston, near the confluence of Passamaquoddy Bay and the St. Croix River, in Washington County, Maine; and an approximately 31-mile-long natural gas sendout pipeline. The Downeast LNG Project would be designed to have a maximum sendout capacity of 625 million cubic feet of natural gas per day.

The proposed sendout pipeline operated by Downeast LNG would transport natural gas from the LNG terminal to an interconnect point with Maritimes & Northeast Pipeline L.L.C.'s (M&NE) existing pipeline system near the town of Baileyville, Maine. The M&NE system currently does not have sufficient capacity to transport the natural gas that would be supplied by the Downeast pipeline. Therefore, if the Downeast LNG Project is authorized and placed into service, M&NE's system would need to be modified or expanded in Maine, New Hampshire, and Massachusetts.

This Supplemental Notice of Intent (NOI) discloses the potential facilities that would likely be required to expand M&NE's system, based on information provided to Downeast by M&NE, and requests comments regarding the possible environmental impact of those facilities. Although M&NE is not proposing to construct these facilities and does not have an application before the FERC, it has been determined that these expanded M&NE facilities are likely a necessary part of the project and that an analysis of the impacts of these facilities will be included in the EIS being prepared for the Downeast LNG facility.

A map depicting the expansion of the M&NE facilities downstream of the interconnection with Downeast is included in Appendix 1. The following facilities have been identified by M&NE as necessary to accommodate the gas volumes to be delivered by Downeast LNG.

Pipeline Looping

Approximately 130.9 miles of 36-inch-diameter pipeline looping would likely be required within or adjacent to the existing M&NE right-of-way or other nearby utility or road rights-of-way, as follows:

- Eliot Loop—approximately 3.4 miles from Newington in Rockingham County, New Hampshire to Eliot in York County, Maine;
- Westbrook Loop—approximately 16.5 miles from Saco in York County, Maine to Westbrook in Cumberland County, Maine;
- Richmond Loop—approximately 27.6 miles from Pownal in Cumberland County, Maine to Richmond in Sagadahoc County, Maine;
- Searsmont Loop—approximately 19.7 miles from Windsor in Kennebec County, Maine and Searsmont in Waldo County, Maine;
- Brewer Loop—approximately 21.9 miles from Monroe in Waldo County, Maine to Brewer in Penobscot County, Maine;
- Woodchopping Ridge Loop—approximately 22.2 miles from Greenfield in Penobscot County, Maine to Township T35 MD in Hancock County, Maine; and
- Baileyville Loop—approximately 19.6 miles from Township T37 MD BPP in Washington County, Maine to the Baileyville Compressor Station in Washington County, Maine.

The potential pipeline loops would generally be adjacent to the existing mainline; however, the exact side that the loop would be located on varies due to numerous crossovers throughout the looping.

Compressor Station Facilities [1]

Compression requirements for the pipeline expansion would likely include adding compression to six existing compressor stations and the construction of one new compressor station as follows:

- Eliot Compressor Station—install a Solar Titan 130 natural gas-driven turbine compressor;
- Westbrook Compressor Station—install a Solar Taurus 70 natural gas-driven turbine compressor;
- Richmond Compressor Station—install a Solar Mars 100 natural gas driven turbine compressor;
- Searsmont Compressor Station—install a Solar Taurus 70 natural gas-driven turbine compressor;
- Brewer Compressor Station—install a Solar Taurus 70 natural gas-driven turbine compressor;
- Woodchopping Ridge Compressor Station—install a Solar Taurus 70 natural gas-driven turbine compressor; and
- A new compressor station located in the City of Methuen, Middlesex County, Massachusetts. This facility would involve the installation of a Solar Taurus 70 natural gas-driven turbine compressor.

By this notice, the Commission specifically requests comments only on these additional M&NE facilities. Your input will help identify the issues that need to be evaluated in the EIS. Comments on the project should be submitted in written form. Further details on how to submit written comments are provided in the Public Participation section below. Please note that comments are due by January 5, 2007.

This NOI is being sent to Federal, State, and local government agencies; elected officials; environmental and public interest groups; Indian tribes; and local libraries and newspapers. We encourage them to comment on their areas of concern.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the M&NE expansion. By becoming a commentor, your concerns will be addressed in the EIS and considered by the Commission. Your comments should focus on the potential environmental effects, reasonable alternatives (including alternative facility sites and pipeline routes), and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please follow these instructions:

- Send an original and two copies of your letter to: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426.
- Label one copy of your comments for the attention of OEP/DG2E/Gas Branch 3.

[1] The Eliot, Westbrook, Searsmont, Brewer, and Woodchopping Compressor Stations are to be constructed as part of the M&NE Phase IV Project that is currently being evaluated by FERC and other cooperating agencies under Docket Number CP06–335–000. This NOI assumes that the facilities in the Phase IV Project are approved and constructed prior to the construction of the M&NE expansion facilities discussed in this NOI.

• Reference Docket No. PF06–13–000 on the original and both copies.

• Mail your comments so that they will be received in Washington, DC on or before January 5, 2006.

The Commission strongly encourages electronic filing of any comments in response to this NOI. For information on electronically filing comments, please see the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link and the link to the User's Guide as well as information in 18 CFR 385.2001(a)(1)(iii). Before you can file comments, you will need to create a free account, which can be accomplished online.

Once Downeast formally files its application with the Commission, you may want to become an ''intervenor,'' which is an official party to the proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in a Commission proceeding by filing a request to intervene. Instructions for becoming an intervenor are included in the User's Guide under the ''e-filing'' link on the Commission's Web site. Please note that you may *not* request intervenor status at this time. You must wait until a formal application is filed with the Commission.

Environmental Mailing List

If you wish to be added to the Downeast LNG environmental mailing list, please return the attached Mailing List Retention Form (Appendix 2 of this NOI). Also, indicate on the form your preference for receiving a paper version of the EIS in lieu of an electronic version of the EIS on CD–ROM. If you do not return this form, we will not add your name to our mailing list.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC (3372) or on the FERC Internet Web site (*http://www.ferc.gov*) using the ''eLibrary link.'' Click on the eLibrary link, select ''General Search'' and enter the project docket number excluding the last three digits (*i.e.*, PF06–13) in the ''Docket Number'' field. Be sure you have selected an appropriate date range. For assistance with eLibrary, the eLibrary helpline can be reached at 1–866–208–3676, TTY (202) 502–8659, or by e-mail at *FercOnlineSupport@ferc.gov.* The eLibrary link on the FERC Internet Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the FERC now offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. To register for this service, go to *http://www.ferc.gov/esubscribenow.htm.*

Public meetings or site visits will be posted on the Commission's calendar located at *http://www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Finally, Downeast has established an Internet Web site for this project at *http://www.downeastlng.com/index.htm.* The Web site includes a project overview, status, potential impacts and mitigation, and answers to frequently asked questions. You can also request additional information by calling Downeast directly at 207–214–5926.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20816 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF06–11–000]

Quoddy Bay LNG, L.L.C.; Supplemental Notice of Intent To Prepare an Environmental Impact Statement for the Quoddy Bay LNG Project and Request for Comments on Environmental Issues Related to the Potential Expansion of the Maritimes & Northeast Pipeline System

December 1, 2006.

The Federal Energy Regulatory Commission (FERC or Commission) is in the process of evaluating the Quoddy Bay Liquefied Natural Gas (LNG) Project planned by Quoddy Bay LNG, L.L.C. (Quoddy Bay). The project would consist of an onshore LNG import terminal located on the Pleasant Point Reservation in Washington County, Maine on the western shore of the Passamaquoddy Bay; a storage facility located in Perry, Maine; and an approximately 35.8-mile-long 36-inch-diameter natural gas sendout pipeline. The Quoddy Bay LNG Project would be designed to have a maximum sendout capacity of 2.0 billion cubic feet of natural gas per day.

The proposed sendout pipeline operated by Quoddy Bay would transport natural gas from the LNG terminal to an interconnect point with the Maritimes & Northeast Pipeline L.L.C.'s (M&NE) existing pipeline system near the town of Princeton, Maine. The M&NE system currently does not have sufficient capacity to transport the natural gas that would be supplied by the Quoddy Bay pipeline. Therefore, if the Quoddy Bay LNG Project is authorized and placed into service, M&NE would need to be modified or expanded in Maine, New Hampshire, and Massachusetts.

This Supplemental Notice of Intent (NOI) discloses the potential facilities that would likely be required to expand M&NE's system, based on information provided to Quoddy Bay by M&NE, and requests comments regarding the possible environmental impact of those facilities. Although M&NE is not proposing to construct these facilities and does not have an application before the FERC, it has been determined that the M&NE facilities are likely a necessary part of the project and that an analysis of the impacts of these facilities will be included in the EIS being prepared for the Quoddy Bay LNG facility.

A map depicting the expansion of the M&NE facilities downstream of the interconnection with Quoddy Bay is included in Appendix 1. The following facilities have been identified by M&NE as necessary to accommodate the gas volumes to be delivered by Quoddy Bay LNG.

Pipeline Looping

Approximately 297.2 miles of 36-inch-diameter pipeline looping would likely be installed within or adjacent to the existing M&NE and Joint Mainline right-of-way or other nearby utility or road rights-of-way, as follows:

• Eliot Loop—approximately 46.3 miles from Methuen, Essex County, Massachusetts to Eliot, York County, Maine;

• Westbrook Loop—approximately 50.1 miles from South Berwick, Cumberland County, Maine to Westbrook, Cumberland County, Maine;

• Richmond Loop—approximately 45.9 miles from Westbrook, Cumberland County, Maine to Richmond, Sagadahoc County, Maine;

• Searsmont Loop—approximately 38.1 miles from Richmond, Sagadahoc County, Maine to Searsmont, Waldo County, Maine;

• Brewer Loop—approximately 40.2 miles from Searsmont, Hancock County,

Maine to Brewer, Penobscot County, Maine;

• Woodchopping Ridge Loop—approximately 40.4 miles from Brewer, Penobscot County, Maine to Township T35 MD, Hancock County, Maine; and

• Baileyville Loop—approximately 36.2 miles from Township T35 MD BPP, Washington County, Maine to milepost (MP) 302.2 on the M&NE System.

The potential pipeline loops would generally be adjacent to the existing mainline; however, the exact side that the loop would be located on varies due to numerous crossovers throughout the looping.

Compressor Station Facilities [1]

Compression requirements for the pipeline expansion would likely include adding compression to six existing compressor stations as follows:

• Eliot Compressor Station (MP 51.2)—Install two Titan 130 natural gas-driven turbine compressors;

• Westbrook Compressor Station (MP 101.5)—Install two Mars 100 natural gas-driven turbine compressors;

• Richmond Compressor Station (MP 147.3)—Install a Titan 130 natural gas-driven turbine compressor;

• Searsmont Compressor Station (MP 185.5)—Install a Titan 130 natural gas-driven turbine compressor;

• Brewer Compressor Station (MP 225.8)—Install a Titan 130 natural gas driven turbine compressor; and

• Woodchopping Ridge Compressor Station (MP 266.1)—Install a Titan 130 natural gas-driven turbine compressor.

By this notice, the Commission specifically requests comments only on these additional M&NE facilities. Your input will help identify the issues that need to be evaluated in the EIS. Comments on the project should be submitted in written form. Further details on how to submit written comments are provided in the Public Participation section of this NOI. Please note that comments are due by January 5, 2006.

This NOI is being sent to Federal, State, and local government agencies; elected officials; environmental and public interest groups; and Indian tribes; and local libraries and newspapers. We encourage them to comment on their areas of concern.

[1] The Eliot, Westbrook, Searsmont, Brewer and Woodchopping Compressor Stations are to be constructed as part of M&NE Phase IV Project that is currently being evaluated by FERC and other cooperating agencies under Docket Number CP06–335–000. This NOI assumes that the facilities in the Phase IV Project are approved and constructed prior to the construction of the M&NE expansion facilities discussed in this NOI.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the M&NE expansion. By becoming a commentor, your concerns will be addressed in the EIS and considered by the Commission. Your comments should focus on the potential environmental effects, reasonable alternatives (including alternative facility sites and pipeline routes), and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please follow these instructions:

• Send an original and two copies of your letter to: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426.

• Label one copy of your comments for the attention of OEP/DG2E/Gas Branch 1.

• Reference Docket No. PF06–11–000 on the original and both copies.

• Mail your comments so that they will be received in Washington, DC on or before January 5, 2006.

The Commission strongly encourages electronic filing of any comments in response to this NOI. For information on electronically filing comments, please see the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link and the link to the User's Guide as well as information in 18 CFR 385.2001(a)(1)(iii). Before you can file comments, you will need to create a free account, which can be accomplished on-line.

Once Quoddy Bay formally files its application with the Commission, you may want to become an ''intervenor,'' which is an official party to the proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in a Commission proceeding by filing a request to intervene. Instructions for becoming an intervenor are included in the User's Guide under the ''e-filing'' link on the Commission's Web site. Please note that you may *not* request intervenor status at this time. You must wait until a formal application is filed with the Commission.

Environmental Mailing List

If you wish to be added to the Quoddy Bay LNG environmental mailing list, please return the attached Mailing List Retention Form (Appendix 2 of this NOI). Also, indicate on the form your preference for receiving a paper version of the EIS in lieu of an electronic version of the EIS on CD–ROM. If you do not return this form, we will not add your name to our mailing list.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC (3372) or on the FERC Internet Web site (*http://www.ferc.gov*) using the ''eLibrary link.'' Click on the eLibrary link, select ''General Search'' and enter the project docket number excluding the last three digits (i.e., PF06–11) in the ''Docket Number'' field. Be sure you have selected an appropriate date range. For assistance with eLibrary, the eLibrary helpline can be reached at 1–866–208–3676, TTY (202) 502–8659, or by e-mail at *FercOnlineSupport@ferc.gov.* The eLibrary link on the FERC Internet Web site also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

In addition, the FERC now offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. To register for this service, go to *http://www.ferc.gov/esubscribenow.htm.*

Public meetings or site visits will be posted on the Commission's calendar located at *http://www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Finally, Quoddy Bay L.L.C. LNG has established an Internet Web site for this project at *http://www.quoddylng.com.* The Web site includes a project overview, status, and answers to frequently asked questions. You can also request additional information by calling Quoddy Bay LNG at 207–853–6631, or by e-mail at *ABarstow@quoddylng.com.*

Magalie R. Salas,

Secretary.

[FR Doc. E6–20825 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP07–017–000]

Southern Star Central Gas Pipeline, Inc.; Notice of Intent To Prepare an Environmental Assessment for the Proposed Piqua Natural Gas Storage Field Expansion and Well Abandonment Project and Request for Comments on Environmental Issues

December 1, 2006.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Piqua Natural Gas Storage Field Expansion and Well Abandonment Project proposed by Southern Star Central Gas Pipeline, Inc. (Southern Star) in Allen and Woodson Counties, Kansas.[1] Southern Star proposes to increase the storage boundary and buffer zone of the Piqua Storage Field by approximately 480 acres, and to permanently abandon 13 injection/withdrawal wells within the Piqua Storage Field. This EA will be used by the Commission in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the public comment period that will be used to gather environmental input from the public and interested agencies on the project. Comments are requested by January 6, 2007.

With this notice, the FERC staff is asking other federal, state, local and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues to cooperate with us in the preparation of the EA. These agencies may choose to participate once they have evaluated Southern Star's proposal relative to their responsibilities. Agencies that would like to request cooperating status should follow the instructions for filing comments described in Appendix 1.

If you are a landowner receiving this notice, you may be contacted by a company representative about the acquisition of an easement related to the storage field expansion and/or well abandonment activities, as proposed in this project. The company would seek to negotiate a mutually acceptable agreement. However, if the project is approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the company could initiate condemnation proceedings in accordance with state law.

A brochure prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is available for viewing on the FERC Web site at *www.ferc.gov.* This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Summary of the Proposed Project

Southern Star seeks authority to increase the certificated storage boundary and buffer zone of the Piqua Storage Field. In addition, they propose to redefine the cap rock for the gas storage formation as the interval from the base of the Fort Scott Limestone to the top of the Pawnee Limestone. The proposed geographic expansion and cap rock redefinition of the gas storage field would protect the integrity of the field and the current geologic confining layer by preventing future gas migration issues that may result from outside shallow oil operators drilling near the field.

Southern Star also requests abandonment authority to permanently plug and abandon 13 injection/withdrawal wells located within the storage field. These wells have been identified to exhibit poor deliverability and/or mechanical risk. Therefore, the permanent plugging and abandonment of these wells would allow Piqua Storage Field to operate more efficiently.

The general location of the project area is shown in Appendix 2.[2]

Land Requirements

As discussed above, approximately 480 acres would be acquired by Southern Star to increase the certificated storage boundary and to redefine the cap rock of the Piqua Storage Field. The acquisition is located at the eastern edge of the current storage field boundary in Allen County, Kansas.

A total of approximately 15.5 acres of land would be temporarily affected by the abandonment activities of the proposed project and includes a construction area of 200 feet by 200 feet for each well. About 11.7 acres of this land would be required as temporary workspace in completing well abandonment activities. Access to each well would be obtained by use of existing, unimproved field roads.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us[3] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping''. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this Notice of Intent, the Commission staff requests public comments on the scope of the issues to address in the EA. All comments received are considered during the preparation of the EA. State and local government representatives are encouraged to notify their constituents of this proposed action and encourage them to comment on their areas of concern.

Our independent analysis of the issues will be in the EA. Depending on the comments received during the scoping process, the EA may be published and mailed to federal, state and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries and the Commission's official service list for this proceeding. A comment period will be allotted for review, if the EA is published. We will consider all comments on the EA before we make our recommendations to the Commission.

Currently Identified Environmental Issues

In the EA, we will discuss impacts that could occur as a result of the construction and abandonment activities of the proposed project. We will also evaluate reasonable alternatives to the proposed project or portions of the project.

One environmental issue we have already identified that we think deserves attention based on a preliminary review of the proposed facilities and the environmental information provided by Southern Star is the Conservation Reserve Program

[1] Southern Star's application was filed with the Commission under section 7 of the Natural Gas Act and Part 157 of the Commission's regulations.

[2] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies of all appendices, other than Appendix 2 (map), are available on the Commission's Web site at the ''eLibrary'' link or from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary refer to the last page of this notice. Copies of the appendices were sent to all those receiving this notice in the mail.

[3] ''We'', ''us'', and ''our'' refer to the environmental staff of the Office of Energy Projects (OEP).

(CRP) land located within the project area. Approximately 3.6 acres of the total land affected by the project is designated as CRP land and would be temporarily impacted by the project's well abandonment activities. Additional issues may be identified based on your comments and our analysis.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. By becoming a commentor, your concerns will be addressed in the EA and considered by the Commission. You should focus on the potential environmental effects of the proposal, alternatives to the proposal (including alternative locations), and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be in completing our environmental analysis. Please carefully follow the instructions below to ensure that your comments are received in time and properly recorded:

• Send an original and two copies of your letter to: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First St., NE., Room 1A, Washington, DC 20426.

• Label one copy of the comments for the attention of Gas Branch 3.

• Reference Docket No. CP07–017–000.

• Mail your comments so that they will be received in Washington, DC on or before January 6, 2007.

The Commission strongly encourages electronic filing of comments. Please refer to 18 Code of Federal Regulations (CFR) 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link and the link to the User's Guide. Prepare your submission in the same manner as you would if filing on paper and save it to a file on your hard drive. Before you can file comments, you will need to create an account by clicking on ''Login to File'' and then ''New User Account.'' You will be asked to select the type of filing you are making. This filing is considered a ''Comment on Filing.''

The determination of whether to distribute the EA for public comment will be based on the response to this notice. If you are interested in receiving a copy of the EA, please return the Information Request form (Appendix 3). An effort is being made to send this notice to all individuals affected by the proposed project. This includes all landowners whose property may be used temporarily for project purposes, or is in the area of new storage fields or proposed expansions of storage fields including any applicable buffer zone.

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an official party to the proceeding, or ''intervenor.'' To become an intervenor, you must file a motion to intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214). Intervenors have the right to seek rehearing of the Commission's decision. Motions to Intervene should be electronically submitted using the Commission's eFiling system at *http://www.ferc.gov*. Persons without Internet access should send an original and 14 copies of their motion to the Secretary of the Commission at the address indicated previously. Persons filing Motions to Intervene on or before the comment deadline indicated above must send a copy of the motion to the Applicant. All filings, including late interventions, submitted after the comment deadline must be served on the Applicant and all other intervenors identified on the Commission's service list for this proceeding. Persons on the service list with e-mail addresses may be served electronically; others must be served a hard copy of the filing.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your environmental comments considered.

Environmental Mailing List

If you wish to remain on our environmental mailing list, please return the Information Request form included in Appendix 3. If you do not return this form, you will be removed from our mailing list.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at 1–866–208–FERC or on the FERC Internet Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number excluding the last three digits in the Docket Number field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries and direct links to the documents. Go to *www.ferc.gov/esubscribenow.htm*.

Finally, public meetings or site visits will be posted on the Commission's calendar located at *http://www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20826 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12470–001]

Notice of Application Accepted for Filing and Soliciting Motions To Intervene and Protests

November 30, 2006.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Original Major License.

b. *Project No.:* 12470–001.

c. *Date Filed:* July 26, 2006.

d. *Applicant:* City of Broken Bow, Oklahoma.

e. *Name of Project:* Broken Bow Re-Regulation Dam Hydropower Project.

f. *Location:* On the Mountain Fork River in McCurtain County, Oklahoma. The project would be located at the United States Army Corps of Engineers' (Corps) Broken Bow Re-Regulation Dam and would occupy lands administered by the Corps.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791 (a)–825(r).

h. *Applicant Contact:* Olen Hill, City Manager, City of Broken Bow, Oklahoma, 210 North Broadway, Broken Bow, Oklahoma 74728; (405) 584–2282.

i. *FERC Contact:* Peter Leitzke at (202) 502–6059, or *peter.leitzke@ferc.gov.*

j. *Deadline for filing motions to intervene and protests:* February 5, 2007.

All documents (original and eight copies) should be filed with: Magalie R.

Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice and Procedures require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Motions to intervene and protests may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filing. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

k. This application has been accepted for filing, but is not ready for environmental analysis at this time.

l. *Description of Project:* The proposed run-of-river project, using the Corps' existing Broken Bow Re-Regulation Dam and Reservoir, would consist of: (1) Three 93.5-foot-long penstocks connecting to; (2) a 112-foot-wide by 129-foot-long powerhouse containing three turbine-generator units and having a total installed capacity of 4 megawatts; (3) a tailrace returning flows to the Mountain Fork River; (4) a 1,600-foot-long, 13.8-kilovolt transmission line or a 3.5-mile-long, 13.8 kilovolt transmission line; and (5) appurtenant facilities. The project would have an average annual generation of 17,450 megawatt-hours.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field (P–12470), to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

You may also register online at *http://www.ferc.gov/esubscribenow.htm* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified deadline date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file a competing development application no later than 120 days after the specified deadline date for the particular application. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

When the application is ready for environmental analysis, the Commission will issue a public notice requesting comments, recommendations, terms and conditions, or prescriptions.

All filings must: (1) Bear in all capital letters the title ''PROTEST'' or ''MOTION TO INTERVENE,'' ''NOTICE OF INTENT TO FILE COMPETING APPLICATION,'' or ''COMPETING APPLICATION;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

o. *Procedural schedule:* The application will be processed according to the following revised Hydro Licensing Schedule. Revisions to the schedule will be made if the Commission determines it necessary to do so:

Action	Tentative date
Issue Scoping Document for comments.	January 2007.
Notice that application is ready for environmental analysis.	April 2007.
Notice of the availability of the draft EA.	October 2007.
Notice of the availability of the final EA (if necessary).	April 2008.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20807 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

December 1, 2006.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12752–000.

c. *Date filed:* November 22, 2006.

d. *Applicant:* AquaEnergy Group Ltd.

e. *Name of Project:* Coos County Offshore Wave Energy Project.

f. *Location:* The project would be located in the Pacific Ocean off the coast of Coos County, Oregon, southwest of the City of Bandon.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contacts:* Ms. Alla Weinstein, President, AquaEnergy Group, Ltd., P.O. Box 1267, Mercer Island, WA 98040, phone: (425)–430–7924, fax: (425)–988–1977, or e-mail address: *allawa@aeg-ltd.com.*

i. *FERC Contact:* Chris Yeakel, (202) 502–8132.

j. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of: (1) 200–300 wave-energy conversion buoys with a generating capacity of 200 kilowatts to 1 megawatt each consisting of; (2) integrated generators; (3) anchoring devices; and (4) interconnection transmission lines. The anticipated annual generation of the project will be approximately 175 gigawatt-hours.

l. *Locations of Applications:* A copy of the application is available for inspection and reproduction at the Commission in the Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Competing Preliminary Permit*—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

o. *Competing Development Application*—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

p. *Notice of Intent*—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

q. *Proposed Scope of Studies under Permit*—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

r. *Comments, Protests, or Motions To Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *See* 18 CFR 385.2001 (a)(1)(iii) and the instructions on the Commission's Web site under ''e-filing'' link. The Commission strongly encourages electronic filing.

s. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'',''COMPETING APPLICATION'' or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

t. *Agency Comments*—Federal, State, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20822 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Non-Project Use of Project Lands and Waters and Soliciting Comments, Motions To Intervene, and Protests

December 1, 2006.

a. *Type of Application:* Application for non-project use of project lands and waters.

b. *Project Number:* P–2055–039.

c. *Date Filed:* November 17, 2006.

d. *Applicant:* Idaho Power Company.

e. *Name of Project:* C.J. Strike Hydroelectric Project.

f. *Location:* The project is located on the Snake River in Owyhee County, Idaho.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. § §791 (a) 825(r) and § §799 and 801.

h. *Applicant Contact:* Mr. L. Lewis Wardle, Idaho Power Company, 1221 West Idaho Street, Boise, ID 83707, phone: (208) 388–2964.

i. *FERC Contact:* Any questions on this notice should be addressed to Chris Yeakel at (202) 502–8132, or e-mail address: *christopher.yeakel@ferc.gov.*

j. *Deadline for filing comments and or motions:* December 29, 2006.

k. *Description of Application:* The licensee proposes to issue a special use permit to Mr. Dale Hooley for the use of less than one acre of land within the project boundary of the C.J. Strike Project for the construction, maintenance, and use of an irrigation pumping station and buried pipeline, and the necessary ingress and egress. The proposed pumping station will consist of: (1) A concrete box 8 feet square by 13 feet deep with a metal grate opening; (2) a pump station cover; (3) an inlet canal 35 feet in length by 8

feet wide and 13 feet deep; (4) an underground irrigation pipeline approximately 750 feet long; and (5) the necessary ingress and egress. The proposed pumping station will divert 1.96 million gallons of water per day.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field (p–2055) to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers (p–2055–039). All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

q. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20823 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

December 1, 2006.

a. *Type of Application:* Application for Amendment of Article 432 (Recreation Plan).

b. *Project Number:* P–2496–153.

c. *Date Filed:* November 13, 2006.

d. *Applicant:* Eugene Water & Electric Board.

e. *Name of Project:* Leaburg-Walterville Hydroelectric Project No. 2496.

f. *Location:* The project is located on the McKenzie River in Lane County, Oregon.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r) and §§ 799 and 801.

h. *Applicant Contact:* Ms. Suzanne Pearce, Compliance Manager, Eugene Water & Electric Board, 500 East 4th Avenue, P.O. Box 10148, Eugene, OR 97440, phone: (541) 984–4719, e-mail address: *Suzanne.Pearce@EWEB.Eugene.OR.US.*

i. *FERC Contact:* Any questions on this notice should be addressed to Chris Yeakel at (202) 502–8132, or e-mail address: *christopher.yeakel@ferc.gov.*

j. *Deadline for filing comments and or motions:* December 29, 2006.

k. *Description of Request:* The licensee proposes to withdraw from the recreation plan the plans to construct a new boat landing, or improve the existing Ikes Landing, in the vicinity of Leaburg Lake due to difficulty identifying a suitable location, high costs, and a less than expected increase in lake level. The licensee further proposes to relocate the approved access trail to the Leaburg powerhouse overlook from the east side to the west side of the Leaburg power canal.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field (p–2496) to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers (p–2496–153). All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any

motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *Agency Comments*—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

q. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link.

Magalie R. Salas,

Secretary.

[FR Doc. E6–20824 Filed 12–7–06; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6681–9]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at 202–564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 7, 2006 (71 FR 17845).

Draft EISs

EIS No. 20060375, ERP No. D–FHW–J40261–MT, Miller Creek Road Project, To Provide Safe and Improved Access between US 93 and the Miller Creek Area, Missoula County, MT.

Summary: EPA does not object to the proposed project. Rating LO.

EIS No. 20060408, ERP No. D–FAA–G51029–NM, Taos Regional Airport (SKX) Airport Layout Plan Improvements, Construction and Operation, Town of Taos, Taos County, NM.

Summary: EPA does not object to the proposed action. Rating LO.

EIS No. 20060412, ERP No. D–FTA–H40190–MO, Branson Transit Study, Proposed Alternatives Analysis selection, Transit Improvements, City of Branson, Taney County, MO.

Summary: EPA does not object to the proposed project. However, EPA recommends an analysis of potential air impacts on a nearby Class I area and a cumulative impact analysis of development in the area be included in the FEIS. Rating LO.

Final EISs

EIS No. 20060306, ERP No. F–FHW–E40800–FL, Indian Street Bridge PD&E Study, New Bridge Crossing of the South Fork of the St. Lucie River County Road 714 (Martin Highway)/SW 36th Street/Indian Street from Florida's Turnpike to East of Willoughby Boulevard, Martin County, FL.

Summary: EPA continues to have environmental concerns about impacts to wetlands and water quality.

EIS No. 20060388, ERP No. F–NOA–B91026–ME, Atlantic Herring Fishery Management Plan (FWP), Amendment 1, Management Measure Adjustment, Implementation, Gulf of Maine, George Bank, ME.

Summary: No formal comment letter was sent to the preparing agency.

EIS No. 20060410, ERP No. F–AFS–J65458–00, Wasatch-Cache National Forest Noxious Weed Treatment Program, Proposes to Treat Noxious Weeds 1.2 Million Acres of Wilderness and Non-Wilderness Areas, several counties, UT and Uinta County, WY.

Summary: EPA continues to have environmental concerns about the monitoring plan and adaptive management program. The monitoring plan should include components that will assess monitor adverse impacts to water quality and affects of herbicide applications on non-targeted plant species.

EIS No. 20060422, ERP No. F–FHW–G40188–LA, I–49 South Wax Lake Outlet to Berwick Route US–90, Transportation Improvements, Funding and Right-of-Way Acquisition, St. Mary Parish, LA.

Summary: No formal comment letter was sent to the preparing agency.

EIS No. 20060426, ERP No. F–AFS–J65466–00, North Zone Range 05 Project, Reauthorizing Livestock Grazing on Eight Existing Allotments, Black Hill National Forest, Bearlodge and Northern Hills Ranger Districts, Crook County, WY and Lawrence County, SD.

Summary: The FEIS addressed EPA's concerns; therefore, EPA does not object to the proposed action.

EIS No. 20060446, ERP No. F–COE–G32059–LA, Port of Iberia Project, To Determine the Feasibility of Deepening the Existing Navigation Channels between the POI and the Gulf of Mexico, Portions of the Gulf Intracoastal Waterway (GIWW) and Freshwater Bayou (FWB), LA.

Summary: No formal comment letter was sent to the preparing agency.

Dated: December 5, 2006.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E6–20892 Filed 12–7–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL–6681–8]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 11/27/2006 Through 12/01/2006.

Pursuant to 40 CFR 1506.9.

EIS No. 20060499, Final EIS, COE, AR, Bayou Meto Basin, Arkansas General Reevaluation Project, Address Waterfowl Management, Water Supply and Flood Control Strategies, Located in Portions of Lonoke, Prairie, Jefferson, Arkansas and Pulaski Counties, AR, Wait Period Ends: 01/09/2007, Contact: Mark Smith 1–800–317–4156 Ext. 6070.

EIS No. 20060498, Draft EIS, COE, CA, Rio del Oro Specific Plan Project, To Establish a Development Framework for Land Use, Resource Protection, Circulation, Public Utilities and Services, City of Rancho Cordova, Sacramento County, CA, Comment Period Ends: 02/05/2007, Contact: Anna Sutton 916–557–7759.

EIS No. 20060500, Draft EIS, AFS, CA, Little Doe and Low Gulch Timber Sale Project, Proposes to Harvest Commercial Timber, Six Rivers National Forest, Mad River Ranger District, Trinity County, CA, Comment Period Ends: 01/22/2007, Contact: Ruben Escatell 707–574–6233.

Amended Notices

EIS No. 20060493, Draft EIS, IBR, CA, Folsom Dam Safety and Flood

Damage Reduction Project, Addressing Hydrologic, Seismic, Static, and Flood Management Issues, Sacramento, El Dorado and Placer Counties, CA, Comment Period Ends: 01/22/2007, Contact: Shawn Oliver 916–989–7256 Revision of FR Notice Published on 12/01/2006: Correction to Comment Period from 1/16/2007 to 01/22/2007.

Dated: December 5, 2006.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. E6–20894 Filed 12–7–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2006–0979; FRL–8253–5]

Board of Scientific Counselors, Safe Pesticides/Safe Products (SP2) Subcommittee Meetings—Winter 2007

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92–463, the Environmental Protection Agency, Office of Research and Development (ORD), gives notice of three meetings of the Board of Scientific Counselors (BOSC) Safe Pesticides/Safe Products (SP2) Subcommittee.

DATES: Two conference call meetings will be held on: (1) Wednesday, January 17, 2007 from 12 p.m. to 2 p.m., and (2) Monday, January 29, 2007 from 12 p.m. to 2 p.m. One face-to-face meeting will begin on Wednesday, February 7, 2007 (8 a.m. to 5 p.m.), and conclude on Friday, February 9, 2007 (8:30 a.m. to 12 p.m.). All times noted are eastern standard time. The meetings may adjourn early if all business is finished.

Requests for the draft agenda or for making oral presentations at the meeting will be accepted up to 1 business day before the meeting.

ADDRESSES: The face-to-face meeting will be held at the EPA's RTP Main Campus Facility, 109 T.W. Alexander Drive, Research Triangle Park, North Carolina 27711. Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2006–0979, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail:* Send comments by electronic mail (e-mail) to: *ORD.Docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2006–0979.
- *Fax:* Fax comments to: (202) 566–0224, Attention Docket ID No. EPA–HQ–ORD–2006–0979.
- *Mail:* Send comments by mail to: Board of Scientific Counselors, Safe Pesticides/Safe Products (SP2) Subcommittee Meetings—Winter 2007 Docket, Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. EPA–HQ–ORD–2006–0979.
- *Hand Delivery or Courier.* Deliver comments to: EPA Docket Center (EPA/DC), Room B102, EPA West Building, 1301 Constitution Avenue, NW., Washington, DC, Attention Docket ID No. EPA–HQ–ORD–2006–0979.

Note: This is not a mailing address. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–ORD–2006–0979. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Board of Scientific Counselors, Safe Pesticides/Safe Products (SP2) Subcommittee Meetings—Winter 2007 Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the ORD Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer via mail at: Heather Drumm, Mail Code 8104–R, Office of Science Policy, Office of Research and Development, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via phone/voice mail at: (202) 564–8239; via fax at: (202) 565–2911; or via e-mail at: *drumm.heather@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information

Any member of the public interested in receiving a draft BOSC agenda or making a presentation at the meeting may contact Heather Drumm, the Designated Federal Officer, via any of the contact methods listed in the **FOR FURTHER INFORMATION CONTACT** section above. In general, each individual making an oral presentation will be limited to a total of three minutes.

Proposed agenda items for the conference calls include, but are not limited to: Charge questions, objective of program reviews, background on the U.S. EPA's SP2 research program, writing assignments, and planning for the face-to-face meeting. Proposed agenda items for the face-to-face meeting include, but are not limited to: Presentations by key EPA staff in the SP2 research program, poster sessions, writing the draft report, and presentation of the subcommittee's draft responses to the charge questions. The conference calls and face-to-face meeting are open to the public.

Information on Services for Individuals with Disabilities: For information on access or services for individuals with disabilities, please contact Heather Drumm at (202) 564–8239 or *drumm.heather@epa.gov.* To request accommodation of a disability,

please contact Heather Drumm, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: December 1, 2006.

Jeff Morris

Director, Office of Science Policy.

[FR Doc. E6–20893 Filed 12–7–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[Docket #EPA–RO4–SFUND–2006–0951; FRL–8253–2]

Constitution Road Drum Site; Atlanta, Dekalb County, GA; Notice of Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of settlement.

SUMMARY: Under Section 122(h)(1) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the United States Environmental Protection Agency has entered into a settlement for reimbursement of past response costs with the CMAC Environmental Group concerning the Constitution Road Drum Site located in Atlanta, Dekalb County, Georgia.

DATES: The Agency will consider public comments on the settlement until January 8, 2007. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate.

ADDRESSES: Copies of the settlement are available from Ms. Paula V. Batchelor. Submit your comments, identified by Docket ID No. EPA–RO4–SFUND–2006–0951 or Site name Constitution Road Drum Superfund Site by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: Batchelor.Paula@epa.gov.*
- *Fax:* 404/562–8842/Attn Paula V. Batchelor.

Mail: Ms. Paula V. Batchelor, U.S. EPA Region 4, WMD–SEIMB, 61 Forsyth Street, SW., Atlanta, Georgia 30303. ''In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.''

Instructions: Direct your comments to Docket ID No. EPA–R04–SFUND–2006–0951. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the U.S. EPA Region 4 office located at 61 Forsyth Street, SW., Atlanta, Georgia 30303. Regional office is open from 7 a.m. until 6:30 p.m. Monday through Friday, excluding legal holidays.

Written comments may be submitted to Ms. Batchelor within 30 calendar days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: Paula V. Batchelor at 404/562–8887.

Dated: November 21, 2006.

Rosalind H. Brown,

Chief, Superfund Enforcement & Information Management Branch, Superfund Division.

[FR Doc. E6–20899 Filed 12–7–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[Docket #EPA–RO4–SFUND–2006–0974; FRL–8253–3]

Jehl Cooperage Superfund Site; Memphis, Shelby County, TN; Notice of Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of settlement.

SUMMARY: Under Section 122(h)(1) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the United States Environmental Protection Agency has entered into a settlement for reimbursement of past response costs concerning the Jehl Cooperage Superfund Site located in Memphis, Shelby County, Tennessee.

DATES: The Agency will consider public comments on the settlement until January 8, 2007. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate.

ADDRESSES: Copies of the settlement are available from Ms. Paula V. Batchelor. Submit your comments, identified by Docket ID No. EPA–RO4–SFUND–2006–0974 or Site name Jehl Cooperage Superfund Site by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: Batchelor.Paula@epa.gov.*
- *Fax:* 404/562–8842/Attn Paula V. Batchelor.

Mail: Ms. Paula V. Batchelor, U.S. EPA Region 4, WMD–SEIMB, 61 Forsyth Street, SW., Atlanta, Georgia 30303. ''In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.''

Instructions: Direct your comments to Docket ID No. EPA–R04–SFUND–2006–0974. EPA's policy is that all comments received will be included in the public docket without change and may be

made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the U.S. EPA Region 4 office located at 61 Forsyth Street, SW., Atlanta, Georgia 30303. Regional office is open from 7 a.m. until 6:30 p.m. Monday through Friday, excluding legal holidays.

Written comments may be submitted to Ms. Batchelor within 30 calendar days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: Paula V. Batchelor at 404/562–8887.

Dated: November 29, 2006.

Rosalind H. Brown,

Chief, Superfund Enforcement & Information Management Branch, Superfund Division.

[FR Doc. E6–20900 Filed 12–7–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8253–1]

Proposed Ability-to-Pay Settlement Under Section 122(h) of the Comprehensive Environmental Response, Compensation and Liability Act Regarding The Pittsburgh Metal and Equipment Superfund Site, Hudson County, NJ

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed Ability to Pay settlement and opportunity for public comment.

SUMMARY: The United States Environmental Protection (''EPA'') is proposing to enter into an administrative settlement to resolve claims under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (''CERCLA''). In accordance with Section 122(h)(1) of CERCLA, notice is hereby given of a proposed administrative settlement concerning the Pittsburgh Metal and Equipment Superfund Site (''the Site''). Section 122(h) of CERCLA provides EPA with the authority to consider, compromise and settle certain claims for costs incurred by the United States. Notice is being published to inform the public of the proposed settlement and of the opportunity to comment.

The Site is a former smelting facility that operated for approximately thirty-five years. It received used metal and dross from a number of clients, including those in the printing industries. EPA confirmed contamination at the Site as high as 15% lead in the top two feet of soil. Other hazardous substances at the site include cadmium, antimony, beryllium, copper, nickel, silver, zinc, and PCBs.

As a result of the release or threatened release of hazardous substances, EPA has undertaken response actions at or in connection with the Site under Section 104 of CERCLA, 42 U.S.C. 9604.

Under the terms of the Agreement, the Settling Parties will pay a total of approximately $59,500.00 to reimburse EPA for certain response costs incurred at the Site. In exchange, EPA will grant a covenant not to sue or take administrative action against the Parties for reimbursement of past response costs pursuant to Section 107(a) of CERCLA. The Attorney General has approved this settlement.

EPA will consider any comments received during the comment period and may withdraw or withhold consent to the proposed settlement if comments disclose facts or considerations that indicate the proposed settlement is inappropriate, improper, or inadequate. EPA's response to any comments received will be available for public inspection at the U.S. Environmental Protection Agency, Office of Regional Counsel, 290 Broadway—17th floor, New York, New York 10007–1866. Telephone: (212) 637–3111.

DATES: Comments must be provided by January 8, 2007.

ADDRESSES: Comments should be sent to the U.S. Environmental Protection Agency, Office of Regional Counsel, 290 Broadway—17th Floor, New York, NY 10007 and should refer to: In the Matter of the Pittsburgh Metal and Equipment Superfund Site, U.S. EPA Index No. CERCLA–02–2006–2009.

FOR FURTHER INFORMATION CONTACT: U.S. Environmental Protection Agency, Office of Regional Counsel, 290 Broadway—17th Floor, New York, NY 10007, (212) 637–3137.

SUPPLEMENTARY INFORMATION: A copy of the proposed administrative settlement, as well as background information relating to the settlement, may be obtained in person or by mail from Patricia Hick, U.S. Environmental Protection Agency, Office of Regional Counsel, 290 Broadway—17th Floor, New York, NY 10007. Telephone: (212) 637–3137.

Dated: November 13, 2006.

George Pavlou,

Director Emergency and Remedial Response Division Region 2.

[FR Doc. E6–20896 Filed 12–7–06; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments

must be received not later than December 22, 2006.

A. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. Thomas G. Damkroger, Firth, Nebraska, and John H. Bergmeyer, Lincoln, Nebraska, as trustees of the Wilber Co. Voting Trust, to acquire voting shares of Wilber Co., Wilber, Nebraska, and thereby indirectly acquire voting shares of First State Bank, Lincoln, Nebraska, and Saline State Bank, Wilber, Nebraska.

Board of Governors of the Federal Reserve System, December 4, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E6–20788 Filed 12–7–06; 8:45 am]

BILLING CODE 6210–01–S

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 January 2, 2007.

A. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. IBERIABANK Corporation, Lafayette, Louisiana; to acquire 100 percent of the voting shares of Pulaski Investment Corporation, and thereby indirectly acquire voting shares of Pulaski Bank & Trust Company, both of Little Rock, Arkansas.

B. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. Oakland Financial Services Inc., Oakland, Iowa; to merge with Southwest Company, Sidney, Iowa, and thereby acquire an additional controlling interest in Otoe County Bancorporation and Otoe Bank, both of Nebraska City, Nebraska.

In connection with this application, Applicant has applied to acquire First Community Bank, Sidney, Iowa, and thereby engage in operating a savings association, pursuant to section 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, December 4, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E6–20787 Filed 12–7–06; 8:45 am]

BILLING CODE 6210–01–S

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 January 4, 2007.

A. Federal Reserve Bank of Cleveland (Douglas A. Banks, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101-2566:

1. C Financial Corporation, Columbus, Ohio; to become a bank holding company by acquiring 100 percent of the voting shares of Cooper State Bank, Columbus, Ohio.

B. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. Signature Bancshares, Inc., Sandy Springs, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Signature Bank of Georgia, Dunwoody, Georgia.

Board of Governors of the Federal Reserve System, December 5, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E6–20850 Filed 12–07–06; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OS–0937–0025]

30-Day Notice; Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions;

(2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension.

Title of Information Collection: Reference Request for Applicants to the U.S. Public Health Service Commissioned Corps.

Form/OMB No.: OS–0937–0025.

Use: These forms will be used by individuals to apply for appointment in the U.S. Public Health Service Commissioned Corps and to obtain references as part of the application process. Information supplied on the forms will be used by appropriate Department officials to evaluate candidates for appointments.

Frequency: On Occasion.

Affected Public: Individuals or Households.

Annual Number of Respondents: 5,000.

Total Annual Responses: 5,000.

Average Burden Per Response: 24 min.

Total Annual Hours: 2,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be received within 30 days of this notice directly to the Desk Officer at the address below:

OMB Desk Officer: John Kraemer, OMB Human Resources and Housing Branch, *Attention:* (OMB #0937–0025), New Executive Office Building, Room 10235, Washington, DC 20503.

Date: November 30, 2006.

Alice Bettencourt,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E6–20915 Filed 12–7–06; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OS–0990–0000]

30-Day Notice; Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection.

Title of Information Collection: Evaluation of Office on Women's Health Publications.

Form/OMB No.: OS–0990–New.

Use: To improve future publications and to demonstrate accountability of efforts, the office of Women's Health (OWH) will evaluate four health communications materials. Discussion groups and web-based or paper-based surveys will be used from randomly selected participants and returned response cards.

Frequency: 1 time.

Affected Public: Individuals or Households.

Annual Number of Respondents: 1648.

Total Annual Responses: 1648.

Average Burden per Response: 17.2 min.

Total Annual Hours: 472.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be received within 30 days of this notice directly to the Desk Officer at the address below:

OMB Desk Officer: John Kraemer, OMB Human Resources and Housing Branch, *Attention:* (OMB #0990–New), New Executive Office Building, Room 10235, Washington, DC 20503.

Date: November 30, 2006.

Alice Bettencourt,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E6–20916 Filed 12–7–06; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft Guidance on Engagement of Institutions in Human Subjects Research

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 announcing the availability of a draft guidance document entitled, ''OHRP Guidance on Engagement of Institutions in Human Subjects Research.'' The draft guidance document would revise and replace two existing OHRP guidance documents on the engagement of institutions in human subjects research: (1) The January 26, 1999 document on ''Engagement of Institutions in Research, and (2) the December 23, 1999 document on ''Engagement of Pharmaceutical Companies in HHS Supported Research.'' To facilitate public review of the draft guidance document, OHRP has developed a table presenting a side-by-side comparison of OHRP's draft revised guidance document and the current guidance documents on the engagement of institution in human subjects research, which is available on the OHRP Web site at *http://www.hhs.gov/ohrp/requests/.*

OHRP's current engagement guidance documents and the proposed draft guidance document provide examples of when institutions generally would be considered to be engaged or not engaged in human subjects research. The draft document is intended primarily for institutional review boards (IRB), research administrators and other relevant institutional officials, investigators, and funding agencies that may be responsible for the conduct, review and oversight of human subject

research that is conducted or supported by HHS. OHRP will consider comments received before issuing the final guidance document.

DATES: Submit written comments by February 6, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled, ''OHRP Guidance on Engagement of Institutions in Human Subjects Research,'' to the Division of Policy and Assurances, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–402–2071. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written comments to ENGAGEMENT GUIDANCE COMMENTS, 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 *engagementohrp@hhs.gov.* or via facsimile at 301-402–2071.

FOR FURTHER INFORMATION CONTACT: Mr. Glen Drew, Office for Human Research Protections, Department of Health and Human Services, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; 301–496–7005; e-mail *glen.drew@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Health and Human Services (HHS), through OHRP, regulates research involving human subjects conducted or supported by HHS in regulations codified at 45 CFR part 46. The HHS human subject protection regulations stipulate substantive and procedural requirements for the conduct of HHS-conducted or -supported research, including requirements for review and approval by an IRB before research involving human subjects may begin, criteria for IRB approval of research, and requirements for informed consent or the waiver of informed consent.

The HHS protection of human subjects regulations at 45 CFR 46.103(a) require that each institution ''engaged'' in human subjects research that is conducted or supported by HHS provide OHRP with a satisfactory assurance that the institution will comply with the regulations, unless all the research meets one or more of the categories for exemption from the regulatory requirements under 45 CFR 46.101(b). The Federalwide Assurance (FWA) is the only type of assurance currently accepted by OHRP. The FWA generally identifies required policies and procedures for the institution and describes the activities to which the regulations apply.

On January 26, 1999, the Office for Protection from Research Risks (OPRR), OHRP's predecessor office, issued guidance on ''Engagement of Institutions in Research.'' OPRR later issued guidance on ''Engagement of Pharmaceutical Companies in HHS Supported Research,'' dated December 23, 1999.

OHRP is proposing to replace these two documents with a single document, ''OHRP Guidance on Engagement of Institutions in Human Subjects Research,'' draft dated October 27, 2006. This guidance is only applicable to research projects that have been determined to involve human subjects and that are not exempt under the HHS regulations at 45 CFR 46.101(b). Once an activity is determined to involve non-exempt human subjects research, this guidance can be used to determine whether an institution involved in some aspect of the research would be considered ''engaged'' in human subjects research, and would thus need to submit an FWA to OHRP. Like OHRP's existing guidance documents on engagement, this draft document provides: (1) Examples of activities that, in general, would result in an institution being considered engaged in a human subjects research project; and (2) examples of activities that, in general, would result in an institution being considered *not* engaged in a human subjects research project. The draft guidance document proposes modifications to the set of examples of when an institution generally would be considered engaged or not engaged in human subjects research. The proposed modifications include combining, clarifying, and changing existing examples, as well as adding further examples and explanation.

To facilitate public review and comments, OHRP has created a comparison table presenting a side-by-side display of the text from OHRP's draft guidance document matched with the comparable text from the 1999 guidance documents. This table is available on the OHRP Web site at *http://www.hhs.gov/ohrp/requests/.* The table is not part of the draft guidance document.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance document on OHRP's Web site at *http://www.hhs.gov/ohrp/requests/.*

III. Request for Comments

OHRP is making its draft guidance document available for public comment. OHRP's revised guidance document on the engagement of institutions in human subjects research will be finalized and issued after the public comments have been considered.

OHRP is particularly interested in the public's comments on two examples of activities which *would not* result in the institution being considered engaged in a human subjects research project under OHRP's current draft guidance document:

1 *Example B(1):* Institutions whose employees or agents release to the investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research; and,

2 *Example B(7):* Institutions (including private practices) not selected as research sites whose employees or agents administer clinical trial-related medical services if all of the following conditions are met:

(a) The institution's employees or agents do not enroll subjects, or obtain the informed consent of any subject for research participation;

(b) The institution's employees or agents do not administer the primary study interventions being tested under the protocol;

(c) The institution's employees or agents provide only services that either are clinically indicated, or are dictated by the protocol but not clinically indicated, and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators, such as a blood test, chest X-ray, CT scan, medical history and physical examination, or an assessment and reporting of an adverse event;

(d) The investigator(s) from an institution engaged in the research retain responsibility for oversight of all protocol-related activities and assure that appropriate arrangements are made for any safety monitoring and adverse event reporting required under the IRB-approved protocol;

(e) When appropriate, the informed consent document states that follow-up data are to be provided to the investigators by the institution's employees or agents; and,

(f) When providing follow-up data to the investigators, the institution's employees or agents provide such data to the investigators in accord with the procedures described in the informed consent.

Proposed example (B)(1) would represent a modification in OHRP

policy. OHRP's current guidance document issued in 1999 states that an institution whose employees or agents release individually identifiable private information about subjects, for research purposes, without the subjects' explicit written permission is considered to be engaged in human subjects research. The proposed modification in guidance is based on the definition of human subject at 45 CFR 46.102(f), which states in part, ''human subject means a living individual about whom an investigator * * * conducting research obtains * * * identifiable private information.'' (emphasis added). OHRP has concluded that releasing identifiable private information for research purposes is not equivalent to obtaining identifiable private information; thus, an institution releasing such identifiable private information is not involved in an activity including a ''human subject'' as defined by the HHS protection of human subjects regulations. Therefore, the revised example would clarify that an institution, whose employees or agents release to the investigators at another institution identifiable private information about living individuals or identifiable biological specimens that came from living individuals, is not considered engaged in human subjects research.

Proposed example (B)(7) would represent another modification in OHRP policy. OHRP's current guidance document states that an institution (or private practitioner) whose clinical staff provide protocol-related care and/or follow-up to subjects enrolled at distant sites by clinical trial investigators in OHRP-recognized Cooperative Protocol Research Programs (CPRPs) (e.g., the oncology group clinical trials sponsored by the National Cancer Institute) is not considered to be engaged in human subjects research provided certain specified conditions are met. OHRP is proposing two key modifications to this current example: (1) That the example not be limited to scenarios involving human subjects research at OHRP-recognized CPRPs; and (2) that the example exclude an institution whose employees or agents administer the primary study intervention being tested in the research. OHRP is proposing to broaden the example beyond OHRP-recognized CPRPs because OHRP does not believe that the conditions specified in example (B)(7) of the current draft guidance document are unique to clinical trials conducted under CPRPs. In addition, to better protect human subjects involved in research, OHRP believes that an institution whose employees or agents administer the primary study intervention being tested in the study should be required: (1) To obtain an OHRP-approved FWA, and (2) to certify to the HHS agency conducting or supporting the research that the application of proposal for research has been reviewed and approved by an IRB designated in the FWA, and will be subject to continuing review by an IRB. Therefore, through example (B)(7) in the current draft engagement guidance document, OHRP is proposing to clarify that institutions whose employees or agents administer the primary study intervention being tested in the study would be engaged in human subjects research. OHRP does not believe the requirement for an FWA will be unduly burdensome for such institutions since OHRP has simplified the assurance process with the implementation of the FWA, and now permits an institution holding an OHRP-approved FWA to extend the applicability of its FWA to cover collaborating independent investigators and collaborating institutional investigators through an Individual Investigator Agreement (IIA) (see *http://www.hhs.gov/ohrp/humansubjects/assurance/guidanceonalternativetofwa.htm*).

In addition, OHRP wants to highlight three other proposed changes in the current draft guidance document:

1. The draft guidance document does not include examples regarding when ''statistical centers,'' ''operations centers,'' or ''coordinating centers'' for multi-site research would be engaged in human subjects research. The existing January 26, 1999 guidance document includes examples of when such entities would be engaged in human subjects research (see the January 26, 1999 document on ''Engagement of Institutions in Research, examples (A)(6) and (A)(7)). OHRP is proposing to delete these examples in the new engagement guidance document since OHRP believes that these entities' activities are subsumed under example (A)(5) in the draft engagement guidance document, which states that an institution would be engaged in human subjects research if the institution's employees or agents ''* * * obtain for research purposes identifiable private information or identifiable biological specimens from any source * * *.'' In addition, the January 26, 1999 document provided guidance on what component(s) of the study would require review by the IRB for the statistical, operations, or coordinating centers. Because this issue of IRB review could apply to any institution engaged in a component of a cooperative research project, OHRP's draft guidance document addressed this general issue separately at the end of the section III. A.

2. OHRP is proposing that an institution be considered *not* engaged in human subjects research in the event the institution's employees or agents consult or collaborate on the human subjects research by obtaining coded private information or human biological specimens from an institution engaged in the research that retains a link to individually identifying information (such as name or social security number), if one of several specified conditions is met (*see* example (B)(2) in the draft engagement guidance document). OHRP believes this additional example helps to clarify the distinction and relationship between: (1) Determining when a research study involving coded private information or human biological specimens involves human subjects (*see* OHRP's August 10, 2004, Guidance on Research Involving Coded Private Information or Biological Specimens at *http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf*), and (2) determining whether an institution is engaged in human subjects research if it receives coded private information or human biological specimens for a research study that already has been determined to involve human subjects.

3. OHRP is proposing that an institution be considered *not* engaged in human subjects research if the institution's employees or agents author a paper, journal article, or presentation describing a human subjects research study (*see* example (B)(8) in the current draft engagement guidance document). This is in contrast to the January 26, 1999 guidance document, which suggests that such authorship would make an institution engaged in human subjects research (*see* example (B)(2) in the January 26, 1999 guidance document). OHRP is proposing this clarification because OHRP believes that for an institution to be engaged in human subjects research, an institution's employees or agents must obtain: (1) Data about the subjects of the research through intervention or interaction with them; or (2) identifiable private information about the subjects of the research. If the institution's employees or agents do not obtain such information, the portion of the activity conducted by the institution does not involve human subjects, as defined by 45 CFR 46.102(f). Because authorship does not always involve obtaining such data or information about the subjects of the research, OHRP does not believe that it is helpful to consider authorship as a factor in determining whether an

institution is engaged in human subjects research.

All of the modifications and clarifications proposed in OHRP's draft guidance document, including those discussed above, are reflected in the comparison table of the previous guidance documents and the new draft guidance document on OHRP's Web site at *http://www.hhs.gov/ohrp/requests/.* OHRP welcomes comments on its draft guidance.

Dated: December 1, 2006.

Melody Lin,

Deputy Director, Office for Human Research Protections.

[FR Doc. E6–20849 Filed 12–7–06; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Nicholas McMaster, University of Chicago: Based on a College Discipline Hearing report and on additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Mr. Nicholas McMaster, undergraduate student, Biological Sciences Collegiate Division in the Departments of Psychology and Comparative Human Development at the University of Chicago (UC), engaged in research misconduct supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant P50 ES12382 and National Institute on Aging (NIA), NIH, grant P01 AG018911.

Specifically, PHS found that Mr. McMaster fabricated data in recording the score for the lordosis reflex and in recording the cell types present in vaginal epithelium from rats in two experimental psychology protocols.

Mr. McMaster has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on November 14, 2006:

(1) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) that any institution which submits an application for PHS support for a research project on which Mr. McMaster's participation is proposed or which uses him in any capacity on PHS supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of his research contribution. Mr. McMaster also agrees to ensure that the institution submits a copy of the supervisory plan to ORI. He further agrees that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. E6–20927 Filed 12–7–06; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Information Collection Activities; Proposed Collection; Comment Request; Alzheimer's Disease Demonstration Grants to States Program Standardized Data Collection

AGENCY: Administration on Aging, HHS.

ACTION: Notice.

SUMMARY: The Administration on Aging (AoA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to Alzheimer's Disease Demonstration Grants to States Program

DATES: Submit written or electronic comments on the collection of information by February 6, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *Lori.Stalbaum@aoa.hhs.gov.* Submit written comments on the collection of information to Administration on Aging, Washington, DC 20201, ATTN: Lori Stalbaum.

FOR FURTHER INFORMATION CONTACT: Lori Stalbaum at 202–357–3452 or e-mail: *lori.stalbaum@aoa.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA's functions, including whether the information will have practical utility; (2) the accuracy of AoA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The Alzheimer's Disease Demonstration Grants to States (ADDGS) Program is authorized through Sections 398, 399 and 399A of the Public Health Service (PHS) Act, as amended by Public Law 101–557 Home Health Care and Alzheimer's Disease Amendments of 1990. The ADDGS program funded through AoA helps states extend family support services provided by subgrantees to underserved populations, including those in rural communities.

The PHS Act requires AoA to ''provide for an evaluation of each demonstration project for which a grant is made.'' The PHS Act further states

that ''not later than 6 months after the completion of such evaluations, submit a report to the Congress describing the findings made as a result of the evaluations.'' In compliance with the PHS Act, AoA developed a new State data collection protocol that will require future ADDGS state grantees (those funded starting in FY 2007) to transmit annual data information to AoA reported to the states by the project partners. Many of the elements for the ADDGS Data Program Report are the same as those collected for Older Americans Act Title III and Title VII programs administered by AoA. To ensure inclusion of essential information the ADDGS Project Officer first contacted all current ADDGS grantees to find out what type of information they are already collecting. Then, the ADDGS Project Officer solicited information on key data elements from experts familiar with the previous ADDGS Program evaluation. Following this input, modifications were made to the data collection tool and input was solicited from all ADDGS state Project Directors and their project partners. Twenty-three (23) of thirty-eight (38) states, approximately 60% responded to the request for feedback. Again, modifications were made to fine tune the data collection tool into a format that would minimize burden on state grantees. Finally, ten (10) ADDGS Project Directors participated in a telephone focus group. The ten Project Directors were selected based on the detail of their responses to the original request for feedback.

The result of this input is the proposed data collection tool and accompanying definition of terms. AoA is aware that different states have different capabilities in terms of data collection. Thus, it is understood that following the approval of the proposed ADDGS data collection tool, AoA will need to work with ADDGS grantees to ensure easy access to a reporting system as well as offer regular training to state grantees to ensure minimal burden.

AoA estimates the burden of this collection of information as follows: 950 hours.

Dated: December 5, 2006.

Josefina G. Carbonell,

Assistant Secretary for Aging.

[FR Doc. E6–20890 Filed 12–7–06; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–07–0017]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Application for Training—Revision—Office of Workforce and Career Development (OWCD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) through its Office of Workforce and Career Development (OWCD) and other Centers, Institutes, and Offices offers training activities on public health topics to professionals worldwide. Employees of hospitals, universities, medical centers, laboratories, state and federal agencies, and state and local health departments apply for training in an effort to learn up-to-date public health practices. CDC's training activities include laboratory training, classroom study, online training, and distance learning activities. The ''National Laboratory Training Network Registration Form'' (paper and electronic forms) and the ''CDC Training and Continuing Education New Participant Registration Form'' (electronic form) are official application forms used for training activities conducted by CDC. CDC form 32.1, ''National Laboratory Training Network Registration Form'', is used for all laboratory field training. The ''CDC Training and Continuing Education New Participant Registration Form'' is completed by health practitioners seeking to register for training available through the CDC's online registration system. CDC was granted OMB approval to use these forms through December 31, 2006, and is now requesting OMB approval for an additional three years.

These forms in various versions have been used by CDC to collect data for the past 16 years. The information requested on the forms is used to grant public health professionals the continuing education credits they need to maintain their licenses and certification required by their professions. This information is also needed to create a transcript or summary of training completed at the participant's request. In addition, the forms are also needed to generate management reports and to maintain training statistics. These reports assist CDC in the management of its training programs, such as, identifying training needs, designing courses, selecting locations for courses, evaluating programs, and conducting impact analysis.

There are no costs to the respondents other than their time. The total estimated annualized burden is 3332 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
National Laboratory Training Network Registration Form (32.1)	20,000	1	5/60
CDC Training and Continuing Education New Participant Registration Form (36.5)	20,000	1	5/60

Dated: December 4, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–20855 Filed 12–7–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through November 25, 2008.

For information, contact Kevin Fenton, M.D., Ph.D., Executive Secretary, CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment, Centers for Disease Control and Prevention, Department of Health and Human Services, 1600 Clifton Road, NE., Mailstop E07, Atlanta, Georgia 30333, telephone 404/639–8000 or fax 404/639–8600.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 1, 2006.

Alvin Hall,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

[FR Doc. E6–20853 Filed 12–7–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Decision To Evaluate a Petition to Designate a Class of Employees at Hanford Nuclear Reservation, Richland, WA, To Be Included in the Special Exposure Cohort

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice as required by 42 CFR § 83.12(e) of a decision to evaluate a petition to designate a class of employees at the Hanford Nuclear Reservation, Richland, Washington, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Hanford Nuclear Reservation.

Location: Richland, Washington.

Job Titles and/or Job Duties: All employees.

Period of Employment: January 2, 1942 through December 31, 1990.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV.*

Dated: November 29, 2006.

John Howard,

Director, National Institutes for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 06–9585 Filed 12–07–06; 8:45 am]

BILLING CODE 4163–19–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice of a decision to designate a class of employees at the Oak Ridge Institute of Nuclear Studies Cancer Research Hospital, Oak Ridge, Tennessee, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On November 9, 2006, the Secretary of HHS designated the following class of employees as an addition to the SEC:

Employees of the Department of Energy (DOE) predecessor agencies and their contractors or subcontractors who were monitored or should have been monitored while working at the Oak Ridge Institute of Nuclear Studies Cancer Research Hospital from May 15, 1950, through December 31, 1963, and who were employed for a number of work days aggregating at least 250 work days or in combination with work days within the parameters established for other classes of employees included in the SEC.

This designation will become effective on December 9, 2006, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV.*

Dated: November 30, 2006.

John Howard,

Director, National Institute for Occupational, Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 06–9586 Filed 12–7–06; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice of a decision to designate a class of employees at the Los Alamos National Laboratory, Los Alamos, New Mexico, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On November 9, 2006, the Secretary of HHS designated the following class of employees as an addition to the SEC:

Employees of the Department of Energy predecessor agencies and their contractors or

subcontractors who were monitored or should have been monitored for exposure to ionizing radiation associated with radioactive lanthanum (RaLa) operations at Technical Area 10 (Bayo Canyon Site), Technical Area 35 (Ten Site), and Buildings H, Sigma, and U (located within Technical Area 1) for a number of work days aggregating at least 250 work days during the period from September 1, 1944, through July 18, 1963, or in combination with work days within the parameters established for one or more classes of employees in the SEC.

This designation will become effective on December 9, 2006, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

Pursuant to 42 U.S.C. § 7384q, in a October 11, 2006 letter to the Secretary of HHS, the Advisory Board on Radiation and Worker Health (''the Board'') advised the Secretary of HHS to designate the class as an addition to the SEC. The Board further stated,

''In their evaluation, NIOSH determined that it was difficult to identify people who worked in these areas of LANL based on job classifications. Therefore, the Board recommends that determination of eligibility for this class take into account this difficulty and in the absence of work history or other information to the contrary, workers at the LANL facility during the period in question should be presumed to have worked in the areas in question.''

Since determination of eligibility is not within the authority of HHS, the Board's recommendation on this issue was not included in the HHS designation.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*.

Dated: November 30, 2006.

John Howard,

Director, National Institute for Occupational, Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 06–9587 Filed 12–7–06; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice of a decision to designate a class of employees at the Oak Ridge Thermal Diffusion Plant (S–50), Oak Ridge, Tennessee, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On November 9, 2006, the Secretary of HHS designated the following class of employees as an addition to the SEC:

Employees of the Department of Energy predecessor agencies and their contractors and subcontractors who were monitored or should have been monitored while working at the S–50 Oak Ridge Thermal Diffusion Plant working for a number of work days aggregating at least 250 work day during the period from July 9, 1944, through December 31, 1951, or in combination with work days within the parameters established for one or more other classes of employees in the SEC.

This designation will become effective on December 9, 2006, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can be submitted by e-mail to *OCAS@CDC.GOV.*

Dated: November 30, 2006.

John Howard,

Director, National Institute for Occupational, Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 06–9588 Filed 12–7–06; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following Federal Committee meeting.

Name: Advisory Committee on Immunization Practices (ACIP).

Times and Dates: 8 a.m.–6 p.m., February 21, 2007, 8 a.m.—4 p.m., February 22, 2007.

Place: Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Global Communications Center, Building 19, Room 232, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available. Meeting space accommodates approximately 330 people. Overflow space for real-time viewing will be available.

Purpose: The Committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. § 1396s, the Committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters to be Discussed: The agenda will include discussions on influenza vaccine; immunization safety; update on use of rotavirus vaccine; update on use of HPV vaccine; update on use of herpes zoster (shingles) vaccine; vaccine supply; Japanese encephalitis and other flavivirus vaccines (e.g., yellow fever vaccine); diphtheria, tetanus, pertussis, polio, Haemophilus B [Hib] combination vaccine (Pentacel®); evidence-based recommendations; and agency updates.

Agenda items are subject to change as priorities dictate.

Additional Information: In order to expedite the security clearance process at the CDC Roybal Campus located on Clifton Road, *all* ACIP attendees are required to register on line at *www.cdc.gov/nip/acip*, which can be found at the ''Upcoming Meetings'' tab. Please complete all the required fields before submitting your registration and submit no later than January 18, 2007.

Please Note: In addition to completing the registration form on line, as described above, all non-U.S. citizens are required to complete the ''Access Request Form.'' The completed access request form should be sent by e-mail directly to Ms. Gardner at *dgardner@cdc.gov*.

Contact Person for More Information: Demetria Gardner, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road, NE, (E–05), Atlanta, Georgia 30333, telephone 404/639–8836, fax 404/639–6258.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and ATSDR.

Dated: December 1, 2006.

Alvin Hall,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

[FR Doc. E6–20859 Filed 12–7–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–R–244]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because the use of normal clearance procedures is reasonably likely to cause a statutory deadline to be missed.

The reporting requirements being filed under this collection do not represent substantively new processes for the Programs of All-inclusive Care for the Elderly (PACE) providers. The reporting requirements have been updated in specific areas to provide a mechanism for disclosure and recusal in the event of a conflict of interest involving members of the PACE governing body or their immediate family members. In addition, the requirement that PACE organizations must furnish a copy of signed contracts for inpatient care facilities to CMS and the State administering agency has been removed.

The Medicare and Medicaid Programs: Programs of All-inclusive Care for the Elderly; program revisions final rule, CMS–1201–F, and the reporting requirements in this collection are required to become effective on the same date.

Type of Information Collection Request: Revision of a currently approved collection.

Title of Information Collection: The Medicare and Medicaid Programs; Programs of All-inclusive Care for the Elderly (PACE).

Form Number: CMS–R–244 (OMB#: 0938–0790).

Use: PACE organizations must demonstrate their ability to provide quality community-based care for the frail elderly who meet their State's nursing home eligibility standards using capitated payments from Medicare and the State. PACE programs must provide all Medicare and Medicaid covered services including hospital, nursing home, home health, and other specialized services. This collection is necessary to ensure that only appropriate organizations are selected to become PACE organizations and that CMS has the information necessary to monitor the care they provide.

Frequency: Reporting—Once and On occasion.

Affected Public: Not-for-profit institutions and State, Local, or Tribal Governments.

Number of Respondents: 54.

Total Annual Responses: 108.

Total Annual Hours: 44131.50.

CMS is requesting OMB review and approval of this collection by *December 29, 2006,* with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by December 22, 2006.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by December 22, 2006: Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850. Attn: Bonnie L Harkless and, OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395–6974.

Dated: November 9, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–20543 Filed 12–7–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10216]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Center for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The

necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with implementation of Public Law No: 109–171 Deficit Reduction Act (DRA) of 2005. CMS does not have sufficient time to complete the normal PRA clearance process.

We request this Paperwork Reduction Act clearance under an emergency approval process to allow States to implement the following DRA provisions: 6036, 6041, 6042, 6043, 6044, and 6083. This emergency request is to ensure that statutory effective dates of the provisions are not missed.

1. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Alternative Benefits State Plan Amendment Health Opportunity Accounts (HOA) Demonstration Program; *Use:* The DRA provides States with numerous flexibilities in operating their State Medicaid programs. For example, Section 6082 of the DRA allows up to 10 States to operate Medicaid demonstrations to test alternative systems for delivering their Medicaid benefits. Under these demonstrations, States would have the flexibility to deliver their Medicaid benefits to volunteer beneficiaries through a program that is comprised of an HOA and a High Deductible Health Plan (HDHP). Under the DRA, States can submit a State Plan Pre-print to CMS to effectuate this change to their Medicaid programs. CMS will provide a State Medicaid Director letter providing guidance on this provision and the implementation of the DRA and the associated State Plan Amendment template for use by States to modify their Medicaid State Plans if they choose to implement this flexibility; *Form Number:* CMS–10216 (OMB#: 0938–New); *Frequency:* Reporting: One-time; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 10; *Total Annual Hours:* 10.

CMS is requesting OMB review and approval of these collections by *December 22, 2006,* with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by *December 18, 2006.*

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995/* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be received by the designees referenced below by *December 18, 2006:*

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Melissa Musotto (CMS–10216) and,

OMB Human Resources and Housing Branch, Attention: Katherine Astrich, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 30, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–20665 Filed 12–7–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10117, 10118, 10119, 10135, 10136 and 10214]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Center for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because the use of normal clearance procedures is reasonably likely to cause a statutory deadline to be missed.

The Social Security Act requires that applicant organizations, offering Part C benefits for January 2008 be contracted with CMS for their approved service area with open enrollment beginning on November 15, 2007. Further, the Act requires the submission of Part C benefit bids from applicant organizations by the

first Monday in June of 2007. In order to meet the Medicare Prescription Drug Improvement and Modernization Act requirements, key preceding events must occur. If these events do not occur according to the statutorily mandated timeline, other statutory requirements will not be met.

For the 2008 contract year, CMS is implementing several steps to reduce the person-hours necessary to complete the Part C solicitations. These steps include automating substantial portions of the Part C Plan solicitations within CMS' Health Plan Management System (HPMS) and streamlining key information previously requested by attachments.

Type of Information Collection Request: Revision of a currently approved collection.

Title of Information Collection; Medicare Advantage Applications: Medicare Advantage (MA) Application Coordinated Care Plans (CMS–10117); Medicare Advantage (MA) Application Private Fee-For-Service Plans (CMS–10118); Medicare Advantage (MA) Application Regional PPO Plans (CMS–10119); Medicare Advantage (MA) Application Service Area Expansion (SAE) for Coordinated Care Plans: Private Fee Service Plans (CMS–10135); Medical Savings Account Plans (CMS–10136); and Employer Group Waiver Plans (CMS–10214).

Form Number: CMS–10117, 10118, 10119, 10135, 10136 and 10214 (OMB#: 0938–0935).

Use: An entity seeking a contract as an MA organization must be able to provide Medicare's basic benefits plus meet the organizational requirements set out under the regulations at 42 CFR Part 422. An applicant must demonstrate that it can meet the benefit and other requirements within the specific geographic area it is requesting. The application forms are designed to give CMS the information needed to determine a health plan's compliance with the regulations at 42 CFR Part 422. The MA application forms will be used by CMS to determine whether an entity is eligible to enter into a contract to provide services to Medicare beneficiaries.

Frequency: Reporting—Once.

Affected Public: Business or other for-profit and Not-for-profit institutions.

Number of Respondents: 220.

Total Annual Responses: 220.

Total Annual Hours: 5580.

CMS is requesting OMB review and approval of this collection by *January 5, 2007*, with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by December 22, 2006.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by December 22, 2006:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Attn: Bonnie L. Harkless, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850, and,

OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395–6974.

Dated: November 30, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–20666 Filed 12–7–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10215 and CMS–10148]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Collection of Physician Administered Drug National Drug Code (NDC) Numbers on State Medicaid Claims and Supporting Regulations at 42 CFR 447.520. *Use:* Section 6002 of the Deficit Reduction Act of 2005 (DRA) added provisions under Section 1927 of the Social Security Act to require physicians in their offices and hospital outpatient settings or other entities (e.g., non-profit facilities) to collect and submit the drug NDC numbers on Medicaid claims to their State within specified timeframes. We estimate that there are 20,000 physician offices, hospital outpatient settings or other entities concentrating in the specialties of oncology, rheumatology and urology that will be required by their State Medicaid Programs to collect and submit ''J'' drug code data match with NDC numbers. *Form Number:* CMS–10215 (OMB#: 0938–NEW); *Frequency:* Reporting—weekly; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 20,000; *Total Annual Responses:* 3,910,000; *Total Annual Hours:* 15,836.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* HIPAA Administrative Simplification Enforcement Non-Privacy Enforcement; *Use:* The Health Insurance Portability and Accountability Act (HIPAA) became law in 1996 (Pub. L. 104–191). Subtitle F of Title II of HIPAA, entitled ''Administrative Simplification,'' requires the Secretary of HHS to adopt national standards for certain information-related activities of the health care industry. The HIPAA provisions, by statute, apply only to ''covered entities'' referred to in section 1320d–2(a)(1) of this title. Responsibility for administering and enforcing the HIPAA Administrative Simplification Transactions, Code Sets, Identifiers and Security rules has been delegated to CMS. The initial information collected to enforce these rules will be used to initiate enforcement actions. This information

collection change clarifies the ''Identify the HIPAA Non-Privacy complaint category'' section of the complaint form. In this section, complainants are given an opportunity to check the ''Unique Identifiers'' option to categorize the type of HIPAA complaint being filed. The revised form now includes a ''For a Unique Identifier Complaint'' section, that allows a complaint to further categorize their identifier complaint as either a ''National Provider Identifier (NPI)'' or an ''Employer Identification Number (EIN)'' complaint. *Form Number:* CMS–10148 (OMB#: 0938–948); *Frequency:* Reporting—On occasion; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit institutions, and State, Local, or Tribal governments; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on February 6, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 30, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–20678 Filed 12–7–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10209, CMS–R–282, CMS–10197, and CMS–R–240]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Chronic Care Improvement Program (CCIP) and Medicare Advantage Quality Improvement Project (QIP); *Use:* 42 CFR 422.152 requires each Medicare Advantage Organization (MAOs) (other than Medicare Advantage (MA) private fee for service and Medical Savings Account (MSA) plans) that offers one or more MA plan to have an ongoing quality assessment and performance improvement program. Information collected in the QIP and CCIP Reporting Templates will be an integral resource for oversight, monitoring compliance and auditing activities necessary to ensure high quality provision of general health services and chronic care services to Medicare beneficiaries. *Form Number:* CMS–10209 (OMB#: 0938–New); *Frequency:* Recordkeeping, and Reporting—Annually; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 426; *Total Annual Responses:* 852; *Total Annual Hours:* 38,050.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Health Plan Appeals and Grievance Data Collection and Reporting Requirements, Data Disclosure Requirements § 422.111; *Use:* Medicare Advantage (MA) organizations and demonstrations are required to disclose information pertaining to the number of disputes, and their disposition in the aggregate. Organizations provide appeals and grievance information to individuals eligible to elect an MA organization, or persons or entities making the request on behalf of the individuals who request this information. MA eligible individuals will use this information to help them make informed decisions about their organization's performance in the area of appeals and grievances. *Form Number:* CMS–R–0282 (OMB#: 0938–0778); *Frequency:* Recordkeeping, Third Party Disclosure and Reporting—Semi-annually; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 434; *Total Annual Responses:* 868; *Total Annual Hours:* 876.

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Evaluation of the Medicare National Competitive Bidding Program for DME; *Use:* Section 302(b) of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the Centers for Medicare and Medicaid Services (CMS) to begin a program of competitive bidding for durable medical equipment (DME), supplies, certain orthotics, and enteral nutrients and related equipment and supplies. Section 303(d) of the MMA requires a Report to Congress on the program, covering program savings, reductions in cost sharing, impacts on access to and quality of affected goods and services, and beneficiary satisfaction. This project's purpose is to provide information for this Report to Congress. *Form Number:* CMS–10197 (OMB#: 0938–New); *Frequency:* Reporting—Other: Baseline and Follow-up; *Affected Public:* Individuals or Households, Business or other for-profit, Federal Government and Not-for-profit institutions; *Number of Respondents:* 12,671; *Total Annual Responses:* 12,671; *Total Annual Hours:* 6,557.

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Provider-based Status Regulations in 42 CFR 413.24 and 413.65; *Use:* Section 1833(t) of the Social Security Act (of the Act), as amended by section 4523 of the Balanced Budget Act of 1997 (the BBA) requires the Secretary to establish a prospective payment system (PPS) for hospital outpatient services. Successful implementation of an outpatient PPS requires that CMS distinguish facilities or organizations that function as departments of hospitals from those that are freestanding, so that CMS can determine which services should be paid under the PPS. Regulations found at 42 CFR 413.65(b)(3) and (c) require the submission of the information CMS needs to make the determination of whether an organization functions as a department of a hospital or functions as

a freestanding facility. In addition, section 1866(b)(2) of the Act authorizes hospitals and other providers to impose deductible and coinsurance charges for facility services, but does not allow such charges by facilities or organizations which are not provider-based. Implementation of this provision requires that CMS have information from the required reports, so it can determine which facilities are provider-based. *Form Number:* CMS–R–240 (OMB#: 0938–0798); *Frequency:* Recordkeeping—On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 750; *Total Annual Responses:* 872; *Total Annual Hours:* 26,063.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: November 30, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–20679 Filed 12–7–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Privacy Act of 1974; Revisions to OIG's Privacy Act System of Records—Criminal Investigative Files

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice of revisions to existing Privacy Act systems of records.

SUMMARY: The Office of Inspector General (OIG) is revising the existing system of records, entitled ''Criminal Investigative Files'' (09–90–0003), by updating the ''Systems Location'' section of that document, and republishing the revised system of records in its entirety. This notice is in accordance with the Privacy Act requirement that agencies publish their amended systems of records in the **Federal Register** when there is a revision, change, or addition. This system of records, maintained by OIG, was last revised and updated on June 19, 2003 (68 FR 36828).

EFFECTIVE DATE: These revisions will become effective on January 22, 2007.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Regulations Officer, Office of External Affairs, (202) 619–0089.

SUPPLEMENTARY INFORMATION: In accordance with the Inspector General Act of 1978, 5 U.S.C. App. 3, the Criminal Investigative Files system of records is maintained for the purpose of (1) Conducting, documenting, and tracking investigations conducted by OIG or other investigative agencies regarding HHS programs and operations; (2) documenting the outcome of OIG reviews of allegations and complaints received concerning HHS programs and operations; (3) aiding in prosecutions brought against the subjects of OIG investigations; (4) maintaining a record of the activities that were the subject of investigations; (5) reporting the results of OIG investigations to other departmental components for their use in operating and evaluating their programs and the imposition of civil or administrative sanctions; and (6) acting as a repository and source for information necessary to fulfill the reporting requirements of 5 U.S.C. App. 3.

This system of records was first published in the **Federal Register** on November 2, 1990 (55 FR 46248). The system of records was last revised and updated on June 19, 2003 (68 FR 36828), by adding a new routine use to allow disclosure of information to authorized officials within the President's Council on Integrity and Efficiency, in compliance with requirements established by the Homeland Security Act of 2002.

In accordance with the Privacy Act requirement that agencies publish their amended systems of records in the **Federal Register** when there is a revision, change, or addition, OIG has reviewed and is revising the criminal investigative files system of records by updating and amending the files' ''System Location'' section. Records in this system have been located and maintained in OIG's regional offices, and the update of the ''Systems Location'' section will simply reflect changes in mailing addresses and a division of a region. Specifically, the updating of the system locations are necessary to reflect new regional mailing addresses, the change of the Region 7 headquarters office from Denver to Kansas City, and the division of Region 9 into two regions (San Francisco and Los Angeles). This change will not otherwise increase access to these records.

Dated: December 4, 2006.

Daniel R. Levinson,

Inspector General.

SYSTEM NAME:

Criminal Investigative Files of the Inspector General HHS/OS/OIG.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of Inspector General, HHS, Room 5409, Wilbur J. Cohen Bldg., 330 Independence Avenue, SW., Washington, DC 20201.

Region 1, Office of Investigations (OI), OIG, JFK Federal Building, Room 2475, Boston, Massachusetts 02203.

Region 2, OI, OIG, 26 Federal Plaza, Room 13–124, New York, New York 10278.

Region 3, OI, OIG, Public Ledger Bldg., 150 South Independence Mall West, Suite 326, Philadelphia, Pennsylvania 19106.

Region 4, OI, OIG, Atlanta Federal Office, 61 Forsyth Street, SW., Suite 5T18, Atlanta, Georgia 30303.

Region 5, OI, OIG, 233 North Michigan Avenue, Suite 1330, Chicago, Illinois 60601.

Region 6, OI, OIG, 1100 Commerce Street, Room 629, Dallas, Texas 75242.

Region 7, OI, OIG, 1201 Walnut, Suite 920, Kansas City, Missouri 64106.

Region 9, OI, OIG, 50 United Nations Plaza, Room 174, San Francisco, California 94102.

Los Angeles Region, OI, OIG, 600 West Santa Ana Blvd., Suite 1100, Santa Ana, California 92701.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals relevant to a criminal investigation, including but not limited to the subjects of an investigation, complainants, and key witnesses where necessary for future retrieval.

CATEGORIES OF RECORDS IN THE SYSTEM:

Criminal investigative files and extracts from that file consisting of a computerized case management and tracking file.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Inspector General Act of 1978, 5 U.S.C. App. 3, authorizes Inspectors

General to conduct, supervise, and coordinate investigations relating to the programs and operations of their respective agencies.

PURPOSE(S):

Pursuant to the Inspector General Act of 1978, 5 U.S.C. App. 3, this system is maintained for the purpose of conducting, documenting, and tracking investigations conducted by the OIG or other investigative agencies regarding HHS programs and operations, documenting the outcome of OIG reviews of allegations and complaints received concerning HHS programs and operations, aiding in prosecutions brought against the subjects of OIG investigations, maintaining a record of the activities that were the subject of investigations, reporting the results of OIG investigations to other departmental components for their use in operating and evaluating their programs and the imposition of civil or administrative sanctions, and acting as a repository and source for information necessary to fulfill the reporting requirements of 5 U.S.C. App. 3.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSE OF SUCH USES:

a. Information from this system of records may be disclosed to any other Federal agency or any foreign, State, or local government agency responsible for enforcing, investigating, or prosecuting violations of administrative, civil, or criminal law or regulation where that information is relevant to an enforcement proceeding, investigation, or prosecution within the agency's jurisdiction.

b. Information from this system of records may be disclosed to (1) The Department of Justice in connection with requests for legal advice and in connection with actual or potential criminal prosecutions or civil litigation pertaining to the Office of Inspector General, and (2) a Federal or State grand jury, a Federal or State court, administrative tribunal, opposing counsel, or witnesses in the course of civil or criminal proceedings pertaining to the Office of Inspector General.

c. Information in this system of records may be disclosed to a Federal, State, or local agency maintaining civil, criminal or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a license, grant or other benefit.

d. Information in this system of records may be disclosed to a Federal agency in response to its request in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

e. Relevant information may be disclosed from this system of records to the news media and general public where there exists a legitimate public interest, *e.g.*, to provide information on events in the criminal process, such as indictments, and where necessary, for protection from imminent threat to life or property.

f. Where Federal agencies having the power to subpoena other Federal agencies' records, such as the Internal Revenue Service, or issue a subpoena to the department for records in this system or records, the department will make such records available.

g. When the department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system, relevant records will be disclosed to such contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

h. Disclosures may be made to organizations deemed qualified by the Secretary to carry out qualify assessments.

i. Information from this system of records may be disclosed in the course of employee discipline of competence determination proceedings.

j. Disclosures may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

k. Information from this system of records may be disclosed to the Department of Justice, to a judicial or administrative tribunal, opposing counsel, and witnesses, in the course of proceedings involving HHS, an HHS employee (where the matter pertains to the employee's official duties), or the United States, or any agency thereof where the litigation is likely to affect HHS, or HHS is a party or has an interest in the litigation and the use of the information is relevant and necessary to the litigation.

l. Information of this system of records may be disclosed to a Federal, State or local agency maintaining pertinent records, if necessary, to obtain a record relevant to a department decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

m. Information from this system of records may be disclosed to third party contacts, including public and private organizations, in order to obtain information relevant and necessary to the investigation of potential violations in HHS programs and operations, or where disclosure would enable the OIG to identify violations in HHS programs or operations or otherwise assist the OIG in pursuing on-going investigations.

n. A record may be disclosed to any official charged with the responsibility to conduct qualitative assessment reviews of internal safeguards and management procedures employed in investigative operations. This disclosure category includes members of the President's Council on Integrity and Efficiency and officials and administrative staff within their investigative chain of command, as well as authorized officials of the Department of Justice and the Federal Bureau of Investigation.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, REVIEWING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM

STORAGE:

The records, which take the form of index cards, investigative reports, microcomputer disks, computer mainframe files and computer printed listings are maintained under secure conditions in limited access areas. Written documents and computer disks are maintained in secure rooms, in security type safes or in lock bar file cabinets with manipulation proof combination locks. Computer mainframe files are on-line in guarded, combination locked computer rooms.

RETRIEVABILITY:

Records are retrievable by manual or computer search of indices containing the name or Social Security number of the individual to whom the record applies. Records may be cross-referenced by case or complaint number.

SAFEGUARDS:

Records are maintained in a restricted area and accessed only by department personnel. Access within the OIG is strictly limited to authorized staff members. All employees are given instructions on the sensitivity of such files and the restrictions on disclosure. Access within HHS is strictly limited to the Secretary, Under-Secretary, and other officials and employees on a need-to-know basis. All mainframe computer files and printed listings are safeguarded

in accordance with the provisions of the National Institute of Standards and Technology Federal Information Processing Standards 41 and 31, and the HHS Information Resources Management Manual, Part 6, ''ADP Systems Security.''

RETENTION AND DISPOSAL:

Investigative files are retained for 10 years after completion of the investigation and/or action based thereon. Paper and computer indices are retained permanently. The records control schedule and disposal standards may be obtained by writing to the Systems Manager at the address below.

SYSTEM MANAGER(S) AND ADDRESS:

Inspector General, Room 5250, Wilbur J. Cohen Building, Department of Health and Human Services, 330 Independence Avenue, SW., Washington, DC 20201.

NOTIFICATION PROCEDURES:

Exempt. However, consideration will be given requests addressed to the system manager. For general inquiries, it would be helpful if the request included date of birth and Social Security number, as well as the name of the individual.

RECORDS ACCESS PROCEDURE:

Same as notification procedures. Requestors should also reasonably specify the record contents being sought.

CONTESTING RECORD PROCEDURES:

Contact the system manager at the address specified above, and reasonably identify the record, specify the information to be contested, and the corrective action sought with supporting justification.

RECORD SOURCE CATEGORIES:

OIG collects information from a wide variety of sources, including information from the department and other Federal, State, and local agencies, witnesses, complaints and other nongovernmental sources.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

In accordance with subsection (j)(2) of the Privacy Act, 5 U.S.C. 552a(j)(2), the Secretary has exempted this system from the access, amendment, correction, and notification provisions of the Act, 5 U.S.C. 552a(c)(3), (d)(1)–(4), (e)(3), and (e)(4)(G) and (H).

[FR Doc. E6–20848 Filed 12–7–06; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[DHS–2006–0060]

Privacy Act of 1974; System of Records

AGENCY: Privacy Office; Department of Homeland Security.

ACTION: Privacy Act System of Records Notice; extension of comment period.

SUMMARY: This document provides additional time for interested persons to submit comments on the system of records notice for the Department of Homeland Security, U.S. Customs and Border Protection Automated Targeting System.

DATES: Comments on the Privacy Act System of Records Notice must be received on or before December 29, 2006.

ADDRESSES: You may submit comments, identified by docket number, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments via docket number DHS 2006–0060.
- *Fax:* 202–572–8727.
- *Mail:* Comments by mail may also be submitted to Hugo Teufel III, Chief Privacy Officer, Department of Homeland Security, Washington, DC 20528.
- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received go to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Laurence E. Castelli (202–572–8790), Chief, Privacy Act Policy and Procedures Branch, Bureau of Customs and Border Protection, Office of Regulations & Rulings, Mint Annex, 1300 Pennsylvania Ave., NW., Washington, DC 20229. For privacy issues please contact: Hugo Teufel III (571–227–3813), Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

Background

To provide expanded notice and transparency to the public, the Department of Homeland Security (DHS), U.S. Customs and Border Protection (CBP) published a Privacy Act system of records notice (SORN) in the **Federal Register** regarding the Automated Targeting System (ATS) on November 2, 2006 (71 Fed. Reg. 64543). As detailed in the SORN, ATS is the enforcement screening module associated with the Treasury Enforcement Communications System and was previously covered by the Treasury Enforcement Communications System ''System of Records Notice.'' This system of records is subject to the Privacy Act of 1974, as amended (5 U.S.C. 552a).

The DHS Privacy Office published the Privacy Impact Assessment (PIA) for ATS on November 24, 2006 on its Web site, *www.dhs.gov/privacy* under ''Privacy Impact Assessments.'' The PIA provides additional background information and context for the SORN, including specific information on measures taken by DHS to protect the privacy of persons whose information might be found in ATS.

The SORN referenced above did not identify or create any new collection of information; rather DHS merely provided additional notice and transparency of the functionality of these pre-existing systems. The SORN provided for a thirty day comment period which expired on December 4, 2006.

Extension of Comment Period

In response to the SORN published in the **Federal Register**, and the PIA published on the web, DHS has received a number of comments from the public requesting an extension of the comment period. DHS has decided to grant the request for the extension. Accordingly, the period of time for the submission of comments is being extended. Comments are now due on or before December 29, 2006.

Dated: December 4, 2006.

Hugo Teufel III,

Chief Privacy Officer.

[FR Doc. 06–9595 Filed 12–5–06; 11:07 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2006–26298)

Homeporting of Four National Security Cutters at Alameda, CA; Environmental Assessment

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Coast Guard (USCG) announces the availability of the draft Environmental Assessment (EA) for the homeporting of four National Security Cutters (NSCs) at Coast Guard Island (CGI), Alameda, California, and requests public comments. The draft EA tiers from the USCG's 2002 Final Programmatic Environmental Impact Statement (PEIS) for the Integrated Deepwater System (IDS) program. The purpose of the proposed action is to replace the four existing 378-foot High Endurance Cutters (WHECs) currently homeported at CGI with the NSCs. The USCG proposes to replace the WHECs on a one for one replacement schedule starting in 2007/2008 and continuing one per year until 2010/2011.

DATES: Comments and related material must reach the Docket Management Facility on or before January 8, 2007.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2006–26298 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, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001.

(3) *Fax:* 202–493–2251.

(4) *Delivery:* Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

Copies of the draft EA are also available at the Alameda Main Library, 2200–A Central Avenue, Alameda, CA 94501; and at the Oakland Public Library, 125 14th Street, Oakland, CA 94612.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, the proposed action, or the associated draft EA, contact CDR Paul Boinay, Coast Guard, telephone 571–218–3382 or e-mail *Paul.Boinay@dwicgs.com.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–493–0402.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to submit comments and related material on the draft EA. 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. Please see DOT's ''Privacy Act'' paragraph below.

Submitting comments: If you submit a comment, please include your name and address, identify the docket number for this notice (USCG–2006–26298), and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period.

Viewing the comments and draft EA: To view the comments and draft EA, go to *http://dms.dot.gov* at any time, click on ''Simple Search,'' enter the last five digits of the docket number for this notice, and click on ''Search.'' You may also visit the Docket Management Facility in room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. Copies of the draft EA are also available at the Alameda Main Library, 2200–A Central Avenue, Alameda, CA 94501; and at the Oakland Public Library, 125 14th Street, Oakland, CA 94612.

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

Proposed Action

To continue to meet America's 21st century maritime threats and challenges, the Coast Guard initiated the Integrated Deepwater System program, the largest and most innovative acquisition in the Coast Guard's history. The IDS will contribute to the Coast Guard's maritime domain awareness, as well as the improved ability to intercept, engage, and deter those activities that pose a direct challenge/threat to U.S. sovereignty and security. IDS will provide the means to extend our layered maritime defenses from our ports and coastal areas to hundreds of miles out to sea.

As part of the IDS program, the Coast Guard proposes a NSC homeporting plan that entails homeporting four NSCs, some pier improvements and a new administrative building at CGI in Alameda, California. The four NSCs would replace, on a one-for-one basis, the four aging 378-foot High-Endurance Cutters (WHECs) currently stationed in Alameda.

To accommodate the vessels and crew, in addition to the proposed homeporting, improvements to the existing waterfront pier and construction of a new administration building would be required at the existing base to provide adequate shore-side support.

Draft Environmental Assessment

We have prepared a draft EA. The draft EA identifies and examines the reasonable alternatives and assesses their potential environmental impact. The draft EA evaluates the potential direct, indirect and cumulative impacts associated with the NSC homeporting plan. The draft EA tiers from the USCG's Final PEIS for the IDS Program (see notice of availability, 67 FR 15275, Mar. 29, 2002).

Our preferred alternative is to homeport the four NSCs into an area where the necessary shore side infrastructure and port environment already exists to support this class and number of vessels. The existing base on CGI provides the shore support necessary to meet the logistical requirements of the four NSCs. This existing support includes secure facilities, easy access for Coast Guard personnel, administrative and support buildings and services, and required shore ties to service in-port cutters.

We are requesting your comments on the draft EA including environmental impacts and resources analyzed in the draft EA or possible sources of data or information not included in the draft EA. Your comments will be considered in preparing the final EA.

Dated: December 5, 2006.

Joseph E. Mihelic,

Chief of Deepwater Transition Management.

[FR Doc. E6–20935 Filed 12–7–06; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2006–26416]

Voyage Data Recorder Study

AGENCY: Coast Guard, DHS.

ACTION: Notice; request for information.

SUMMARY: This notice solicits public input as part of a study on the feasibility, cost and associated concerns or benefits with the installation of voyage data recorders on passenger vessels. In the Coast Guard and Maritime Transportation Act of 2006, the Congress directed the U.S. Coast Guard to conduct a study of the carriage of voyage data recorders (VDR) by certain passenger vessels. As part of this study, the Coast Guard is to look at the standards, the methods for approval of models, and the procedures for the annual testing of the VDR.

DATES: Information and related material must reach the Docket Management Facility on or before February 6, 2007.

ADDRESSES: You may submit information identified by Coast Guard docket number USCG–2006–26416 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, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001.

(3) Fax: 202–493–2251.

(4) Delivery: Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(5) Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions on the Web site.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or e-mail Ms. Dolores Mercier, U.S. Coast Guard Office of Design and Engineering Standards, telephone 202–372–1381, e-mail *dolores.mercier@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–493–0402.

SUPPLEMENTARY INFORMATION:

Request for Information

All comments and information 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. Please see DOT's ''Privacy Act'' paragraph below.

Submitting comments and information: If you submit information, please include your name and address, identify the docket number for this notice (USCG–2006–26416) and give the reason for each comment or for bringing information to our attention. You may submit your information by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your information by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and information received during the comment period.

Viewing comments and documents: To view comments, go to *http://dms.dot.gov* at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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

Background and Purpose

In the Coast Guard and Maritime Transportation Act of 2006, section 420, Congress directed the U.S. Coast Guard to conduct a study of the carriage of voyage data recorders (VDR) by passenger vessels described in section 2101(22)(D) of title 46, United States Code, carrying more than 399 passengers. The study is to include the standards, the methods for approval of models, and the procedures for the annual testing of the VDR's.

The vessels that this study involves are ferries of at least 100 gross tons as measured under title 46 U.S.C. section 14502 or an alternative tonnage measured under title 46 U.S.C. 14302, providing transportation only between places that are not more than 300 miles apart carrying more than 399 passengers.

This study will review the history of VDR's, their current regulation and carriage requirements, the cost of the equipment, and the potential benefits. Consultation from both VDR manufacturer's and the operators of the affected ferries will be included.

Through this notice, the Coast Guard asks for comments and information related to the carriage of VDR's. The most helpful comments will be those that include details about:

- Installation;
- Equipment costs;
- Operational requirements;
- VDR equipment standards and approval methods; and
- Training requirements.

In submitting comments on these issues, the Coast Guard recognizes and encourages input from all parties that will be affected if the carriage requirement becomes mandatory. The following questions should assist you in submitting your comments.

- What are the potential benefits from the installation of a VDR?
- For passenger vessels subject to the Safety of Life at Sea (SOLAS) 2000 amendments, the Coast Guard has implemented standards for VDR's as well as methods of approval and procedures for the annual performance testing. Should the Coast Guard use these established standards and procedures for the purposes of this study?
- What would be the potential cost of equipment and installation?
- What types of equipment inputs would be required vs. the equipment inputs that are actually available?
- Would the crew need to change operational practices?
- What additional training, if any would be required?
- In what type of marine incidents (*e.g.*, grounding, collisions, etc) would VDR's prove the most useful?
- Should the Coast Guard consider the use of a Simplified Voyage Data Recorder (S–VDR) in lieu of a VDR?
- What is the operational feasibility of recovering the VDR data box?
- What would be the guidelines for the ownership and or rights to access the data?
- If carriage of the VDR becomes mandatory, what would be a reasonable timeline for implementation?
- Would the carriage of VDR's on other domestic vessels be beneficial? If so, which vessels and why?

• Is the current threshold of 399 passengers or more appropriate? Should other thresholds be considered?

The voyage data recorder study report will be available to the public, and comments submitted in response to this notice will be addressed in the report.

Dated: December 4, 2006.

Howard L. Hime,

Acting Director of National and International Standards, Assistant Commandant for Prevention, U.S. Coast Guard.

[FR Doc. E6–20801 Filed 12–7–06; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5045–N–49]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: December 8, 2006.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, Department of Housing and Urban Development, Room 7262, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: November 30, 2006.

Mark R. Johnston,

Acting Deputy Assistant, Secretary for Special Needs.

[FR Doc. 06–9533 Filed 12–07–06; 8:45am]

BILLING CODE 4210–67–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of the Final Comprehensive Conservation Plan and Finding of No Significant Impact for St. Marks National Wildlife Refuge in Wakulla, Jefferson, and Taylor Counties, FL

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: The Fish and Wildlife Service announces that a Final Comprehensive Conservation Plan and Finding of No Significant Impact for St. Marks National Wildlife Refuge in Wakulla, Jefferson, and Taylor Counties, Florida, is available for distribution. The plan was prepared pursuant to the National Wildlife Refuge System Improvement Act of 1997, and in accordance with the National Environmental Policy Act of 1969, and describes how the refuge will be managed for the next 15 years.

ADDRESSES: A copy of the plan may be obtained by writing: Mary Morris, Natural Resources Planner, St. Marks National Wildlife Refuge, P.O. Box 68, St. Marks, Florida 32355, or by calling: 850/925–6121. The plan may also be accessed and downloaded from the Service's Website: *http://southeast.fws.gov/planning/,* or from the refuge's Website: *http://www.fws.gov./saintmarks/.*

SUPPLEMENTARY INFORMATION: The availability of the Draft Comprehensive Conservation Plan and Environmental Assessment for a 60-day public review and comment period was announced in the **Federal Register** on January 20, 2006 (71 FR 3317). Three public meetings were held on February 16, 22, and 23, 2006, in Panacea, Crawfordville, and Tallahassee, Florida, respectively. At least 56 persons attended these public meetings. Numerous letters and e-mails were received from individuals and organizations expressing comments on the draft plan and environmental assessment. The draft plan and environmental assessment was circulated to ten agencies as part of the Florida Clearinghouse process. The Florida Department of Environmental Protection found the draft plan and environmental assessment consistent with the State's Coastal Management Program.

The draft plan and environmental assessment identified and evaluated three alternatives for managing the refuge. Alternative 1, the ''status quo'' alternative, would continue current management and public use. Alternative 2 would focus on enhancement of wildlife populations and related habitats and would provide visitors with more opportunities for wildlife-dependent recreation. Environmental education and outreach would expand under this alternative. Under Alternative 3, the biological programs of the refuge would be greatly enhanced.

Based on the environmental assessment and the comments received, the Service adopted Alternative 2 as its preferred alternative. The priority issues addressed under this alternative are: Habitat protection and land conservation; migratory birds; partnerships; fire and forest management; exotic, invasive, and nuisance species; wildlife inventory and monitoring; imperiled species management; visitor services; and wilderness and cultural resources protection.

The Service believes that Alternative 2 will best achieve national, ecosystem, and refuge-specific goals and objectives and positively address significant issues and concerns expressed by the public.

St. Marks National Wildlife Refuge was established in 1931 as a breeding ground for wild animals and birds. The refuge is situated along the Gulf coast of northwest Florida, about 25 miles south of Tallahassee. It currently covers about 69,155 acres with an approved acquisition boundary of 74,469 acres. Refuge personnel also manage 947 acres of State land and 334 acres of USDA Forest Service land within the approved acquisition boundary. The Wilderness Act designated 17,446 acres as the St. Marks Wilderness. The refuge aims to provide habitat for a natural diversity of plants and animals with a primary purpose of wildlife habitat conservation. The refuge is also being managed to provide opportunity for compatible wildlife-dependent recreation.

Authority: This notice is published under the authority of the National Wildlife Refuge System Improvement Act of 1997, Public Law 105–57.

Dated: July 5, 2006.

Cynthia K. Dohner,

Acting Regional Director.

Editorial note: This document was received at the Office of the Federal Register on 12–5–06.

[FR Doc. 06–9591 Filed 12–7–06; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

U.S. Geological Survey

Request for Public Comments on Information Collection To Be Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

A request extending the collection of information listed below will be submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the USGS Clearance Officer at the phone number listed below. Comments and suggestions on the requirement should be made within 60 days directly to the USGS Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192.

As required by OMB regulations at CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments regarding the proposed information collection as to:

1. Whether the collection of information is necessary for the proper performance of the functions of the USGS, including whether the information will have practical utility;

2. the accuracy of the USGS estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

3. the utility, quality, and clarity of the information to be collected; and

4. how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated electronic, mechanical, or other forms of information technology.

Title: Production Estimate, Construction Sand and Gravel and Crushed and Broken Stone.

Current OMB approval number: 1028–0065.

Abstract: This collection is needed to provide data on mineral production for annual reports published by commodity for use by Government agencies, industry, education programs, and the general public. One publication is the ''Mineral Commodity Summaries,'' the first preliminary publication to furnish estimates covering the previous year's nonfuel mineral industry.

Bureau form numbers: 9–4042–A, 9–4124–A, 9–4142–A.

Frequency: Quarterly and Annually.

Description of respondents: Producers of industrial minerals and metals.

Annual Responses: 2,802.

Annual burden hours: 612.

Bureau clearance officer: Alfred Travnicek, 703–648–7231.

John H. DeYoung, Jr.,

Chief Scientist, Minerals Information Team.

[FR Doc. 06–9583 Filed 12–07–06; 8:45 am]

BILLING CODE 4310–47–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–921–06–1320–EL; COC 67232]

Notice of Competitive Coal Lease Offering By Sealed Bid, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Competitive Coal Lease Sale, Lease Application COC 67232.

SUMMARY: Notice is hereby given that the United States Department of the Interior, Bureau of Land Management (BLM), Colorado State Office, will offer certain coal resources in the B, D/E seams in Gunnison County, Colorado, hereinafter described as Federal coal lease application (LBA) COC 67232 for competitive lease by sealed bid in accordance with the provisions for competitive lease sales in 43 CFR 3422.2(a), and the Mineral Leasing Act of 1920, as amended and supplemented (30 U.S.C. 181 *et seq.*).

DATES: The lease sale will be held at 11 a.m., Wednesday, January 24, 2007. Sealed bids must be sent by certified mail, return receipt requested, or be hand delivered to the address indicated below, and must be received on or before 10 a.m., Wednesday, January 24, 2007. The cashier will issue a receipt for each hand delivered sealed bid. Any bid received after the time specified will not be considered and will be returned. The outside of the sealed envelope containing the bid must clearly state that the envelope contains a bid for Coal Lease Sale COC 67232, and is not to be opened before the date and hour of the sale.

ADDRESSES: The lease sale will be held in the BLM, Colorado State Office, Conference Room, Fourth Floor, 2850 Youngfield Street, Lakewood, Colorado. Sealed bids must be submitted, hand delivered or mailed to the Cashier, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215.

FOR FURTHER INFORMATION CONTACT: Karen Zurek at BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215 or telephone 303–239–3795.

SUPPLEMENTARY INFORMATION: The coal resource to be offered consists of all recoverable coal reserves to be mined by underground mining methods in the following lands:

T. 13 S., R. 90 W., 6th P.M.
Sec. 35, lots 5 through 7, inclusive, and lots 9 through 16, inclusive, except lands embraced in coal leases C–1362 and COC 56447, as modified;
Sec. 36, W½SW¼NW¼, and W½SW¼, except lands embraced in coal lease COC 56447, as modified.
T. 14 S., R. 90 W., 6th P.M.
Sec. 1, lots 3, 4, S½NW¼, SW¼, W½NW¼SE¼, and SW¼SE¼;
Sec. 2, lots 1 through 4, inclusive, S½N½, and S½;
Sec. 11, N½N½;
Sec. 12, N½NW¼, and NW¼NE¼.
Containing approximately 1,517.13 acres in Gunnison County, Colorado.

Total recoverable reserves are estimated to be 17.3 million tons. The underground mineable coal is ranked as high volatile B bituminous coal. Although other seams are included in the application, only the B and D/E seams are considered mineable. The estimated coal quality on an as-received basis for the B and D/E Seams are as follows:

B Seam:	
BTU	11,886 BTU/lb.
Volatile Matter	35.80%
Moisture	8.50%
Fixed Carbon	47.00%
Sulfur Content	0.62%
Ash Content	8.56%
D/E Seam:	
BTU	11,726 BTU/lb
Moisture	10.45%
Sulfur Content	0.46%
Ash Content	6.62%

The tract will be leased to the qualified bidder of the highest cash amount, provided that the high bid meets the fair market value (FMV) for the tract as determined by the authorized officer after the Sale. The Department of the Interior has established a minimum bid of $100 per acre or fraction thereof for Federal coal tracts. The minimum bid is not intended to represent FMV. In the event identical high sealed bids are received, the tying high bidders will be requested to submit follow-up bids until a high bid is received. All tie-breaking sealed bids must be submitted within 15 minutes following the Sale Official's announcement at the sale that identical high bids have been received.

The lease issued as a result of this offering will provide for payment of an annual rental of $3.00 per acre or fraction thereof and a royalty payable to the United States of 8 percent of the value of coal mined by underground methods. The value of the coal will be

determined in accordance with 30 CFR 206.250.

Bidding instructions for the offered tract are included in the Detailed Statement of Coal Lease Sale. Copies of the Detailed Statement and the proposed coal lease are available upon request in person or by mail from the Colorado State Office at the address given above. The case file is available for inspection in the Public Room, Colorado State Office, during normal business hours at the address given above.

Karen Zurek,

Solid Minerals Staff, Division of Energy, Lands and Minerals.

[FR Doc. E6–20913 Filed 12–7–06; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–100–05–1310–DB]

Notice of the Pinedale Anticline Working Group Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (1976) and the Federal Advisory Committee Act (1972), the U.S. Department of the Interior, Bureau of Land Management (BLM) Pinedale Anticline Working Group (PAWG) will meet in Pinedale, Wyoming, for business meetings. Group meetings are open to the public.

DATES: Eleven meeting dates have been set for the following dates: 12–5 December 18, 2006. 9–5 January 25, 8–12 January 26, 2007. 12–5 February 22, 2007. 12–5 March 22, 2007. 12–5 April 26, 2007. 12–5 May 24, 2007. 12–5 June 28, 2007. 12–5 July 26, 2007. 12–5 September 27, 2007. 12–5 October 25, 2007.

ADDRESSES: The meetings are scheduled to be held in the Bureau of Land Management conference room, 432 E. Mill St. Pinedale, WY, 82941.

FOR FURTHER INFORMATION CONTACT: Matt Anderson, BLM/PAWG Liaison, Bureau of Land Management, Pinedale Field Office, 432 E. Mills St., P.O. Box 738, Pinedale, WY, 82941; 307–367–5328.

SUPPLEMENTARY INFORMATION: The Pinedale Anticline Working Group (PAWG) was authorized and established with release of the Record of Decision (ROD) for the Pinedale Anticline Oil and Gas Exploration and Development Project on July 27, 2000. The PAWG advises the BLM on the development and implementation of monitoring plans and adaptive management decisions as development of the Pinedale Anticline Natural Gas Field proceeds for the life of the field.

Dated: November 28, 2006.

William Lanning,

Field Office Manager.

[FR Doc. 06–9606 Filed 12–7–06; 8:45 am]

BILLING CODE 4310–22–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–310–1310–PB–24 1A]

Oil and Gas Leasing: Onshore Oil and Gas Operations—Fees, Rentals, and Royalty

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of termination of the stripper well royalty reductions program.

SUMMARY: The termination of benefits for stripper well properties was effective February 1, 2006, and replaced by Section 343 of the Energy Policy Act of 2005, which was established a Marginal Property Production Incentives Program (MPPIP).

FOR FURTHER INFORMATION CONTACT: Rudy Baier, Division of Fluid Minerals, BLM, (202) 452–5024. Persons who use a telecommunications device for the deaf may call the Federal Information Relay Service at 1–800–877–8339, 24 hours a day, 7 days a week, except holidays, for assistance in reaching Mr. Baier.

SUPPLEMENTARY INFORMATION: By **Federal Register** notice (70 FR 42093) dated July 21, 2005, the Bureau of Land Management (BLM) provided six-month notification, as required by regulation, to terminate the benefits of the royalty rate reductions granted under the stripper well royalty reductions (*see* 43 CFR 3103.4–2) program. In that FR notice, the BLM requested comments specifically on the financial conditions under which the BLM would reestablish the benefits under that program. The BLM received five comments. The comments will be considered if BLM develops a stripper/marginal property replacement program.

The BLM has determined that it will not establish the current program since the MPPIP was established by Congress to take its place until the Secretary of the Interior issues regulations prescribing different relief.

The current regulations authorize royalty rate reduction on a case-by-case basis (*see* 43 CFR 3103.4–1).

Dated: October 19, 2006.

Thomas P. Lonnie,

Assistant Director, Minerals, Realty, and Resource Protection.

[FR Doc. 06–9530 Filed 12–07–06; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF THE INTERIOR

National Park Service

National Park Service Benefits-Sharing Draft Environmental Impact Statement

AGENCY: National Park Service, Department of the Interior.

ACTION: This notice informs the public that the comment period for the National Park Service Benefits-Sharing Draft Environmental Impact Statement covering all units of the National Park System is extended.

SUMMARY: The National Park Service published a Notice of Availability on September 26, 2006, (71 FR 186) for the National Park Service Benefits-Sharing Draft Environmental Impact Statement. The public comment period was to expire December 15, 2006. This notice extends the public comment period until January 29, 2007.

DATES: Comments on the Draft Environmental Impact Statement will be accepted through January 29, 2007.

ADDRESSES: Information will be available for public review and comment on the Internet at *http://parkplanning.nps.gov* (Select ''Washington Office'' from the ''Choose a park'' pick list and then click on the link for ''benefits-sharing''), in the office of the National Park Service Associate Director for Natural Resource Stewardship and Science, 1849 C Street, NW., Washington, DC, and in the office of the Superintendent, Yellowstone National Park, Wyoming.

FOR FURTHER INFORMATION CONTACT: Susan Mills, Benefits-Sharing EIS, Center for Resources, P.O. Box 168, Yellowstone National Park, Wyoming 82190, (307)344–2203, *benefitseis@nps.gov*.

SUPPLEMENTARY INFORMATION: If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to Benefits-Sharing EIS Team, Center for Resources, P.O. Box 168, Yellowstone National Park, Wyoming 82190. You may also comment via the Internet at *http://parkplanning.nps.gov*. If you do not receive a confirmation from the

system that we have received your Internet message, contact us directly at the Yellowstone Center for Resources 307–344–2203. Finally, you may hand-deliver comments to the Yellowstone Center for Resources in Yellowstone National Park, Wyoming. Our practice is to make comments, including names, home addresses, home phone numbers, and e-mail addresses of respondents, available for public review. Individual respondents may request that we withhold their names and/or home addresses, etc., but if you wish us to consider withholding this information you must state this prominently at the beginning of your comments. In addition, you must present a rationale for withholding this information. This rationale must demonstrate that disclosure would constitute a clearly unwarranted invasion of privacy. Unsupported assertions will not meet this burden. In the absence of exceptional, documentable circumstances, this information will be released. We will always make submissions from organizations or businesses, and from individuals identifying themselves as representatives of or officials of organizations or businesses, available for public inspection in their entirety.

Dated: November 20, 2006.

Michael A. Soukup,

Associate Director, Natural Resource Stewardship and Science, National Park Service.

[FR Doc. E6–20854 Filed 12–7–06; 8:45 am]

BILLING CODE 4312–CT–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

South Delta Improvements Program, Sacramento-San Joaquin Bay Delta, CA

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of Availability of the Final Environmental Impact Statement/ Environmental Impact Report (EIS/EIR).

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA) and the California Environmental Quality Act (CEQA), the Bureau of Reclamation (Reclamation) and the California Department of Water Resources (DWR) have prepared a Final EIS/EIR for the South Delta Improvements Program (SDIP).

The SDIP is being pursued to address the needs of the Sacramento-San Joaquin River Delta (Delta) aquatic environment, as well as longstanding statewise, regional and local water supply needs. Reclamation and DWR have identified the following objectives and purpose: reduce the movement of San Joaquin River watershed Central Valley fall-/late fall-run juvenile Chinook salmon into the south Delta via Old River; maintain adequate water levels and, through improved circulation, water quality available for agricultural diversions in the south Delta, downstream of the head of Old River; and increase water deliveries and delivery reliability for Central Valley Project (CVP) and State Water Project (SWP) water contractors south of the Delta and provide opportunities to convey water for fish and wildlife purposes by increasing the maximum permitted level of diversion through the existing intake gates at Clifton Court Forebay from 6680 cubic feet per second (cfs) to 8500 cfs.

DATES: Reclamation will not make a decision on the proposed action until at least 30 days after release of the Final EIS/EIR. After the 30-day waiting period, Reclamation will complete a Record of Decision (ROD). The ROD will state the action that will be implemented and will discuss all factors leading to the decision.

ADDRESSES: A compact disc of the Final EIS/EIR may be requested from Ms. Sammie Cervantes, Bureau of Reclamation, 2800 Cottage Way, Sacramento CA 95825, by calling 916–978–5189, TDD 916–978–5068, or by e-mail at *scervantes@mp.usbr.gov.* The Final EIS/EIR is accessible at the following Web site: *http://www.usbr.gov/mp/nepa/nepa_projdetails,cfm?Project_ID=316.*

See Supplemental Information section for locations where a compact disc is available for viewing.

FOR FURTHER INFORMATION CONTACT: Ms. Sharon McHale, Reclamation Program Manager, Bureau of Reclamation, at 916–978–5086, TDD 916–978–5608, or by e-mail at *smchale@mp.usbr.gov.*

SUPPLEMENTARY INFORMATION: The Final EIS/EIR addresses facilities-related impacts including the effects of project construction and operation on hydrology, water quality, fish resources, recreation, vegetation and wildlife, visual resources, cultural resources, land use, geology, soils, seismicity, groundwater, traffic and circulation, air quality, noise, and public health and safety. Diversion-related impacts include the effects of increased diversions from the Bay Delta and associated changes in Reclamation's operation of CVP facilities and DWR's operation of SWP facilities. Project diversions therefore may directly or indirectly affect the Sacramento River, its tributaries, San Joaquin River, its tributaries, and Delta resources including water supply, fish and aquatic habitat, riparian vegetation and habitat, water quality, recreation, visual and cultural resources. The Final EIA/EIR also evaluated potential growth-inducing impacts for the CVP and SWP water service areas. An evaluation of cumulative hydrologic and water service area impacts associated with reasonably foreseeable actions is also included.

The Notice of Availability of the Draft EIS/EIR was published in the **Federal Register** on Thursday, November 10, 2005, (70 FR 68475). The written comment period on the Draft EIS/EIR ended Tuesday, February 7, 2006. The Final EIS/EIR contains responses to all comments received and changes made to the text of the Draft EIS/EIR as a result of those comments and any additional information received during the review period.

Public meetings to discuss the purpose and content of the Draft EIS/EIR were held on the following dates and locations: December 6, 2005, in Sacramento CA; December 7, 2005, in Stockton CA; December 8, 2005, in Oakland CA; December 13, 2005, in Visalia CA; and December 14, 2005, in Los Angeles CA. Public hearings were held on January 18, 2006, in Sacramento CA; January 25, 2005, in Los Angeles CA; and January 26, 2006, in Stockton CA.

A compact disc of the Final EIS/EIR is available for viewing at the following locations:

- California Department of Water Resources, Bay-Delta Office, 1416 Ninth Street, Sacramento, CA 95814.
- Bureau of Reclamation, Regional Library, 2800 Cottage Way, Sacramento, CA 95825–1898.
- Bureau of Reclamation, Denver Office Library, Building 67, Room 167, Denver Federal Center, 6th and Kipling, Denver, CO 80225.
- Natural Resources Library, U.S. Department of the Interior, 1849 C Street, NW., Main Interior Building, Washington, DC 20240–0001.
- Sacramento Public Library, 828 I Street, Sacramento, CA 95814.
- Tracy Branch Library, 20 E. Eaton Avenue, Tracy, CA 95376.
- Lathrop Branch Library, 15461 Seventh Street, Lathrop, CA 95330.
- Cesar Chavez Central Library, 60 North El Dorado Street, Stockton, CA 95202.
- Shasta County Main Library, 1855 Shasta Street, Redding, CA 96001.
- Oakland Main Library, 125 14th Street, Oakland, CA 94612.

• Los Angeles Central Library, 630 West 5th Street, Los Angeles, CA 90071.

• Visalia Branch Library—Main Library, 200 West Oak Avenue, Visalia, CA 932891–4993.

Public Disclosure Statement: Comments received in response to this notice will become part of the administrative record and are subject to public inspection. Our practice is to make comments, including names, home addresses, home phone numbers, and e-mail addresses of respondents, available for public review. Individual respondents may request that we withhold their names and/or home addresses, etc., but if you wish us to consider withholding this information, you must state this prominently at the beginning of your comments. In addition, you must present a rationale for withholding this information. This rationale must demonstrate that disclosure would constitute a clearly unwarranted invasion of privacy. Unsupported assertions will not meet this burden. In the absence of exceptional, documentable circumstances, this information will be released. We will always make submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Frank J. Michny,

Acting Assistant Regional Director, Mid-Pacific Region.

[FR Doc. 06–9601 Filed 12–7–06; 8:45 am]

BILLING CODE 4310–MN–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection for 1029–0089

AGENCY: Office of Surface Mining Reclamation and Enforcement.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request renewed authority for the following collection of information: 30 CFR part 702 regarding the exemption of coal extraction incidental to the extraction of other minerals. This information collection activity was previously approved by the Office of the Management and Budget (OMB), and assigned clearance number 1029–0089.

DATES: Comments on the proposed information collection must be received by February 6, 2007, to be assured of consideration.

ADDRESSES: Comments may be mailed to John A. Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave., NW., Room 202—SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection request and explanatory information contact John A. Trelease, at (202) 208–2783 or e-mail at the address provided above.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. This notice identifies an information collection that OSM will be submitting to OMB for approval. This collection is contained in 30 CFR Part 702, Exemption for Coal Extraction Incidental to the Extraction of Other Minerals. OSM will request a 3-year term of approval for this information collection activity.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

The following information is provided for each information collection: (1) Title of the information collection; (2) OMB control number; (3) summary of the information collection activity; and (4) frequency of collection, description of the respondents, estimated total annual responses, and the total annual reporting and recordkeeping burden for the collection of information.

Title: 30 CFR Part 702, Exemption for Coal Extraction Incidental to the Extraction of Other Minerals.

OMB Control Number: 1029–0089.

Summary: This part implements the requirement in Section 701(28) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), which grants an exemption from the requirements of SMCRA to operators extracting not more than 16⅔ percentage tonnage of coal incidental to the extraction of other minerals. This information will be used by the regulatory authorities to make that determination.

Bureau Form Number: None.

Frequency of Collection: Once and annually thereafter.

Description of Respondents: Producers of coal and other minerals and State regulatory authorities.

Total Annual Responses: 120.

Total Annual Burden Hours: 535.

Total Non-wage Costs: $200.

Dated: December 4, 2006.

John R. Craynon,

Chief, Division of Regulatory Support.

[FR Doc. 06–9592 Filed 12–7–06; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF LABOR

Office of the Solicitor; Public Forum on the Department of Labor Freedom of Information Act (FOIA) Improvement Plan

AGENCY: Office of the Solicitor (SOL), Department of Labor.

ACTION: Scheduling of public forum; invitation to participate and request for comments.

SUMMARY: The Department of Labor is scheduling a public forum to seek input from the public on how it might improve the quality and efficiency of the Department's administration of the Freedom of Information Act (FOIA). This forum is part of the Department's FOIA Improvement Plan finalized earlier in 2006. Interested persons are encouraged to submit written comments in response to the questions contained in this notice and offer additional suggestions for improving the quality and efficiency of the Department's FOIA efforts. Attendees are invited to speak on these questions and other related issues at the public forum; those who only wish to observe the forum are welcome to attend as well. The Department's FOIA Improvement Plan is available at *http://www.dol.gov/dol/foia/* (See link for ''Agency Plan and Report'').

Background: On June 14, 2006, the Department submitted its FOIA Improvement Plan and Report pursuant to Executive Order 13392 (''Improving Agency Disclosure of Information''). As part of its FOIA Improvement Plan, the Department has been examining various components of its FOIA practices and

procedures. One key component of the plan is outreach to the requester community and solicitation of input concerning ways the Department could improve the quality and efficiency of its FOIA efforts. At this time, the Department is soliciting input on ways to improve its FOIA efforts and, in particular, its written communication with individual requesters.

The Department is convening this forum to begin the public input process. The first part of the program will consist of presentations by Departmental officials involved in the FOIA process. The second part of the program will be set aside to allow members of the requester community and the public to make suggestions or ask questions about the Department's FOIA Improvement Plan or its FOIA processes generally.

DATES: *Forum.* The public forum will take place at the DOL Auditorium, Frances Perkins Building, U.S. Department of Labor, 200 Constitution Ave., NW., Washington DC 20210. The forum is scheduled for 10 a.m. to 12 p.m., December 18, 2006.

Written comments. The Department invites oral and written comments in connection with the forum. Comments may be submitted by mail, facsimile or electronically.

Notice of intention to speak at the forum. In order to accommodate maximum participation at the forum, the Department asks that individuals wishing to speak submit a written intention to speak at the forum by December 14, 2006. Notices may be submitted by mail, facsimile or electronically. If possible, please include an e-mail address or fax number in your notice, so we may contact you about scheduling. The Department requests that presentations be limited to no more than 10 minutes. The amount of time allotted will depend on the number of speakers who wish to speak.

ADDRESSES: Written comments and notices of intention to speak at the forum may be submitted by mail, facsimile, or electronic means:

Written comments: The Department encourages written comments (including electronic or facsimile form) relating to the subject of the forum on an ongoing basis. They may be submitted to the address below.

Mail: Submit three copies of written comments to: Mr. Brad Mantel, Office of Legal Counsel, Office of the Solicitor, U.S. Department of Labor, 200 Constitution Ave., NW., Room N–2700, Washington DC 20210, telephone (202) 693–4964.

Facsimile: If your comments are 10 pages or fewer, you may fax them to Mr. Mantel at (202) 693–5774.

Electronic: You may submit comments electronically to Mr. Mantel at *mantel.brad@dol.gov*.

Notice of intention to speak at the forum:

Mail: You may submit a notice of intention to speak to Mr. Brad Mantel, Office of Legal Counsel, Office of the Solicitor, U.S. Department of Labor, 200 Constitution Ave., NW., Room N–2700, Washington, DC 20210, telephone (202) 693–4964.

Facsimile: You may fax your notice of intention to speak to Mr. Mantel at (202) 693–5774.

Electronic: You may also electronically submit your intention to speak to Mr. Mantel at *mantel.brad@dol.gov*.

FOR FURTHER INFORMATION CONTACT: Brad Mantel, Office of Legal Counsel, Office of the Solicitor, telephone (202) 693–4964.

SUPPLEMENTARY INFORMATION: The forum will include agency presentations from Departmental officials on the FOIA Improvement Plan and agency FOIA processes, including the Department's Chief FOIA Officer and the FOIA Public Liaison. The forum is also designed to obtain input from the requester community through an open-microphone session in which participants can address suggestions or questions to the Departmental FOIA agency staff. The Department is particularly interested in hearing from the requester community and the public on the following issues, but encourages input on a broad range of issues and ideas relating its FOIA process:

Question 1: What additional information can the Department provide on its Web site to assist members of the public in making FOIA requests?

Question 2: What additional methods can the Department utilize to improve communication with the requester community?

Question 3: What is the best way of providing requesters information on the status of their FOIA requests?

Question 4: What information should be included in all FOIA acknowledgement letters?

Question 5: Would a continuing dialogue with the requester community about the Department's FOIA process be useful? If so, what is the optimal format? Should DOL establish an ''electronic'' suggestion box for FOIA matters?

Individuals with disabilities wishing to attend the forum who need special accommodation should contact Mr. Mantel at (202) 693–4964, or at *mantel.brad@dol.gov*.

Authority: This notice was prepared under the direction of Robert A. Shapiro, Associate Solicitor for Legal Counsel and Chief FOIA Officer.

Signed at Washington, DC, this 5th day of December, 2006.

Robert A. Shapiro,

Associate Solicitor for Legal Counsel and Chief FOIA Officer.

[FR Doc. E6–20922 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–23–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Proposed Information Collection; Request for Public Comment Health Disclosure and Claims Issues Project Survey

ACTION: Notice

SUMMARY: The Department of Labor (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This program helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. Currently, the Employee Benefits Security Administration is soliciting comments on a proposed new information collection entitled the Health Disclosure and Claims Issues Project Survey. A copy of the information collection request (ICR) can be obtained without charge by contacting the office listed below in the Addresses section of this notice.

DATES: Written comments must be submitted on or before February 6, 2007.

ADDRESSES: Direct all written comments to Susan G. Lahne, Office of Policy and Research, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–5716, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers. Comments may also be submitted electronically to the following Internet e-mail address: *ebsa.opr@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 1999, the Department conducted a pilot project under which approximately 200 group health plans were investigated for compliance with

Part 7 of the Employee Retirement Income Security Act of 1974 (ERISA). In 2001, the Department initiated the Health Disclosure and Claims Issues: Fiscal Year 2001 Compliance Project (HDCI), which sought to increase compliance through investigations and improve the Department's ability to provide effective compliance assistance by assessing more comprehensively the extent and nature of compliance with Part 7 of ERISA among group health plans. As a result of that project, the Department broadened its compliance assistance efforts through a combination of publications, outreach, self-audit materials, and other compliance tools. As a follow-up to the Fiscal Year 2001 Compliance Project, the Department proposes to conduct a second project, HDCI 2, which is intended to measure changes in compliance with Part 7 of ERISA and to improve the effectiveness of future compliance assistance efforts. As part of HDCI 2, the Department proposes to conduct a narrow scope telephone survey for the sole purpose of identifying an appropriate sample of ERISA-covered single-employer group health plans in two categories: (1) Plans sponsored by firms with 3–99 employees, and (2) plans sponsored by firms with 100 or more employees. The survey is necessary because the Department has no available information from which to identify an appropriate sample of ERISA-covered single-employer group health plans. Group health plans that are identified through the telephone survey will be subject to investigation for compliance with the requirements of the health coverage provisions of Part 7 of ERISA. The investigations will be conducted under the investigative authority of the Department and are not part of the Health Disclosure and Claims Issues Project Survey. The Department has determined that conducting a telephone survey is the simplest, least burdensome method of obtaining the information necessary to identify ERISA-covered single-employer plans for this purpose.

The telephone survey will be limited in scope and designed to elicit only enough information to determine whether the firm that has been contacted sponsors or is part of a controlled group of firms that sponsors a group health plan subject to the provisions of Part 7. Respondents will be asked by telephone if they provide health benefits to their employees and, if so, the number of employees they have (to determine whether the plan is subject to Part 7 of ERISA or if a small plan exemption applies), and questions to determine whether the firm is a subsidiary that is part of a controlled group of employers and, therefore, whether the plan is sponsored by a parent that will need to be contacted. A respondent's participation in the call will be voluntary. The Department estimates that it will need to contact up to 5,000 firms in order to derive an adequate sample of ERISA-covered single-employer group health plans in each of the two categories described above. The goals of HDCI 2 are to identify and correct violations of Part 7 of ERISA, calculate compliance rates, provide compliance assistance regarding these provisions, and shape the Department's future compliance assistance and investigative resources strategies more efficiently and effectively.

II. Current Actions

This notice requests public comment pertaining to Office of Management and Budget (OMB) approval of the information collection contained in the telephone survey described above, which is necessary for purposes of the Health Disclosure and Claims Issues Project Survey. The Department intends, following the receipt of comments pursuant to this notice, to submit an ICR to OMB requesting its approval of this information collection. An agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a valid OMB control number. A summary of the ICR and the current burden estimates follows:

Type of Review: New collection.

Agency: Employee Benefits Security Administration.

Title: Health Disclosure and Claims Issues Project Survey.

OMB Number: 1210–NEW.

Affected Public: Business or other for-profit; not-for-profit organizations.

Total Respondents: 5000.

Total Responses: 5000.

Frequency: Once.

Average Time per Response: 5 minutes.

Estimated Total Annual Hour Burden: 417 hours.

Estimated Total Annual Cost Burden: $0.

III. Desired Focus of Comments

The Department is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the 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 respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., by permitting electronic submission of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR submitted for OMB approval. They will also become a matter of public record.

Joseph A. Piacentini,

Director, Office of Policy and Research, Employee Benefits Security Administration.

[FR Doc. E6–20912 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,456]

American Wood Dryers Incorporated, Clackamas, OR; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on November 17, 2006 in response to a petition filed by a company official on behalf of workers of American Wood Dryers Incorporated, Clackamas, Oregon.

The petition regarding the investigation has been deemed invalid. The petitioner was not a company official, but was one dislocated worker. A petition filed by workers requires three (3) signatures. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 30th day of November, 2006.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–20839 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,413]

Bendix Commercial Vehicle Systems (C.V.S.) LLC Air Compressor Products, Frankfort, KY; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on November 14, 2006 in response to a petition filed by the Paper, Allied-Industrial, Chemical, & Energy Workers International Union, Local 5–5–32 on behalf of workers of Bendix C.V.S. LLC, Air Compressor Products, Frankfort, Kentucky.

The workers are covered by an active certification (TA–W–56,215), which expires on January 26, 2007. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Dated: November 30, 2006.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–20836 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,491]

Hipwell Manufacturing Co., Pittsburgh, PA; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on November 28, 2006, in response to a petition filed on behalf of workers at Hipwell Manufacturing Co., Pittsburgh, Pennsylvania.

The petition dated November 27, 2006 regarding the investigation has been deemed invalid. In order for employees to establish a valid petition, there must be at least three petitioners that were terminated no more than one year from the petition date. On further review, it became apparent that one petitioner was terminated on August 12, 2005, more than one year from the date on the petition. Consequently, the investigation has been terminated.

Dated: December 1, 2006.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–20840 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,372]

International Truck and Engine Warrenville, IL; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on November 7, 2006, in response to a worker petition filed by a company official on behalf of workers at International Truck and Engine, Warrenville, Illinois.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Dated: November 22, 2006.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–20835 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–59,940]

Liberty Throwing Co., Inc., Kingston, PA; Notice of Revised Determination on Reconsideration

By application of October 24, 2006 a company official requested administrative reconsideration of the Department's negative determination regarding eligibility for workers and former workers of the subject firm to apply for Trade Adjustment Assistance (TAA) and Alternative Trade Adjustment Assistance (ATAA).

The initial investigation resulted in a negative determination signed on September 26, 2006 was based on the finding that imports of elastic yarn did not contribute importantly to worker separations at the subject plant and no shift of production to a foreign source occurred. The denial notice was published in the **Federal Register** on October 16, 2006 (71 FR 60763).

In the request for reconsideration, the petitioner provided additional information regarding the subject firm's customers and requested an investigation relating to secondary impact concerning the subject firm as an upstream supplier in the production of fabric. A review of the new facts determined that the workers of the subject firm may be eligible for TAA on the basis of a secondary upstream supplier impact.

The Department conducted an investigation of subject firm workers on the basis of secondary impact. It was revealed that Liberty Throwing Co., Inc., Kingston, Pennsylvania supplied elastic yarn that was used in the production of stretch fabric, and a loss of business with domestic manufacturers (whose workers were certified eligible to apply for adjustment assistance) contributed importantly to the workers separation or threat of separation.

In accordance with Section 246 the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor herein presents the results of its investigation regarding certification of eligibility to apply for alternative trade adjustment assistance (ATAA) for older workers.

In order for the Department to issue a certification of eligibility to apply for ATAA, the group eligibility requirements of Section 246 of the Trade Act must be met. The Department has determined in this case that the 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 facts obtained in the investigation, I determine that all workers of Liberty Throwing Co., Inc., Kingston, Pennsylvania qualify as adversely affected secondary workers under Section 222 of the Trade Act of 1974, as amended. In accordance with the provisions of the Act, I make the following certification:

All workers of Liberty Throwing Co, Inc., Kingston, Pennsylvania, who became totally or partially separated from employment on or after August 22, 2005, 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.

Dated: November 30, 2006.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–20834 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,433]

Moll Industries, Fort Smith Division, Fort Smith, AR; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on November 15, 2006 in response to a petition filed by a Company Official and on behalf of workers at Moll Industries, Fort Smith Division, Fort Smith, Arkansas.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 27th day of November, 2006.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–20838 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–30–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 December 18, 2006.

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 December 18, 2006.

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.

Dated: November 28, 2006.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

APPENDIX

[TAA petitions instituted between 11/20/06 and 11/24/06]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
60457	NewPage—Luke Maryland Coated Paper Mill (Comp).	Luke, MD	11/20/06	11/20/06
60458	Wheeling Pittsburgh Steel Corp. (Union)	Allenport, PA	11/20/06	11/08/06
60459	Sandusky Limited (Wkrs)	Sandusky, OH	11/20/06	11/20/06
60460	Roseburg Forest Products (Union)	Coquille, OR	11/20/06	11/10/06
60461	Davis Industries Inc./dba Astro-Lounger/ Davis (Comp).	Houlka, MS	11/21/06	11/17/06
60462	St. Louis Braid (Union)	St. Louis, MO	11/21/06	11/21/06
60463	Cott Wyomissing (IBT)	Wyomissing, PA	11/21/06	11/20/06
60464	Key Technology (State)	Medford, OR	11/21/06	11/20/06
60465	Emerson Motors (Wkrs)	Paragould, AR	11/21/06	11/20/06
60466	International Textile Group (Comp)	Cordova, NC	11/21/06	11/20/06
60467	Spaulding Lighting (IUE)	Cincinnati, OH	11/22/06	11/20/06
60468	USR Metals, Inc. (Comp)	Bloomsburg, PA	11/22/06	11/20/06
60469	TMT International, Inc. (Wkrs)	Elgin, TX	11/22/06	11/21/06
60470	Lanxess Corporation (Wkrs)	Wellford, SC	11/22/06	11/10/06
60471	Armstrong Wood Products (Comp)	Nashville, TN	11/22/06	11/21/06
60472	Camillus Cutlery Company (USW)	Camillus, NY	11/22/06	11/16/06
60473	R.G. Barry Corporation (Wkrs)	Pickerington, OH	11/22/06	11/13/06
60474	General Chemical Performance Products (Comp).	Newark, NJ	11/24/06	11/22/06
60475	Deco Engineering, Inc. (Comp)	Royal Oak, MI	11/24/06	11/22/06
60476	Ultra Flex (Comp)	High Point, NC	11/24/06	11/22/06
60477	American Uniform Company (Comp)	Cleveland, TN	11/24/06	11/22/06
60478	Ford Motor Company (UAW)	Hazelwood, MO	11/24/06	11/21/06
60479	Omnova Solutions (Wkrs)	Auburn, PA	11/24/06	11/16/06
60480	Emcor Facilities Services, Inc. (Wkrs)	Costa Mesa, CA	11/24/06	11/22/06

[FR Doc. E6–20841 Filed 12–7–06; 8:45 am]
BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–58,831]

Water Pik, Inc. Personal Healthcare Products Including Former On-Site Leased Workers of AppleOne Currently Employed With Employment Solutions, Loveland, CO; 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 March 24, 2006, applicable to workers of Water Pik, Inc., Personal Healthcare Products, including on-site leased workers of AppleOne, Loveland, Colorado. The notice was published in the **Federal Register** on April 12, 2006 (71 FR 18772).

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 water treatment filtration and shower heads.

New information shows that in August 2006, the leased workers of AppleOne, employed on-site at the Loveland, Colorado location of Water Pik, Inc., Personal Healthcare Products, became employees of Employment Solutions due to a change in contracting firms.

Accordingly, the Department is amending this certification to properly reflect this matter.

The intent of the Department's certification is to include all workers employed at Water Pik, Inc., Personal Healthcare Products, Loveland, Colorado who were adversely affected by a shift in production to China.

The amended notice applicable to TA–W–58,831 is hereby issued as follows:

All workers of Water Pik, Inc., Personal Healthcare Products, including former on-site leased workers of AppleOne, currently employed with Employment Solutions, Loveland, Colorado, who became totally or partially separated from employment on or after February 10, 2005, through March 24, 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.

Dated: November 30, 2006.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–20833 Filed 12–7–06; 8:45 am]
BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of November 20 through November 24, 2006.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issued a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) of the Trade Act have been met.

TA–W–60,325; West Tennessee Machining, Camden, TN: October 27, 2005.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) of the Trade Act have been met.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–60,245; R.L. Stowe Mills, Chronicle Division, Sewing Department, Belmont, NC: October 12, 2005.

TA–W–60,320; Agilent Technologies, Global Infrastructure Organization, Santa Clara, CA: October 24, 2005.

TA–W–60,378; Chemtrade Performance Chemical US, LLC, A Wholly Owned Subsidiary of Chemtrade Logistics, Carlisle, SC: November 3, 2005.

TA–W–60,173; LeRocato Manufacturing, Plainfield, CT: September 29, 2005.

TA–W–60,286; Himmelberger Harrison Mfg Co., Frame Components Division, Morehouse, MO: October 24, 2005.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–60,291; Photometrics, A Division of Roper Scientific, Tucson, AZ: October 20, 2005.

TA–W–60,330; Paige Electric, McConnellsburg, PA: October 24, 2005.

TA–W–60,336; Ward Products LLC, New Jersey Division, North Brunswick, NJ: October 30, 2005.

TA–W–60,345; Pride Manufacturing Co., A Subsidiary of Cintsa Corporation, Cutting Line, Portal, GA: October 25, 2005.

TA–W–60,350; Clariant Corporation, Pigments and Additives Division, Coventry, RI: October 27, 2005.

TA–W–60,416; Moore's Machine Co., Of Fayetteville, Inc., Fayetteville, NC: November 9, 2005.

TA–W–60,423; 3M Company, Electronic Solutions Division, Columbia, MO: November 13, 2005.

TA–W–60,441; ITW Tomco, Bryan, OH: November 13, 2005.

TA–W–60,279; Aquaria, Inc., dba Marineland, Consumer Division, Moorpark, CA: October 20, 2005.

TA–W–60,289; Vesuvius USA, Beaver Falls, PA: October 24, 2005.

TA–W–60,452; Coleman Cable, Siler City, NC: November 15, 2005.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–60,185; Southern Steel and Wire Co., A Subsidiary of SSW Holding Co., Fort Smith, AR: October 2, 2005.

TA–W–60,377; Springfield LLC, Customer Service and Administrative Center, Rockhill, SC: November 3, 2005.

TA–W–60,379; Springfield LLC, Limestone Plant, Gaffney, SC: November 3, 2005.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

None.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of Section 246 has not been met. Workers at the firm are 50 years of age or older.

TA–W–60,325; West Tennessee Machining, Camden, TN: October 27, 2005.

The Department has determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable.

None.

The Department has determined that criterion (3) of Section 246 has not been met. Competition conditions within the workers' industry are not adverse.

None.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

TA–W–60,182; Oaklawn Packaging, Inc., Fort Smith, AR.

TA–W–60,365; KHS USA, Inc., Waukesha Division, Waukesha, WI.

TA–W–60,422; Ahlstrom Corporation, LLC, Mt. Holly Springs, PA.

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

None.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–60,236; Tracewell Electronics, Cuba, NY.

TA–W–60,295; Hickory Springs Manufacturing Co., Bedding Division, Micaville, NC.

TA–W–60,300; Wak Industries, Gastonia, NC.

TA–W–60,366; Jones Apparel Group, NY Better Apparel Production, New York, NY.

TA–W–60,159; Brown International Corporation, Covina, CA.

The investigation revealed that the predominate cause of worker separations is unrelated to criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.C) (shift in production to a foreign country under a free trade agreement or a beneficiary country under a preferential trade agreement, or there has been or is likely to be an increase in imports).

None.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–60,265; Physical Rehab Works, Working Onsite at Maytag Corp., Herrin, IL.

TA–W–60,265A; Executive Security Specialists, Working Onsite at Maytag Corp., Herrin, IL.

TA–W–60,272; Elder Manufacturing Co., Dexter Facility, Dexter, MO.

The investigation revealed that criteria of Section 222(b)(2) has not been met. The workers' firm (or subdivision) is not a supplier to or a downstream producer for a firm whose workers were certified eligible to apply for TAA.

None.

I hereby certify that the aforementioned determinations were issued during the period of November 20 through November 24, 2006. Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: November 30, 2006.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–20832 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,429]

Xyron Inc., Garden Grove, CA; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on November 14, 2006, in response to a petition filed on behalf of workers of Xyron Inc., Garden Grove, California. The workers produced adhesive coated liners.

This petitioning group of workers is covered by an earlier petition (TA–W–60,355) filed on November 2, 2006, that is the subject of an ongoing investigation for which a determination has not yet been issued. Accordingly, further investigation in this case would serve no purpose and this investigation has been terminated.

Dated: November 29, 2006.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E6–20837 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Approval for Missouri for Avoidance of 2006 Credit Reduction Under the Federal Unemployment Tax Act

Sections 3302(c)(2) and 3302(d)(3) of the Federal Unemployment Tax Act (FUTA) provide that employers in a state that has an outstanding balance of advances under Title XII of the Social Security Act on January 1 of two or more consecutive years are subject to a reduction in credits otherwise available against the FUTA tax for a calendar year, if a balance of advances remains on November 10 of that year. Because the account of Missouri in the Unemployment Trust Fund had a balance of advances on January 1 of 2004, 2005, and 2006, and still had a balance of advances on November 10, 2006, Missouri employers were potentially liable for a reduction in their FUTA offset credit for 2006.

Section 3302(g) of FUTA provides that a state may avoid credit reduction for a year by meeting certain criteria. Missouri applied for avoidance of the 2006 credit reduction under this section. Pursuant to delegation of authority to me under Secretary's Order 4–75, I have determined that Missouri meets all of the criteria of section 3302(g) and thus qualifies for credit reduction avoidance. Therefore, Missouri employers will have no reduction in FUTA offset credit for calendar year 2006.

Dated: November 24, 2006.

Emily Stover DeRocco,

Assistant Secretary for Employment and Training.

[FR Doc. E6–20910 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–30–P

NATIONAL NANOTECHNOLOGY COORDINATION OFFICE

Nanoscale Science, Engineering and Technology Subcommittee, National Science and Technology Council, Committee on Technology; Research Needs and Priorities Related to the Environmental, Health, and Safety Aspects of Engineered Nanoscale Materials: Public Meeting

ACTION: Notice of public meeting.

SUMMARY: The National Nanotechnology Coordination Office (NNCO), on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology, National Science and Technology Council (NSTC), will hold a public meeting on January 4, 2007, to receive input on research needs related to the environmental, health, and safety aspects of engineered nanoscale materials (hereafter referred to as nanomaterials). Specifically, the NSET Subcommittee is seeking comment on the research needs and prioritization criteria for the research identified in the NSET Subcommittee document Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials, which was released on September 15, 2006.

Date and Address: The public meeting will be held on Thursday, January 4, 2007, beginning at 8:30 a.m. at the FDIC Training Center, 3501 North Fairfax Drive, Arlington, VA 22226. A schedule will be published prior to the meeting. Directions to the facility are available on the registration web page (see below).

Registration: Persons interested in attending the meeting may register at *http://www.nano.gov/public_ehs.html* prior to the meeting. Due to space limitations, early registration is suggested. On-site registration will be available on a first-come basis, space permitting.

Persons interested in presenting comments at the meeting also should register at *http://www.nano.gov/public_ehs.html* and should do so no later than Wednesday, December 20, 2006.

Written or electronic comments may be submitted on the same web page until January 31, 2007.

Information on this meeting also will be posted on *http://www.nano.gov.*

FOR FURTHER INFORMATION, CONTACT: For information regarding this Notice, please contact Cate Alexander Brennan, National Nanotechnology Coordination Office. Telephone: (703) 292–4399. E-mail: *calexand@nnco.nano.gov.*

SUPPLEMENTARY INFORMATION: The Nanoscale Science, Engineering, and Technology (NSET) Subcommittee coordinates planning, budgeting, and program implementation and review to ensure a balanced and comprehensive National Nanotechnology Initiative (NNI). The NSET Subcommittee is composed of representatives from agencies participating in the NNI. The NNCO provides technical and administrative support to the NSET Subcommittee in its work.

On September 15, 2006, the NSET Subcommittee released a document identifying environmental, health, and safety research and information needs related to understanding and management of potential risks of nanomaterials. The document was created by the Nanotechnology Environmental and Health Implications (NEHI) Working Group of the NSET Subcommittee, which is composed of scientists and other agency representatives. The document also reflects expert input from industry liaison groups and other research needs-identification efforts.

This foundational document will be used by the NSET Subcommittee and the Federal agencies participating in the NNI as they set research priorities for Government-funded research programs.

The meeting is an opportunity for public participation in the prioritization of research related to environmental, health, and safety aspects of nanomaterials. Specific comment on research needs and prioritization criteria in the Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials document and input regarding the criteria for evaluating research priorities is welcome. (To read the document, see *http://www.nano.gov/NNI_EHS_research_needs.pdf.)*

The public meeting will be chaired by leadership of the NEHI Working Group, the NSET Subcommittee, and the NNCO.

For more information on the National Nanotechnology Initiative and its various working entities, please *visit www.nano.gov.*

How Can You Participate?

You can participate through oral presentation at the meeting or through written electronic material submitted to the NNCO at *http://www.nano.gov/public_ehs.html.* The meeting is open to the public, up to the limit set by facility fire codes. Pre-registration is required for participation (see above).

How Will the Meeting Day Be Structured?

Due to significant interest in and the breadth of this subject, our plan is to organize the public meeting around subject areas, including research prioritization criteria and the five research areas identified in the Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials document: Instrumentation, Metrology, and Analytical Methods; Nanomaterials and Human Health; Nanomaterials and the Environment; Health and Environmental Surveillance; and Risk Management Methods. Speakers are requested to indicate which research area you wish to speak to; if you will direct your comments to topics outside of those identified above, please indicate that as well, so that you can be scheduled accordingly.

In addition to indicating the topical area of your presentation, please also provide a short description of the content you intend to cover. The final organization of the meeting may change depending on the nature of the requests for presentations that are received. The speaker schedule will be distributed before the meeting.

How Will Public Input Be Used?

All comments and recommendations made at the meeting or in written submissions will be considered by the NEHI Working Group as it proceeds with prioritizing the research needs. Input from multiple stakeholders with various interests will be valuable to the NNI, especially with regard to strategic and interim goals for filling the EHS information needs gaps for nanomaterials. The NSET Subcommittee and NNI member agencies plan to make the priority-setting process a dynamic, open, and transparent process.

Mihail Roco,

Senior Advisor, Nanoscale Science, Engineering, and Technology Subcommittee of the National Science and Technology Council Committee on Technology.

[FR Doc. E6–20864 Filed 12–7–06; 8:45 am]

BILLING CODE 3170–WF–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–400]; [License Nos. Npf–63]

Carolina Power & Light Company; Receipt of Request for Action Under 10 Cfr 2.206

Notice is hereby given that by petition dated September 20, 2006, and its supplements dated October 23, and October 30, 2006, Mr. John D. Runkle (attorney for the petitioners) has requested that the U.S. Nuclear Regulatory Commission (NRC) take action with regard to Shearon Harris Nuclear Power Plant (SHNPP). The petitioners request that NRC take enforcement action in the form of an Order that would revoke SHNPP's Operating License or impose maximum fines for each violation for each day the plant has been in violation of fire protection regulations.

As the basis for this request, the petitioners discuss several fire safety violations at SHNPP which could affect the safe operation of the plant and safe shutdown of the plant in emergency situations. The petitioners' concerns focus on faulty fire barriers, reliance on indefinite compensatory measures, the risk associated with the noncompliances, and the NRC's enforcement discretion policy. The petitioners have also requested open and public proceedings with the NRC; the licensee, Carolina Power & Light, now doing business as Progress Energy; and external stakeholders in the vicinity of the SHNPP.

The request is being treated pursuant to Title 10 of the Code of Federal Regulations Section 2.206 (10 CFR 2.206) of the Commission's regulations. As provided by 10 CFR 2.206, the agency will take appropriate action on this petition within a reasonable time. A copy of the petition is available for inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by e-mail to *pdr@nrc.gov.*

For Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 4th day of December 2006.

J.E. Dyer,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. E6–20858 Filed 12–7–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–27]

Summary of Environmental Assessment and Finding of No Significant Impact for Exemption to Licensed Physician Requirements for BWX Technologies, Inc., Lynchburg, VA

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of proposed action.

FOR FURTHER INFORMATION CONTACT: Billy Gleaves, Project Manager, Fuel Facility Licensing Directorate, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission (NRC), Mail Stop T–8F42, Washington, DC 20852. Telephone: (301) 415–5848; fax number: (310) 415–5955; e-mail: *bcg@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering issuing an exemption to BWX Technologies, Inc. (BWXT), the holder of NRC special nuclear materials License SNM–42. The proposed action would exempt BWXT from certain requirements set forth in 10 CFR 73.46(b) and Part 73 Appendix B. The exemptions would authorize the licensee to allow medical examinations to be given by licensed nurse practitioners authorized to practice medicine by the Commonwealth of Virginia. The exemptions would allow such nurses, in addition to licensed physicians, to give medical examinations that are required prior to allowing personnel to participate in physical fitness tests. The exemptions would be to requirements stated in 10 CFR 73.46(b)(10)(iii) and (iv); 73.46(b)(11)(iii) and (v); 73.46(b)(12)(ii); and Part 73 Appendix B paragraphs I.B.1.b, I.B.2.b, and I.C.

In accordance with the requirements of 10 CFR Part 51 the NRC has prepared an Environmental Assessment (EA) in support of this action. Based on the EA, the NRC has concluded that a Finding of No Significant Impact is appropriate. If approved, the exemption would be issued following the publication of this Notice.

II. EA Summary

As stated above, the staff has prepared an EA in support of the proposed action. The EA contains sensitive information and is not publicly available. The NRC staff has concluded that issuing the proposed exemptions will not result in a significant impact to the environment. The NRC staff concluded that the proposed action will not adversely affect federally listed species or federally designated critical habitat because no federally listed species are known to occur in the project area. The NRC staff found that no historic properties will be affected by the proposed action.

The proposed action does not have a potential to affect the probability or consequences of accidents; the types or amounts of effluents; nor occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

III. Finding of No Significant Impact

On the basis of the EA, the NRC has concluded that there are no significant environmental impacts from the proposed action, and has determined that the preparation of an environmental impact statement is not required.

IV. Further Information

Documents related to this action can be accessed on the NRC's Agencywide Document Access and Management System (ADAMS) that provides electronic copies of NRC's public documents. The ADAMS accession number for the **Federal Register** notice related to this action is: Notice of License Amendment Request of BWX Technologies, Inc., Lynchburg, VA (ML063050294). If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's Public Document Room (PDR) Reference staff at 800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 27th day of November 2006.

For the U.S. Nuclear Regulatory Commission.

Brian Smith,

Acting Chief, Fuel Facility Licensing Directorate, Division of Fuel Cycle Safety, and Safeguards, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. E6–20857 Filed 12–7–06; 8:45 am]

BILLING CODE 7590–01–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

Summary: In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and Purpose of Information Collection

Application and Claim for Sickness Insurance Benefits; OMB 3220–0039

Under Section 2 of the Railroad Unemployment Insurance Act (RUIA), sickness benefits are payable to qualified railroad employees who are unable to work because of illness or injury. In addition, sickness benefits are payable to qualified female employees if they are unable to work, or if working would be injurious, because of pregnancy, miscarriage or childbirth. Under Section 1(k) of the RUIA, a statement of sickness with respect to days of sickness of an employee is to be filed with the RRB within a 10-day period from the first day claimed as a day of sickness. The RRB's authority for requesting supplemental medical information is Section 12(i) and 12(n) of the RUIA. The procedures for claiming sickness benefits and for the RRB to obtain supplemental medical information needed to determine a claimant's eligibility for such benefits are prescribed in 20 CFR Part 335.

The forms currently used by the RRB to obtain information needed to determine eligibility for and the amount of sickness benefits due a claimant follows: Form SI–1a, Application for Sickness Benefits; Form SI–1b, Statement of Sickness; Form SI–3, Claim for Sickness Benefits; Form SI–7, Supplemental Doctor's Statement; Form SI–8, Verification of Medical Information; Form ID–7h, Non-Entitlement to Sickness Benefits and Information on Unemployment Benefits; Form ID–11a, Requesting Reason for Late Filing of Sickness Benefit and ID–11b, Notice of Insufficient Medical and Late Filing. Completion is required to obtain or retain benefits. One response is requested of each respondent.

The RRB proposes the addition an equivalent Internet version of Form SI–3, Claim for Sickness Benefits to the information collection. The internet equivalent Form SI–3 will essentially mirror the manual RRB Form SI–3 currently in use, but will also provide the claimant the ability to change their direct deposit information in addition to the ability to complete and file the claim via the Internet. Revisions to Form ID–11a and ID–11b to add an item requesting information regarding why a claimant filed their claim late are also proposed.

No changes are proposed to Form(s) SI–1b, SI–7, SI–8, and ID–7h. Minor, non-burden impacting editorial changes are proposed to Form(s) SI–1a and SI–3.

Estimate of Annual Respondent Burden

The estimated annual respondent burden is as follows:

Form #(s)	Annual responses	Time (min)	Burden (hrs)
SI–1a	22,200	10	3,700
SI–1b(Doctor)	22,200	8	2,960
SI–3 (manual)	135,200	5	11,267
SI–3 (Internet)	33,800	5	2,816
SI–7	33,600	8	4,480
SI–8	50	5	4
ID–7H	50	5	4
ID–11A	800	4	53
ID–11B	1,000	4	67
Total	248,900	.....	25,351

Additional Information or Comments

To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, please call the RRB Clearance Officer at (312) 751–3363 or send an e-mail request to *Charles.Mierzwa@RRB.GOV*. Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or send an e-mail to *Ronald.Hodapp@RRB.GOV*. Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Clearance Officer.

[FR Doc. E6–20914 Filed 12–7–06; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Rule 17f–6; SEC File No. 270–392; OMB Control No. 3235–0447.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17f–6 (17 CFR 270.17f–6) under the Investment Company Act of 1940 (15 U.S.C. 80a) permits registered investment companies (''funds'') to maintain assets (*i.e.*, margin) with futures commission merchants (''FCMs'') in connection with commodity transactions effected on both domestic and foreign exchanges.[1] Prior to the rule's adoption, funds generally were required to maintain these assets in special accounts with a custodian bank.

The rule requires a written contract that contains certain provisions designed to ensure important safeguards and other benefits relating to the custody of fund assets by FCMs. To protect fund assets, the contract must require that FCMs comply with the segregation or secured amount requirements of the Commodity Exchange Act (''CEA'') and the rules under that statute. The contract also must contain a requirement that FCMs obtain an acknowledgment from any clearing organization that the fund's assets are held on behalf of the FCM's customers according to CEA provisions. Finally, FCMs are required to furnish to the Commission or its staff on request information concerning the fund's assets in order to facilitate Commission inspections.

The Commission estimates that approximately 2,275 funds effect commodities transactions and could deposit margin with FCMs under Rule 17f–6 in connection with those transactions. Commission staff estimates that each fund uses and deposits margin with two different FCMs in connection with its commodity transactions.[2]

The Commission estimates that each of the 2,275 funds spends an average of 1 hour annually complying with the contract requirements of the rule (*i.e.*, executing contracts that contain the requisite provisions with additional FCMs), for a total of 2,275 annual burden hours. The estimate does not include the time required by an FCM to comply with the rule's contract requirements because, to the extent that complying with the contract provisions could be considered ''collections of information,'' the burden hours for compliance are already included in other PRA submissions or are de minimis.[3] The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction

[1] Custody of Investment Company Assets With Futures Commission Merchants and Commodity Clearing Organizations, Investment Company Act Release No. 22389 (Dec. 11, 1996) (61 FR 66207 (Dec. 17, 1996)).

[2] This estimate is based on information conversations with representatives of the fund industry.

[3] The rule requires a contract with the FCM to contain three provisions. Two of the provisions require the FCM to comply with existing requirements under the CEA and rules adopted under that Act. Thus, to the extent these provisions could be considered collections of information, the hours required for compliance would be included in the collection of information burden hours submitted by the Commodity Futures Trading Commission for its rules. The third contract provision requires that the FCM produce records or other information requested by the Commission or its staff. Commission staff has requested this type of information from an FCM so infrequently in the past that the annual burden hours are de minimis.

Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms.

Compliance with the collection of information requirements of the rule is necessary to obtain the benefit of relying on the rule. If an FCM furnishes records pertaining to a fund's assets at the request of the Commission or its staff, the records will be kept confidential to the extent permitted by relevant statutory or regulatory provisions. The rule does not require these records be retained for any specific period of time. 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 control number.

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days after this publication.

Please direct your written comments to R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov*.

Dated: November 30, 2006.

Nancy M. Morris,

Secretary.

[FR Doc. E6–20805 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Securities Act of 1933, Release No. 8757/ December 4, 2006; Securities Exchange Act of 1934, Release No. 54865/ December 4, 2006]

Order Approving Public Company Accounting Oversight Board Budget and Annual Accounting Support Fee for Calendar Year 2007

The Sarbanes-Oxley Act of 2002 (the ''Act'') established the Public Company Accounting Oversight Board (''PCAOB'') to oversee the audits of public companies and related matters, to protect investors, and to further the public interest in the preparation of informative, accurate and independent audit reports. The PCAOB is to accomplish these goals through registration of public accounting firms and standard setting, inspection, and disciplinary programs. Section 109 of the Act provides that the PCAOB shall establish a reasonable annual accounting support fee, as may be necessary or appropriate to establish and maintain the PCAOB. Section 109(h) amends Section 13(b)(2) of the Securities Exchange Act of 1934 to require issuers to pay the allocable share of a reasonable annual accounting support fee or fees, determined in accordance with Section 109 of the Act. Under Section 109(f), the aggregate annual accounting support fee shall not exceed the PCAOB's aggregate ''recoverable budget expenses,'' which may include operating, capital and accrued items. Section 109(b) of the Act directs the PCAOB to establish a budget for each fiscal year in accordance with the PCAOB's internal procedures, subject to approval by the Securities and Exchange Commission (the ''Commission'').

On July 18, 2006, the Commission amended its Rules of Practice related to its Informal and Other Procedures to add a rule that facilitates the Commission's review and approval of PCAOB budgets and accounting support fees.[1] The new budget rule provides, among other things, a timetable for the preparation and submission of the PCAOB budget and for Commission actions related to each budget, a description of the information that should be included in each budget submission, limits on the PCAOB's ability to incur expenses and obligations except as provided in the approved budget, procedures relating to supplemental budget requests, requirements for the PCAOB to furnish on a quarterly basis certain budget-related information, and a list of definitions that apply to the rule and to general discussions of PCAOB budget matters.

Although the new budget rule will not take effect until the budget process for fiscal year 2008, the PCAOB staff and the Commission staff used their best efforts to substantially comply with the timetable and other requirements in the new rule for the PCAOB budget submission for 2007. Accordingly, in March 2006 the PCAOB provided the Commission with a narrative description of its program issues and outlook for the 2007 budget year, and in April the Commission staff provided to the PCAOB staff economic assumptions and budgetary guidance for the 2007 budget year. The PCAOB subsequently delivered a preliminary budget and budget justification to the Commission. The staff from the Commission's Offices of the Chief Accountant, Executive Director and Information Technology dedicated a substantial amount of time to the review and analysis of the PCAOB's programs, projects and budget estimates, reviewed the PCAOB's estimates of 2006 actual spending, and attended several meetings with management and staff of the PCAOB to develop an understanding of the PCAOB's budget and operations. During the course of the Commission's review, the Commission staff relied upon representations and supporting documentation from the PCAOB. Also, substantially as provided in the new rule, there was a ''pass back'' from the Commission to the PCAOB. The PCAOB approved its 2007 budget on November 30, 2006 and submitted that budget for Commission approval.

After considering the above, the Commission did not identify any proposed disbursements in the 2007 budget adopted by the PCAOB that are not properly recoverable through the annual accounting support fee, and the Commission believes that the aggregate proposed 2007 annual accounting support fee does not exceed the PCAOB's aggregate recoverable budget expenses for 2007.

As part of its review of the 2007 PCAOB budget, the Commission notes that the PCAOB has reaffirmed its commitments, among other things, to build upon its 2007 goals and objectives to develop a comprehensive multi-year strategic plan that is integrated with the PCAOB budget process; to have the auditors of its 2007 annual financial statements opine on the PCAOB's internal control over financial reporting; to devote staff resources to train both PCAOB staff and the public on revisions to the standard for auditing internal control over financial reporting; and to comply with the new Commission rule related to the PCAOB budget approval process in connection with its budget for 2008. The Commission also recognizes that the PCAOB, upon the arrival of Chairman Olson in mid 2006, appropriately has undertaken reviews in a number areas, including its compensation, recruiting and information technology programs. Because of the potential significance of those reviews, during 2007 the PCAOB

[1] 17 CFR 202.11. *See* Release No. 33–8724 (July 18, 2006) [71 FR 41998 (July 24, 2006)].

should supplement the quarterly reports made available to the Commission under the new budget rule with periodic reports on the progress and results of those reviews and with monthly reports showing variances of actual or estimated expenditures from budgeted amounts, to the extent such progress reports and monthly reports are prepared for internal purposes.

Based on the foregoing, the Commission has determined that the PCAOB's 2007 budget and annual accounting support fee are consistent with Section 109 of the Act. Accordingly,

It is ordered, pursuant to Section 109 of the Act, that the PCAOB budget and annual accounting support fee for calendar year 2007 are approved.

By the Commission.

Nancy M. Morris,

Secretary.

[FR Doc. E6–20878 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54851; File No. SR-Amex-2006–48]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing and Order Granting Accelerated Approval to Proposed Rule Change and Amendment No. 1 Thereto Modifying the Exchange's Independent Director and Audit Committee Corporate Governance Standards

November 30, 2006.

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 May 17, 2006, 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 and II below, which Items have been substantially prepared by the Exchange. Amex filed Amendment No. 1 with the Commission on September 25, 2006.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons and to approve the proposal on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Section 121 of the Amex Company Guide (''Company Guide'') to clarify and modify certain corporate governance standards applicable to companies listed on the Amex, including the definition of ''independent director,'' and audit committee requirements. The text of the proposed rule change is below.[4] Proposed new language is in *italics*; proposed deletions are in [brackets].

* * * * *

Company Guide

Independent Directors and Audit Committee

Sec. 121. A. Independent Directors:

(1) Each [listed company] *issuer* must have a sufficient number of independent directors on its [B]*b*oard of [D]*d*irectors [(1)] *(a)* such that at least a majority of such directors are independent directors (subject to the exceptions set forth in Section 801 and, with respect to small business issuers, Section 121B(2)(c)), and [(2)] *(b)* to satisfy the audit committee requirement set forth below.

(2) ''Independent director'' means a person other than an *executive* officer or employee of the company [or any parent or subsidiary]. No director qualifies as independent unless the *issuer's* [B]*b*oard of [D]*d*irectors affirmatively determines that the director does not have a [material] relationship [with the listed company] that would interfere with the exercise of independent judgment *in carrying out the responsibilities of a director*. In addition *to the requirements contained in this Section 121A, directors serving on*[,] audit committees [members] must also comply with the *additional, more stringent* requirements set forth in *Section* [paragraph] *121*B(2) below. The following is a non-exclusive list of persons who shall not be considered independent:

(a) a director who is, or during the past three years was, employed by the company [or by any parent or subsidiary of the company], other than prior employment as an interim *executive officer* [Chairman or CEO*] *(provided the interim employment did not last longer than one year) (See Commentary .08)*;

(b) a director who accept*ed*[s] or has an immediate family member who accept*ed*[s] any [payments] *compensation* from the company [or any parent or subsidiary of the company] in excess of $60,000 during *any period of twelve consecutive months within the three years preceding the determination of independence* [the current or any of the past three fiscal years], other than the following:

[(1)] *(i)* compensation for board *or board committee* service,

[(2) payments arising solely from investments in the company's securities,

(3)] *(ii)* compensation paid to an immediate family member who is [a non-executive] *an* employee (*other than an executive officer*) of the company [or of a parent or subsidiary of the company],

[(4)] *(iii)* compensation received for former service as an interim *executive officer* [Chairman or CEO] *(provided the interim employment did not last longer than one year) (See Commentary .08)*, *or*

[(5)] *(iv)* benefits under a tax-qualified retirement plan, *or* [(6)] non-discretionary compensation;[,]

[(7) loans permitted under Section 13(k) of the Exchange Act

(8) loans from a financial institution provided that the loans (i) Were made in the ordinary course of business, (ii) were made on substantially the same terms, including interest rates and collateral, as those prevailing at the time for comparable transactions with the general public, (iii) did not involve more than a normal degree of risk or other unfavorable factors, and (iv) were not otherwise subject to the specific disclosure requirements of SEC Regulation S–K, Item 404, or

(9) payments from a financial institution in connection with the deposit of funds or the financial institution acting in an agency capacity, provided such payments were (i) Made in the ordinary course of business, (ii) made on substantially the same terms as those prevailing at the time for comparable transactions with the general public, and (iii) not otherwise subject to the disclosure requirements of SEC Regulation S–K, Item 404.*]

(c) a director who is an immediate family member of an individual who is, or *at any time during* [has been in any of] the past three years *was*, employed by the company [or any parent or subsidiary of the company] as an executive officer;[*]

(d) a director who is, or has an immediate family member who is, a

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 replaced and superseded the original filing in its entirety. Amendment No. 1 clarified certain details of the Exchange's initial proposal, and conformed it with recent revisions to the corporate governance standards of The NASDAQ Stock Market LLC (''Nasdaq''). *See* Securities Exchange Act Release No. 54583 (October 6, 2006), 71 FR 60782 (October 16, 2006) (approving SR–NASDAQ–2006–021) (''Nasdaq Corporate Governance Order'').

[4] With the Exchange's consent, a few technical spacing changes have been made to the text of the proposed rule change. Telephone conversation between Kristie Diemer, Special Counsel, Division of Market Regulation, Commission and Courtney McBride, Assistant General Counsel, Amex.

partner in, or a controlling shareholder or an executive officer of, any organization to which the company made, or from which the company received, payments (other than those arising solely from investments in the company's securities or payments under non-discretionary charitable contribution matching programs) that exceed 5% of the organization's consolidated gross revenues for that year, or $200,000, whichever is more, in any of the most recent three fiscal years;[*]

(e) a director [of the listed company] who is, or has an immediate family member who is, employed as an executive officer of another entity where at any time during the most recent three fiscal years any of the [listed company's] *issuer's* executive officers serve on [that entity's] *the* compensation committee *of such other entity;*[*] *or*

(f) a director who is, or has an immediate family member who is, a current partner of the company's outside auditor, or was a partner or employee of the company's outside auditor who worked on the company's audit at any time during any of the past three years.[*]

[(g)] *(3)*[i]*I*n the case of an investment company, in lieu of [paragraphs] *Sections 121A(2)*(a) through (f), a director who is an ''interested person'' of the *investment* company as defined in Section 2(a)(19) of the Investment Company Act of 1940, other than in his or her capacity as a member of the board of directors or any board committee.

B. Audit Committee

(1) Charter

Each [I]*i*ssuer must certify that it has adopted a formal written audit committee charter and that the [A]*a*udit [C]*c*ommittee has reviewed and reassessed the adequacy of the formal written charter on an annual basis. The charter must specify the following:

[(i)]*(a)* the scope of the audit committee's responsibilities, and how it carries out those responsibilities, including structure, processes, and membership requirements;

[(ii)]*(b)* the audit committee's responsibility for ensuring its receipt from the outside auditors of a formal written statement delineating all relationships between the auditor and the [company] *issuer*, consistent with Independence Standards Board Standard 1, and the audit committee's responsibility for actively engaging in a dialogue with the auditor with respect to any disclosed relationships or services that may impact the objectivity and independence of the auditor and for taking, or recommending that the full board take, appropriate action to oversee the independence of the outside auditor; [and]

[(iii)]*(c)* the *audit* committee's purpose of overseeing the accounting and financial reporting processes of the issuer and the audits of the financial statements of the issuer; *and*

[(iv)]*(d)* the specific audit committee responsibilities and authority set forth in [paragraph (4) of this subs]*S*ection *121B(4)*.

(2) Composition

(a) Each issuer must have, and certify that it has and will continue to have, an [A]*a*udit [C]*c*ommittee of at least three members, each of whom:

(i) satisfies the independence standards specified in Section 121A and Rule 10A–3 under the Securities Exchange Act of 1934; [and]

(ii) *must not have participated in the preparation of the financial statements of the issuer or any current subsidiary of the issuer at any time during the past three years; and*

(iii) is able to read and understand fundamental financial statements, including a company's balance sheet, income statement, and cash flow statement. Additionally, each issuer must certify that it has, and will continue to have, at least one member of the audit committee who is financially sophisticated, in that he or she has past employment experience in finance or accounting, requisite professional certification in accounting, or any other comparable experience or background which results in the individual's financial sophistication, including but not limited to being or having been a chief executive officer, chief financial officer, other senior officer with financial oversight responsibilities. A director who qualifies as an audit committee financial expert under Item 401(h) of Regulation S–K, Item 401(e) of Regulation S–B or Item 3 of Form N–CSR (in the case of a registered management investment company) is presumed to qualify as financially sophisticated.

(b) Notwithstanding [paragraph] *Section 121B(2)*(a), one director who is not independent as defined in Section 121A, but who satisfies the requirements of Rule 10A–3 under the Securities Exchange Act of 1934 (see [sub-paragraph] *Section 121B(2)*(a)(i)), and is not a current officer or employee or an immediate family member of such officer or employee, may be appointed to the [A]*a*udit [C]*c*ommittee, if the board, under exceptional and limited circumstances, determines that membership on the committee by the individual is required by the best interests of the [company] *issuer* and its shareholders, and the board discloses, in the next annual meeting proxy statement (or in its next annual report on SEC Form 10–K or equivalent if the issuer does not file an annual proxy statement) subsequent to such determination, the nature of the relationship and the reasons for that determination. A director appointed to the [A]*a*udit [C]*c*ommittee pursuant to this exception may not serve for in excess of two consecutive years and may not chair the [A]*a*udit [C]*c*ommittee.

(c) Small Business Issuers—Small Business Issuers (as defined in SEC Regulation S–B) are subject to all requirements specified in this Section 121B(2), except that such issuers are only required to maintain a [B]*b*oard of [D]*d*irectors comprised of at least 50% independent directors, and an [A]*a*udit [C]*c*ommittee of at least two members, comprised solely of independent directors who also meet the requirements of Rule 10A–3 under the Securities Exchange Act of 1934.

(3) Meeting Requirements

The [A]*a*udit [C]*c*ommittee of each [listed company] *issuer* must meet on at least a quarterly basis, except that with respect to [listed] registered closed-end management investment companies, the [A]*a*udit [C]*c*ommittee must meet on a regular basis as often as necessary to fulfill its responsibilities, including at least annually in connection with issuance of the *investment* company's audited financial statements.

(4) Audit Committee Responsibilities and Authority

The [A]*a*udit [C]*c*ommittee of each [listed company] *issuer* must have the specific audit committee responsibilities, authority and procedures necessary to comply with Rule 10A–3(b)(2), (3), (4) and (5) under the Securities Exchange Act of 1934 (subject to the exemptions provided in Rule 10A–3(c) under the Securities Exchange Act of 1934), concerning responsibilities relating to: ([i]*a*) registered public accounting firms, ([ii]*b*) complaints relating to accounting, internal accounting controls or auditing matters, ([iii]*c*) authority to engage advisors, and ([iv]*d*) funding as determined by the audit committee. Audit committees for investment companies must also establish procedures for the confidential, anonymous submission of concerns regarding questionable accounting or auditing matters by employees of the investment adviser, administrator,

principal underwriter, or any other provider of accounting related services for the investment company, as well as employees of the investment company.

(5) Exception

At any time when an issuer has a class of common equity securities (or similar securities) that is listed on another national securities exchange or national securities association subject to the requirements of SEC Rule 10A–3 under the Securities Exchange Act of 1934, the listing of classes of securities of a direct or indirect consolidated subsidiary or an at least 50% beneficially owned subsidiary of the issuer (except classes of equity securities, other than non-convertible, non-participating preferred securities, of such subsidiary) shall not be subject to the requirements of this Section 121B.

See Also Section 803.

[* With respect to independent directors who are not members of the Audit Committee, the applicable ''look-back'' period will be only one year for the first year after the amendment or adoption (as applicable) of Sections 121A(1), 121B(2)(c) and 802(a) with respect to board of director composition. With respect to independent directors who are members of the Audit Committee, the applicable ''look-back'' period will be only one year for the first year after the amendment or adoption (as applicable) of paragraphs (b), (e) and (f) of Section 121A. The applicable three-year ''look-back'' periods specified in Section 121A will begin to apply only from and after December 1, 2004.]

* * * Commentary

.01 No change.

.02 *''Company'' includes any parent or subsidiary of the issuer listed on the Exchange.* ''Parent'' or ''subsidiary'' includes entities that are consolidated with the issuer's financial statements *as filed with the SEC (but not if the issuer reflects such entity solely as an investment in its financial statements).*

.03–.05 No change.

.06 In order to affirmatively determine that an independent director does not have a material relationship with the [listed company] *issuer* that would interfere with the exercise of independent judgment, as specified in [paragraph] *Section 121*A, the board of directors of each [listed company] *issuer* must obtain from each such director full disclosure of all relationships which could be material in this regard[, including but not limited to any payments specified in paragraphs (b)(8) and (9)].

.07 The three year look-back periods referenced in Sections 121A(2)(a), (c), (e) and (f) commence on the date the relationship ceases. For example, a director employed by the company is not independent until three years after such employment terminates.

.08 For purposes of Section 121A(2)(a), employment by a director as an executive officer on an interim basis shall not disqualify that director from being considered independent following such employment, provided the interim employment did not last longer than one year. A director would not be considered independent while serving as an interim officer. Similarly, for purposes of Section 121A(2)(b), compensation received by a director for former service as an interim executive officer need not be considered as compensation in determining independence after such service, provided such interim employment did not last longer than one year. Nonetheless, the issuer's board of directors still must consider whether such former employment and any compensation received would interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director. In addition, if the director participated in the preparation of the company's financial statements while serving as an interim executive officer, Section 121B(2)(a)(ii) would preclude service on the issuer's audit committee for three years.

.09 Section 121A(2)(b) is generally intended to capture situations where compensation is made directly to (or for the benefit of) the director or an immediate family member of the director. For example, consulting or personal service contracts with a director or an immediate family member of the director would be analyzed under Section 121A(2)(b). In addition, political contributions to the campaign of a director or an immediate family member of the director would be considered indirect compensation under Section 121A(2)(b). Non-preferential payments made in the ordinary course of providing business services (such as payments of interest or proceeds related to banking services or loans by an issuer that is a financial institution or payment of claims on a policy by an issuer that is an insurance company), payments arising solely from investments in the company's securities and loans permitted under Section 13(k) of the Securities Exchange Act of 1934 will not preclude a finding of director independence as long as the payments are non-compensatory in nature. Depending on the circumstances, a loan or payment could be compensatory if, for example, it is not on terms generally available to the public.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Amex included statements concerning the purpose of and basis for the proposal and discussed any comments it received on the proposal. The text of these statements may be examined at the places specified in Item IV below. Amex has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In 2003, the Commission approved broad enhancements to the corporate governance standards applicable to issuers listed on the Amex.[5] The enhancements related to, among other things, board of director composition and independence standards, as well as audit committee composition, authority, and disclosure obligations. These revisions also included new tests to determine the independence of directors. Comparable standards were adopted by Nasdaq and by the New York Stock Exchange (''NYSE'').[6]

Since implementing the enhanced corporate governance standards, the Exchange has proposed various changes to these standards based upon its experience administering the corporate governance program. The Exchange now proposes several changes to the independent director and audit committee requirements applicable to listed issuers that, according to the Exchange, are designed to: (i) Eliminate unnecessary restrictions; (ii) clarify certain aspects of the Exchange's corporate governance requirements; and (iii) make these requirements consistent with those of Nasdaq and NYSE.

Section 121A of the Company Guide (*Independent Directors*) requires most listed issuers to have a board of directors comprised of a majority of independent directors. It also specifies

[5] *See* Securities Exchange Act Release No. 48863 (December 1, 2003), 68 FR 68432 (December 8, 2003) (approving SR–Amex–2003–65).

[6] *See* Securities Exchange Act Release No. 48745 (November 4, 2003), 68 FR 64154 (November 12, 2003) (approving SR–NYSE–2002–33, SR–NASD–2002–77, SR–NASD–2002–80, SR–NASD–2002–138, SR–NASD–2002–139, and SR–NASD–2002–141).

the criteria the board of directors must utilize in determining whether a director can be considered independent and sets forth certain ''bright line'' tests that preclude a finding of independence. Section 121B of the Company Guide (*Audit Committee*) sets forth the requirements for the composition of an issuer's audit committee, which must consist of, among other things, at least three directors who satisfy the independence standards in Section 121A. Such independence standards are substantially the same as Nasdaq standards[7] and are conceptually similar to NYSE standards.[8]

(i) *Definition of Independent Director*[9]

Section 121A of the Company Guide currently provides that an independent director of a listed company may not be an officer or employee of the company or any parent or subsidiary thereof, or have a material relationship with the listed company that would interfere with the exercise of independent judgment. The Exchange proposes to clarify that any relationship, not just a material relationship, that would interfere with the exercise of judgment in specifically carrying out the responsibilities of a director may preclude a determination of independence. According to the Exchange, this clarifying change will make the Amex's definition of independent director consistent with the Nasdaq's definition of independent director.[10]

(ii) *Service as a Compensated Interim Officer*[11]

Pursuant to current Section 121A(a) of the Company Guide, a director who is, or during the past three years was, employed by a company or by a parent or subsidiary of such company as an interim Chairman or CEO is not automatically precluded from being considered independent. Further, compensation received in excess of $60,000 during the current or past three fiscal years for former service as an interim Chairman or CEO does not automatically preclude a director from being considered independent. The Exchange proposes to expand both exceptions to cover the former service and compensation of all interim executive officers, not just the Chairman and CEO. Amex believes that the proposed rule change will enable issuers to more easily fill director seats by broadening the pool of prospective independent directors to include interim executive officers and others with particular expertise.

However, the Exchange proposes to limit the ability to exclude such past service and compensation as an interim executive officer to one year, in order to prevent potential abuse of the exceptions. The Exchange also proposes to clarify in new Commentary .08 that current service as an interim officer would preclude a director from being considered independent. In addition, if, while acting as an interim officer, a director participated in the preparation of the financial statements of an issuer or current subsidiary of the issuer, the director would be precluded from serving on such issuer's audit committee for three years. Of course, depending upon the magnitude of the compensation and the length of service as a former interim executive officer, a board could still determine on its own—without regard to a ''bright line'' test—that an individual should not be considered independent. In this respect, the proposed new Commentary .08 to Section 121 specifies the board's obligation to consider such former service and related compensation in making an independence determination.

In its proposal, Amex notes that the Commission recently published notice of a filing by Nasdaq in which Nasdaq proposed similar changes to its corporate governance standards.[12] According to the Exchange, NYSE standards also provide that compensated service as an interim officer does not disqualify a director from being considered independent following such service.[13] In Amex's view, the proposed rule change would result in more uniformity across market centers with respect to how interim service by directors is treated for independence purposes.

(iii) *Compensation over $60,000*[14]

Section 121A(b) of the Company Guide currently precludes a finding of independence if a director, or an immediate family member of the director, accepts any payments from the company or any parent or subsidiary of the company in excess of $60,000 during the current or any of the past three fiscal years preceding the determination of independence. Certain types of payments that are unlikely to taint a director's independence are excluded from the $60,000 test.[15]

The Exchange notes that over the course of administering Section 121A(b), additional types of payments have been identified that should be excepted from the test because they are unlikely to taint a director's independence. Rather than continuing to codify examples of ''payments'' that should be excluded from the test as they arise, the Exchange believes that the more effective approach is to amend Section 121A(b) to focus on ''compensation.'' As a result, the Exchange proposes to modify Section 121A(b) to provide that a finding of independence is precluded if a director accepts, or has an immediate family member who accepts, any compensation, with certain exceptions, from a company or its affiliates in excess of $60,000 during any consecutive twelve-month period within the three years prior to the independence determination.

To provide further guidance, the Exchange proposes adding new Commentary .09, which would specify that Section 121A(b) is intended to capture situations where compensation is made directly to (or for the benefit of) the director or the director's immediate family member. In order to illustrate such intention, proposed Commentary .09 provides specific examples of direct and indirect compensation that would preclude a finding of director independence, such as contributions made to the political campaign of a director or an immediate family member of the director.[16] The Exchange also proposes modifying Section 121A(b) to clarify that compensation for service on a board committee will not preclude a

[7] Nasdaq Rule 4200(a)(15) and IM–4200. *See also* Nasdaq Corporate Governance Order, *supra* note 3.

[8] Section 303A.02 of the NYSE Listed Company Manual.

[9] The change described in this subsection relates to a provision in the preamble to current Section 121A of the Company Guide that would become the preamble to Section 121A(2) as part of Amex's proposed numbering scheme.

[10] Nasdaq Rule 4200(a)(15).

[11] The change described in this subsection relate to current Sections 121A(a) and 121A(b)(4) of the Company Guide, which would become Sections 121A(2)(a) and 121A(2)(b)(iii), respectively, in Amex's proposed numbering scheme.

[12] The Commission notes that the Nasdaq proposal has since been approved. See Nasdaq Corporate Governance Order, supra note 3.

[13] Commentary to Sections 303A.02(b)(i) and (ii) of the NYSE Listed Company Manual.

[14] The change described in this subsection relate to current Section 121A(b) of the Company Guide, which would become Section 121A(2)(b) in the new numbering scheme Amex proposes in this filing.

[15] Exceptions in the current rule, for example, include payments from a financial institution (*e.g.*, interest on a savings account), payments arising solely from investments in the company's securities, and loans permitted under Section 13(k) of the Act.

[16] Proposed Commentary .09 further clarifies that, in general, under the proposed rule, non-preferential payments made in the ordinary course of providing business services (such as payments of interest or proceeds related to banking services or loans by an issuer that is a financial institution or payment of claims on a policy by an issuer that is an insurance company) will not preclude a finding of director independence as long as the payments are non-compensatory in nature. *See* Company Guide, Section 121, proposed Commentary .09.

finding of independence. The Amex indicates that, while the current provision carves out compensation for board service and was meant to cover compensation for service on board committees, there appears to be some confusion in this regard among companies.

The Exchange believes that a revised rule based on compensation rather than payments will better capture the types of compensation that bear on a director's independence. Amex notes that a similar proposed rule change recently filed by Nasdaq [17] and published by the Commission, and a comparable NYSE provision,[18] preclude independence if a director or family member has received direct compensation above a minimum threshold. Accordingly, the Exchange believes that the proposed rule change will make Section 121A(b) consistent with the corresponding provisions of Nasdaq and NYSE, thereby creating greater uniformity across market centers with respect to the standards for evaluating a director's independence.

(iv) *Timeframes for Determining Independence* [19]

The Exchange proposes that the applicable one-year period or three-year period preceding the determination of independence set forth in current Section 121A(b) of the Company Guide be measured chronologically rather than by fiscal year. Under the proposed rule, the look-back period would be any period of twelve consecutive months within the three years preceding the date independence is to be determined. The Exchange believes that such proposed modification is appropriate because it introduces a simpler calculation that is not dependent on a company's particular fiscal year end. Additionally, the Exchange proposes to clarify in new Commentary .07 that the three-year look-back periods referenced in current paragraphs (a), (c), (e), and (f) of Section 121A commence on the date the relationship ceases. These proposed rule changes would conform the Exchange's look-back periods to the Nasdaq look-back periods.[20]

(v) *Other Changes*

The Exchange also proposes to make other clarifying changes to Section 121. First, the Exchange proposes to clarify that the term ''non-executive employee'' in current Section 121A(b)(3) (proposed Section 121A(2)(b)(ii)) means an employee other than an executive officer, a term defined by reference to Commission Rule 16a–1(f) under the Act.[21] Second, the Exchange proposes to clarify that references to ''the company'' in Section 121 include any parent or subsidiary of the listed issuer. Third, the Exchange proposes to clarify in proposed new Section 121B(5) that an exception to the audit committee requirements contained in Commission Rule 10A–3(c)(2) under the Act [22] for certain subsidiaries of listed issuers also is applicable to the Amex's audit committee requirements. The Amex states that such clarifying revisions will make Section 121 consistent with Nasdaq's recent proposed rule change.[23]

Finally, the Exchange proposes several organizational and grammatical changes to Section 121 which, though non-substantive, are intended to simplify reading of its corporate governance standards.

(vi) *Transition*

The Exchange will implement the proposed rule change immediately upon approval by the Commission. In order to facilitate transition to the modified standards, any director that would be considered independent under the current standards, but that would no longer be deemed independent under the modified standards, would be permitted to continue serving on the board of directors as an independent director until no later than 90 days after the approval of this filing.[24]

The Exchange believes that the proposed rule change is responsive to concerns of its listed issuers and would benefit investors and issuers by providing additional transparency and clarity to Amex's corporate governance standards. The Exchange notes that such additional transparency and clarity also would facilitate uniform application and ease administration of corporate governance standards. Furthermore, the Exchange believes that by making the Amex standards more consistent with those of Nasdaq and NYSE, the proposed rule change would promote greater uniformity across listing markets.

2. Statutory Basis

The Amex believes that the proposed rule change is consistent with Section 6(b) of the Act,[25] in general, and furthers the objectives of Section 6(b)(5) of the Act,[26] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the Exchange believes that the proposed rule change will promote greater uniformity with the corporate governance standards of other markets.

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. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–Amex–2006–48 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–2006–48. 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/*

[17] The Nasdaq proposal has since been approved. *See* Nasdaq Corporate Governance Order, *supra* note 3.

[18] Section 303A.02(b)(2) of the NYSE Listed Company Manual.

[19] The changes described in this subsection relate to current Section 121A(b) of the Company Guide, which would become Section 121A(2)(b), and to current Sections 121A(a), (c), (e), and (f), which would become Sections 121A(2)(a), (c), (e), and (f) in Amex's proposed numbering scheme.

[20] Nasdaq Rule 4200(a)(15) and IM–4200.

[21] 17 CFR 240.16a–1(f).

[22] 17 CFR 240.10A–3(c)(2).

[23] *See* Nasdaq Corporate Governance Order, *supra* note 3.

[24] The Commission notes that this transition period does not affect an issuer's obligation to comply with the requirements relating to audit committee composition.

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Amex–2006–48 and should be submitted on or before December 29, 2006.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[27] In particular, the Commission believes that the proposal is consistent with Section 6(b)(5) of the Act,[28] which requires that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general to protect investors and the public interest.

The Commission believes that the proposed rule change would provide clarity and guidance to Amex listed companies, particularly with respect to the determination of whether a director is independent. In particular, the proposed rule change would preclude a finding of independence if a director accepts any compensation from the company or its affiliates in excess of $60,000 during the prescribed time period.[29] This proposed change would align the Amex rule with corresponding rules of Nasdaq and NYSE relating to corporate governance standards of listed issuers.[30] The proposal also would revise various other provisions of Amex's corporate governance standards, including by amending several provisions to conform more closely with Nasdaq's and NYSE's corporate governance standards for its listed issuers.[31]

The Commission finds good cause, consistent with Section 19(b)(2) of the Act,[32] for approving this proposal, as amended, before the thirtieth day after the publication of notice thereof in the **Federal Register**. The Commission notes that the proposal raises no new issues and believes that accelerating its approval would harmonize corporate governance listing standards among exchanges.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[33] that the proposed rule change, as amended (SR–Amex–2006–48), is hereby approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[34]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E6–20804 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

[27] In approving this proposal, the Commission has considered its impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f). 28 15 U.S.C. 78f(b)(5).

[28] 15 U.S.C. 78f(b)(5).

[29] Under current Section 121A of the Company Guide, a director of a listed company would not be considered independent if the director or a family member of the director has accepted more than $60,000 in payments from the company or its parent or subsidiary during the time period set forth in the rule. The proposed rule change would amend the rule to refer to compensation in excess of $60,000 from the company, rather than payments.

[30] *See* Nasdaq's IM–4200 to Nasdaq Rule 4200 and Section 303A.02(b)(ii) of the NYSE Listed Company Manual. Proposed changes to Section 121A of the Company Guide would provide examples of non-compensatory payments, such as interest related to banking services, insurance proceeds, and non-preferential loans from financial institutions. At the same time, the proposed changes to Section 121A of the Company Guide would make clear that payments made by the company for the benefit of the director—such as political contributions to the campaign of a director or a family member and loans to a director or family member that are on terms not generally available to the public—could be considered indirect compensation so as to preclude a finding that the director was independent.

[31] These other changes relate to: status of independent directors who served as interim officers for a maximum one-year period; the definition of ''non-executive employee;'' inclusion of parent and subsidiary within the meaning of ''company;'' and an exception in Amex's standards relating to audit committees for certain issuers that have a listed parent, consistent with a similar exception contained in Rule 10A–3 under the Act, 17 CFR 240.10A–3.

[32] 15 U.S.C. 78s(b)(2).

[33] 15 U.S.C. 78s(b)(2).

[34] 34 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54855; File No. SR–DTC–2006–15]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of a Proposed Rule Change Relating to the Canadian Link Service

December 1, 2006.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 10, 2006, The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by DTC. 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 proposed rule change would amend DTC's Rule 30, Canadian-Link Service, to allow certain Canadian-Link transactions to settle in U.S. dollars.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DTC 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. DTC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

DTC's Canadian-Link Service currently allows participants of DTC (''DTC Participants'') to clear and settle two categories of securities transactions in Canadian dollars: (1) Transactions with participants of The Canadian Depository for Securities Limited (''CDS Participants'') and (2) transactions with other DTC Participants. The Canadian-Link Service also allows DTC Participants to transfer Canadian dollar funds to CDS Participants through the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

facilities of CDS and to other DTC Participants through Canadian settlement banks acting for DTC and such DTC Participants. The proposed rule change would add an additional functionality to the Canadian-Link Service to allow DTC Participants to settle certain securities transactions with CDS Participants in U.S. dollars (''cross-border U.S. dollar securities transactions''). Set forth below is a description of the current Canadian-Link Service and a description of the proposed change.

Current Functionality of the Canadian-Link Service

The Canadian-Link Service allows DTC Participants to clear and settle valued securities transactions in Canadian dollars with CDS Participants through the link between DTC and CDS. The securities that may be the subject of these transactions are securities that are eligible for book-entry transfer through the facilities of CDS and DTC (''Full-Service Canadian-Link Securities'') and securities that are eligible for book-entry transfer through the facilities of CDS but not through DTC (''Limited Service Canadian-Link Securities''). The securities are delivered to and from CDS Participants through the facilities of CDS. Money settlement between DTC and CDS is included in Canadian dollar money settlement at CDS. Money settlement between DTC and DTC Participants takes place between Canadian settlement banks acting for DTC and such DTC Participants.

The Canadian-Link Service allows DTC Participants to clear and settle valued transactions in Canadian dollars with other DTC Participants through the facilities of DTC. The securities that may be the subject of these transactions are Full-Service Canadian-Link Securities. The securities are delivered to and from DTC Participants through the facilities of DTC. Money settlement between DTC and DTC Participants takes place through Canadian settlement banks acting for DTC and such DTC Participants.

The Canadian-Link Service allows DTC Participants to transfer Canadian dollar funds without any corresponding delivery or receipt of securities to CDS Participants or other DTC Participants. Transactions between DTC Participants and CDS Participants are processed through the facilities of CDS. Transactions between DTC Participants and other DTC Participants are processed through Canadian settlement banks acting for such DTC Participants.

The proposed rule change would not change any of the existing components of the Canadian-Link Service and except for cross-border U.S. dollar securities transactions, as set forth below, would not change how securities transactions are currently processed through the Canadian-Link Service.

Proposed Enhancement of the Canadian-Link Service

The proposed rule change would enhance the Canadian-Link Service to allow DTC Participants to clear and settle certain valued securities transactions in U.S. dollars with CDS Participants through the link between DTC and CDS.[3] The securities that would be the subject of the enhancement are Limited-Service Canadian-Link Securities, *i.e.*, securities that are eligible for book-entry transfer through the facilities of CDS but not DTC. The securities would be delivered to and from CDS Participants through the facilities of CDS. Money settlement between DTC and CDS would be included in U.S. dollar money settlement at DTC. Money settlement between DTC and DTC Participants would also be included in U.S. dollar money settlement at DTC together with the settlement of DTC Participants' other transactions at DTC. As the foregoing indicates, these cross-border U.S. dollar securities transactions would be processed in substantially the same way that transactions are now processed except that these transactions would settle in U.S. dollars rather than in Canadian dollars and the place of money settlement will be at DTC rather than at CDS or through Canadian settlement banks.

The proposed rule change would also add new definitions to DTC Rule 30 to distinguish between transactions between DTC Participants and CDS Participants (''Cross-Border Securities Transactions'') and transactions between only DTC Participants (''Intra-DTC Securities Transactions''). The proposed rule change would also add new definitions to distinguish between transactions that settle in U.S. dollars and transactions that settle in Canadian dollars (for example, ''Cross-Border CAD Securities Transactions'' and ''Intra-DTC USD Securities Transactions'').

Risk Management Controls

Set forth below is a description of DTC's risk management controls with respect to the Canadian-Link Service and how these risk management controls would be affected as a result of the proposed rule change.

1. Canadian-Link Required Participants Fund Deposit. A DTC Participant that uses the Canadian-Link Service is currently required to make an additional required deposit to the DTC participants fund that is determined in accordance with a formula that takes into account the volume of cross-border Canadian dollar securities transactions processed by DTC for such DTC Participant. Under the proposed rule change, such formula would also take into account the volume of cross-border U.S. dollar securities transactions processed by DTC for such DTC Participant.

2. Security for Canadian-Link Transactions. A DTC Participant that uses the Canadian-Link Service is currently required to pledge to DTC its interest in the securities subject to cross-border Canadian dollar securities transactions that are held by DTC for such DTC Participant at CDS. Under the proposed rule change, such DTC Participant will also be required to pledge to DTC its interest in the securities subject to cross-border U.S. dollar securities transactions that are held by DTC for such DTC Participant at CDS.

3. Canadian-Link Service Net Debit Caps. A DTC Participant that uses the Canadian-Link Service is currently subject to a net debit cap on the negative Canadian dollar balance that may, from time to time, be incurred by such DTC Participant with respect to its use of the Canadian-Link Service. Under the proposed rule change, a DTC Participant would also be subject to a net debit cap on the negative U.S. dollar balance that may from time to time be incurred by such DTC Participant with respect to its cross-border U.S. dollar securities transactions. The proposed rule change would add new definitions to DTC Rule 30 to take into account that there would be separate Net Debit Caps for U.S. and for Canadian dollar transactions.

4. Collateral Monitor of Canadian-Link Participants. A DTC Participant that uses the Canadian-Link Service is currently subject to the DTC collateral monitor with respect to its use of the Canadian-Link Service. Under the proposed rule change, a DTC Participant would also be subject to the DTC collateral monitor with respect to its cross-border U.S. dollar securities transactions.

As the foregoing indicates, cross-border U.S. dollar securities transactions will be subject to essentially the same robust risk management controls that are already

[3] DTC has represented to the Commission that some transactions executed in Canadian markets, either on a stock exchange or over-the-counter, are settled in U.S. dollars. Transactions that settle in U.S. dollars would be reported to DTC in U.S. dollar amounts. DTC would not convert settlement amounts from Canadian to U.S. dollars.

applicable to the other securities transactions currently processed through the Canadian-Link Service.

Statutory Basis for the Proposed Rule Change

Section 17A(a)(3)(F) of the Act requires that the rules of a registered clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and to assure the safeguarding of securities and funds which are in its possession or control or for which it is responsible. The proposed enhancement to the Canadian-Link Service should promote the prompt and accurate clearance and settlement of cross-border securities transactions between DTC Participants and CDS Participants and between DTC Participants and other DTC Participants in a secure, efficient, and regulated environment.

B. Self-Regulatory Organization's Statement on Burden on Competition

DTC does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments relating to the proposed rule change have been solicited or received by DTC from members, participants, or other persons. DTC will notify the Commission of any written comments it receives.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(a) By order approve the proposed rule change or,

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–DTC–2006–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–DTC–2006–15. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing also will be available for inspection and copying at the principal office of DTC. 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–DTC–2006–15 and should be submitted on or before December 29, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E6–20868 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

[4] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54854; File No. SR–NASDAQ–2006–046]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Regarding Guidance for Adjudicating Clearly Erroneous Transactions Under Rule 11890

December 1, 2006.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 7, 2006, The NASDAQ Stock Market LLC (''Nasdaq''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by Nasdaq. Nasdaq filed the proposal as a ''non-controversial'' rule change pursuant to Section 19(b)(3)(A) of the Act,[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is providing guidance regarding factors it generally considers in adjudicating clearly erroneous transactions under Nasdaq Rule 11890.

The text of the proposed rule change is below. Proposed new language is in *italics.*

* * * * *

IM–11890–4. Clearly Erroneous Transaction Guidance for Filings under Rule 11890(a) and Single Stock Events under Rule 11890(b)

Nasdaq is providing the following guidance on how it generally considers:

- *All complaints filed by market participants under Rule 11890(a); and*
- *Many events involving a single security considered on Nasdaq's own motion pursuant to Rule 11890(b).*

Nasdaq generally considers a transaction to be clearly erroneous when the print is substantially inconsistent with the market price at the time of execution. In making such a determination, Nasdaq takes into account the circumstances at the time of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

the transaction, the maintenance of a fair and orderly market, and the protection of investors and the public interest. Participants in Nasdaq are responsible for ensuring that the appropriate price and type of order are entered into Nasdaq's systems. Simple assertion by a firm that it made a mistake in entering an order or a quote, or that it failed to pay attention or to update a quote, may not be sufficient to establish that a transaction was clearly erroneous.

Numerical factors for review

Nasdaq primarily considers the execution price of a trade in determining whether it is clearly erroneous.

Execution price	Range away from reference price
$1.75 and under	Equal to or greater than the minimum threshold required for adjudication under Rule 11890(a)(2)(C)(ii).
Over $1.75 and up to $25	10%
Over $25 and up to $50	5%
Over $50	3%

Nasdaq uses different Reference Prices based on the time of the trade and the listing venue of the security in order to establish an appropriate comparison point. These Reference Prices are detailed below. In unusual circumstances, however, Nasdaq may use a different Reference Price.

Time of trade and listing venue	Reference price
Nasdaq-listed securities for trades executed between 9:30 am and 4 pm Eastern Time ("Regular Session").	The best bid (best offer) ("BBO") in Nasdaq at the time of execution of first share of the disputed order.
Non-Nasdaq-listed securities for trades executed during Regular Session and after primary market has posted first two-sided quote.	The national BBO at the time of execution of first share of the disputed order.
Non-Nasdaq-listed securities for trades executed during Regular Session and before primary market has posted first two-sided quote.	The national BBO at the time of execution of first share of the disputed order. If national BBO does not appear substantially related to market, Nasdaq may consider other Reference Prices including the opening trade, indication of interest and first two-sided quote in the primary market (which may occur after the execution) and the closing price for the prior Regular Session for the security's primary market.
Nasdaq-listed and non-Nasdaq-listed securities for trades executed after 4 pm and before 9:30 am Eastern Time.	Closing price of security for the last Regular Session on the security's primary market.

Additional Factors

In occasional circumstances, Nasdaq may consider additional factors in determining whether a transaction is clearly erroneous. These include:

- *Material news released for the security*
- *Suspicious trading activity*
- *System malfunctions or disruptions*
- *Locked or crossed markets*
- *Trading in the security was recently halted/resumed*
- *The security is an initial public offering*
- *Volume and volatility for the security*
- *Stock-split, reorganization or other corporate action.*
- *Validity of consolidated tape trades and quotes and Nasdaq BBO comparison to national BBO.*
- *General volatility of market conditions.*
- *Reason for the error.*

Additional Information Concerning Rule 11890(b)

Nasdaq may on its own motion review transactions in any security in the event of:

- *A disruption or malfunction in the use or operation of any quotation, execution, communication, or trade reporting system owned or operated by Nasdaq and approved by the SEC;*
- *Extraordinary market conditions or other circumstances in which the nullification or modification of transactions may be necessary for the maintenance of a fair and orderly market or the protection of investors and the public interest.*

Consequently, Rule 11890(b) is focused on systemic problems that involve large numbers of parties or trades, or market conditions where it would not be in the best interests of the market to proceed under the processes set forth in Rule 11890(a). Sometimes events involving a single security will meet the standards of Rule 11890(b). However, market participants should not assume that Rule 11890(b) will be available where, for example, they failed to file a complaint within the time periods specified in Rule 11890(a). The rule could be available, however, in cases where a trade not eligible for adjudication under Rule 11890(a) nevertheless could present systemic risks if permitted to stand.

The guidance set forth in IM–11890–4 applies to many events involving a single security adjudicated pursuant to Rule 11890(b). However, Nasdaq may apply the guidance set forth in IM 11890–5 to some events involving a single security, such as some situations where trading activity occurs in multiple market centers and Nasdaq is acting in consultation with other markets.

IM–11890–5. Clearly Erroneous Transaction Guidance for Multi-Stock Events Under Rule 11890(b)

Nasdaq is providing the following guidance on how it generally considers multi-stock events adjudicated on Nasdaq's own motion pursuant to Rule 11890(b).

Nasdaq generally considers a transaction to be clearly erroneous when the print is substantially inconsistent with the market price at the time of execution. In making such a determination, Nasdaq takes into account the circumstances at the time of the transaction, the maintenance of a fair and orderly market, and the protection of investors and the public interest. Participants in Nasdaq are responsible for ensuring that the appropriate price and type of order are entered into Nasdaq's systems. Simple assertion by a firm that it made a mistake in entering an order or a quote,

or that it failed to pay attention or to update a quote, may not be sufficient to establish that a transaction was clearly erroneous.

Nasdaq may on its own motion review transactions in any security in the event of:

- *A disruption or malfunction in the use or operation of any quotation, execution, communication, or trade reporting system owned or operated by Nasdaq and approved by the SEC; or*
- *Extraordinary market conditions or other circumstances in which the nullification or modification of transactions may be necessary for the maintenance of a fair and orderly market or the protection of investors and the public interest.*

Consequently, Rule 11890(b) is focused on systemic problems that involve large numbers of parties or trades, or market conditions where it would not be in the best interests of the market to proceed under the processes set forth in Rule 11890(a). Even in cases involving multiple securities, however, market participants should not assume that Rule 11890(b) will be available where, for example, they failed to file a complaint within the time periods specified in Rule 11890(a). The rule could be available, however, in cases where a trade not eligible for adjudication under Rule 11890(a) nevertheless could present systemic risks if permitted to stand. The determination of whether to adjudicate an event under Rule 11890(b) is made by Nasdaq in its sole discretion pursuant to the terms of the rule.

Numerical Factors for Review

Nasdaq primarily considers the execution prices of the trades in question in determining whether trades should be nullified in a multi-stock event pursuant to Rule 11890(b). Generally all trades more than 10% away from the Reference Price would be clearly erroneous.

NASDAQ uses different Reference Prices based on time of the trade in order to establish an appropriate comparison point. These Reference Prices are detailed below. In unusual circumstances, however, Nasdaq may use a different Reference Price.

Time of trade	*Reference price*
All trades executed after the opening of trading during regular market hours and until the end of regular market hours.	*For Nasdaq-listed securities, the best bid (best offer) ("BBO") in Nasdaq at the time of execution of first share of the disputed order.* *For Non-Nasdaq-listed securities, the national BBO at the time of execution of first share of the disputed order.*
All securities for trades executed: • *after 4 p.m., Eastern Time (ET)* • *before 9:30 a.m., ET* • *during the market opening process for regular market hours*	*The closing price of the security for regular market hours on the security's primary market.*

In occasional circumstances, Nasdaq may consider additional factors in determining whether the transactions are clearly erroneous. These include:

- *Material news released for individual securities*
- *Suspicious trading activity*

Nasdaq may also apply the guidance set forth in IM 11890–5 to some events involving a single security, such as some situations where trading activity occurs in multiple market centers and Nasdaq is acting in consultation with other markets.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq is adopting Interpretive Material under Nasdaq Rule 11890 to provide guidance with regard to its consideration of transactions that may be clearly erroneous. Paragraph (a) of Nasdaq Rule 11890 allows market participants to petition Nasdaq to nullify or modify trades that they allege to be clearly erroneous. Paragraph (b) allows Nasdaq to nullify or modify trades on its own motion in the event of a disruption or malfunction in the use or operation of Nasdaq systems or extraordinary market conditions or other circumstances in which the nullification or modification of transactions may be necessary for the maintenance of a fair and orderly market or the protection of investors and the public interest. Nasdaq is providing one set of Interpretive Material relating to Nasdaq Rule 11890(a) and many events involving a single stock under Rule 11890(b), and a second set of Interpretive Material relating to events involving multiple stocks under Nasdaq Rule 11890(b). In each case, the Interpretive Material is intended to provide market participants with insights into the factors generally considered by Nasdaq in determining whether to nullify or modify trades under the rule.[5]

At its basic level, Nasdaq Rule 11890 is intended to allow Nasdaq to adjudicate disputes between firms as to the status of a trade, with a goal of preventing unjust enrichment of one market participant at the expense of another in circumstances where the terms of a trade are clearly out of line with objective market conditions for a security. Thus, Nasdaq Rule 11890(a) allows the party that believes it made a significant error to petition for an adjudication, and in appropriate circumstances, to be relieved of the obligation to settle the trade. The rule may not be used as an insurance policy against trades that merely lose money, however. Accordingly, the NASD's

[5] The Interpretive Material includes language relating to trades in non-Nasdaq securities. Although Nasdaq is not yet operative as an exchange in these securities, Nasdaq is filing this language in anticipation of an operational date for these securities in the near future. Because Nasdaq's parent company, The Nasdaq Stock Market, Inc. (''Nasdaq Inc.''), currently trades non-Nasdaq securities pursuant to authority delegated by the National Association of Securities Dealers, Inc. (''NASD'') and administers NASD Rule 11890 with respect to these securities pursuant to that delegation, Nasdaq Inc. is also filing a version of the Interpretive Material as an NASD Rule. *See* SR–NASD–2006–123 (November 7, 2006).

predecessor rule was amended in 2005 [6] to establish a conclusive presumption that a trade is not eligible for review under Nasdaq Rule 11890(a) unless its price deviates from the inside market for the security by an amount in excess of certain bright-line numerical thresholds. This aspect of the rule reflects the view that it is preferable to promote market certainty and accountability by market participants by allowing all trades close to the inside market to stand, even if a particular trade may arguably have been caused by a market participant error.

Nevertheless, in an environment of continual increases in the scope and speed of electronic trading, Nasdaq Rule 11890(b) provides an important safeguard against market disruptions caused by trader errors or system malfunctions that result in executions affecting multiple market participants and/or securities. Thus, Nasdaq Rule 11890(b) mitigates systemic risk by providing a mechanism to break erroneous trades that may have a serious detrimental effect on one or more market participants. Nasdaq Rule 11890(b) has been used both with respect to events affecting a single stock, as where an erroneous order causes a large number of trades involving multiple market participants to execute, and events affecting multiple stocks, as where a system malfunction results in a more widespread problem. Because of its focus on system malfunctions and overall market integrity, market participants should not assume that Nasdaq Rule 11890(b) will be used where, for example, they failed to file a complaint within the time periods specified in Nasdaq Rule 11890(a). However, the rule could be available in cases where a trade not eligible for adjudication under Nasdaq Rule 11890(a) nevertheless could present systemic risks if permitted to stand. Thus, for example, if a firm's erroneous trades had the potential to cause a firm's insolvency but its petition was untimely, Nasdaq might consider using Nasdaq Rule 11890(b)(ii) to prevent the insolvency.[7]

Thus, under both parts of the rule, Nasdaq strives to strike a balance between certainty and flexibility, to ensure that (i) similar situations are addressed in a similar manner, (ii) market participants do not attempt to use the rule to attain unfair advantage, and (iii) the rule is not written or construed in a way that may prevent action necessary to protect market quality or prevent systemic problems and thereby maintain a fair and orderly market and protect investors and the public interest. With these considerations in mind, Nasdaq believes that the Interpretive Material allows market participants to achieve a better understanding of Nasdaq's application of the rule without limiting its adaptability. In effect, the Interpretive Material describes Nasdaq's understanding of the precedents that have emerged through years of adjudications under the rule; as with judicial precedents, they serve as a guide to future cases without constricting adaptability to new or unique fact patterns.

Both sets of Interpretive Material reflect that Nasdaq generally considers a transaction to be clearly erroneous when the print is substantially inconsistent with the market price at the time of execution. In making such a determination, Nasdaq takes into account the circumstances at the time of the transaction, the maintenance of a fair and orderly market, and the protection of investors and the public interest. The Interpretive Material also stresses that participants in Nasdaq are responsible for ensuring that the appropriate price and type of order are entered into Nasdaq's systems. Simple assertion by a firm that it made a mistake in entering an order or a quote, or that it failed to pay attention or to update a quote, may not be sufficient to establish that a transaction was clearly erroneous.

IM–11890–4 concerns all complaints filed by market participants under Nasdaq Rule 11890(a), as well as many events involving a single security considered on Nasdaq's own motion pursuant to Nasdaq Rule 11890(b). Nasdaq primarily considers the execution price of a trade in determining whether it is clearly erroneous. Specifically, Nasdaq generally uses the following guidelines: [8]

Execution price	Range away from reference price
$1.75 and under	Equal to or greater than the minimum threshold required for adjudication under Rule 11890(a)(2)(C)(ii).
Over $1.75 and up to $25	10 percent.
Over $25 and up to $50	5 percent.
Over $50	3 percent.

Thus, the degree of deviation from a specified reference price needed for a trade to be declared clearly erroneous depends on the execution price: securities trading at lower prices require a higher percentage deviation before they will be considered clearly erroneous, since the normal daily trading ranges for these securities generally involve larger percentage movements. In the case of securities priced at $1.75 or below, a trade will generally be considered clearly erroneous if it is eligible for adjudication at all under the minimum thresholds under Nasdaq Rule 11890(a)(2)(C)(ii), since these thresholds require significant percentage deviation before a low-priced trade is eligible.

Nasdaq uses different Reference Prices based on time of the trade and the listing venue of the security in order to establish an appropriate comparison point. These Reference Prices are detailed below. In unusual circumstances, however, Nasdaq may use a Reference Price not specifically described in the Interpretive Material. For example, in a case where material news about a security was released after market close for the security and a trade occurring after 4 p.m. and before 9:30 a.m. is at issue, it may be more appropriate to use a Reference Price derived from after-hours trading activity than to use the closing price of the security. Similarly, in the case of several large orders that execute at multiple prices, a Reference Price based on a weighted average of the BBO at relevant times may be more appropriate than a Reference Price based solely on the BBO

[6] *See* Securities Exchange Act Release No. 52141 (July 27, 2005), 70 FR 44709 (August 3, 2005) (SR–NASD–2004–009).

[7] As is the case in all instances where a firm's erroneous trades raise questions as to the adequacy of its internal controls, Nasdaq would also refer the firm for investigation by the NASD in its capacity as Nasdaq's regulatory services provider.

[8] Nasdaq stated that at all execution prices, the guidelines are equal to or greater than the minimum threshold required for adjudication under Rule 11890(a)(2)(C)(ii). Telephone conversation by and between John Yetter, Senior Associate General Counsel, Nasdaq, and Terri Evans, Special Counsel and David Hsu, Special Counsel, Division of Market Regulation, Commission, on November 17, 2006.

immediately prior to the execution of the first share of the order.

Time of trade and listing venue	Reference price
Nasdaq-listed securities for trades executed between 9:30 a.m. and 4 p.m. Eastern Time (''Regular Session'').	The best bid (best offer) (''BBO'') in Nasdaq at the time of execution of first share of the disputed order.
Non-Nasdaq-listed securities for trades executed during Regular Session and after primary market has posted first two-sided quote.	The national BBO at the time of execution of first share of the disputed order.
Non-Nasdaq-listed securities for trades executed during Regular Session and before primary market has posted first two-sided quote.	The national BBO at the time of execution of first share of the disputed order. If national BBO does not appear substantially related to market, Nasdaq may consider other Reference Prices including the opening trade, indication of interest and first two-sided quote in the primary market (which may occur after the execution) and the closing price for the prior Regular Session for the security's primary market.
Nasdaq-listed and non-Nasdaq-listed securities for trades executed after 4 p.m. and before 9:30 a.m. Eastern Time.	Closing price of security for the last Regular Session on the security's primary market.

In occasional circumstances, Nasdaq may consider additional factors in determining whether a transaction is clearly erroneous. These include:

- Material news released for the security.
- Suspicious trading activity.
- System malfunctions or disruptions.
- Locked or crossed markets.
- Trading in the security was recently halted/resumed.
- The security is an initial public offering.
- Volume and volatility for the security.
- Stock-split, reorganization or other corporate action.
- Validity of consolidated tape trades and quotes and Nasdaq BBO comparison to national BBO.
- General volatility of market conditions.
- Reason for the error.

IM–11890–5 concerns multi-stock events adjudicated on Nasdaq's own motion pursuant to Nasdaq Rule 11890(b). In such cases, Nasdaq primarily considers the numerical factors of the execution prices in determining whether trades should be nullified. Generally all trades more than 10% away from the Reference Price would be clearly erroneous.[9]

Nasdaq uses different Reference Prices based on time of the trade in order to establish an appropriate comparison point. These Reference Prices are detailed below. In unusual circumstances, however, Nasdaq may use a different Reference Price.

Time of trade	Reference price
All trades executed after the opening of trading during regular market hours and until the end of regular market hours.	For Nasdaq-listed securities, the best bid (best offer) (''BBO'') in Nasdaq at the time of execution of first share of the disputed order. For Non-Nasdaq-listed securities, the national BBO at the time of execution of first share of the disputed order.
All securities for trades executed: • after 4 p.m., Eastern Time (ET) • before 9:30 a.m., ET • during the market opening process for regular market hours	The closing price of the security for regular market hours on the security's primary market.

In occasional circumstances, Nasdaq may consider additional factors in determining whether the transactions in a multi-stock event are clearly erroneous, including material news released for individual securities or suspicious trading activity.

The guidance set forth in IM–11890–4 will apply to many events involving a single security adjudicated pursuant to Nasdaq Rule 11890(b). However, Nasdaq may apply the guidance set forth in IM–11890–5 to some events involving a single security, such as some situations where trading activity occurs in multiple market centers and Nasdaq is acting in consultation with other markets.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[10] in general, and with Section 6(b)(5) of the Act,[11] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to a free and open market and a national market system, and, in general, to protect investors and the public interest. The Interpretive Materials will promote market participants' understanding of Nasdaq's application of Nasdaq Rule 11890, thereby promoting greater certainty and accountability.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

[9] Nasdaq generally uses 10% threshold in these cases, in contrast to the sliding scale of percentages described in IM–11890–4, because multi-stock events adjudicated under Rule 11890(b) generally require coordination with other venues trading the stock in order to ensure consistent treatment of trades across all venues affected by the event. Nasdaq has found that the 10% threshold is generally used by other venues and therefore facilitates a coordinated and timely response.

[10] 15 U.S.C. 78f.

[11] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change is subject to Section 19(b)(3)(A)(iii) of the Act[12] and Rule 19b–4(f)(6) thereunder[13] because the proposal: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative prior to 30 days after the date of filing or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest; provided that the self-regulatory organization has given the Commission notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

Nasdaq provided the Commission with written notice of its intent to file this proposed rule change at least five business days prior to the date of filing the proposed rule change. Nasdaq has requested that the Commission waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the filing promotes market participants' understanding of Nasdaq's application of Nasdaq Rule 11890, thereby promoting greater certainty with regard to the administration of the rule. For these reasons, the Commission designates the proposal to be effective upon filing with the Commission.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[15]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2006–046 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2006–046. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2006–046 and should be submitted on or before December 29, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E6–20806 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[15] *See* Section 19(b)(3)(C) of the Act, 15 U.S.C. 78s(b)(3)(C).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54857; File No. SR–NASD–2006–101]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto To Provide for the Payment of a $200 Honorarium Per Case for Each Arbitrator Who Considers Contested Motions for the Issuance of Subpoenas

December 1, 2006.

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 23, 2006, the National Association of Securities Dealers, Inc. (''NASD'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by NASD. On November 13, 2006, NASD filed Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASD is proposing to provide for the payment of a $200 honorarium per case for each arbitrator who considers contested motions for the issuance of subpoenas. Below is the text of the proposed rule change.[4] Proposed new language is in italics.

* * * * *

IM–10104. Arbitrators' Honorarium

(a)–(e) No change

(f) *Payment for Deciding Contested Subpoena Requests Without a Hearing Session*

(1) The honorarium for deciding one or more contested motions requesting the issuance of a subpoena without a hearing session shall be $200. The

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, NASD clarified provisions to the proposed rule change.

[4] If the Commission approves the pending revisions to the NASD Code of Arbitration Procedure for Customer Disputes, the rules proposed in this filing will be renumbered as appropriate; *see* Securities Exchange Act Release No. 51856 (June 15, 2005) (SR–NASD–2003–158), 70 FR 36442 (June 23, 2005); and the NASD Code of Arbitration Procedure for Industry Disputes; *see* Securities Exchange Act Release No. 51857 (June 15, 2005) (SR–NASD–2004–011), 70 FR 36430 (June 23, 2005).

honorarium shall be paid on a per case basis to each arbitrator who decides the contested motion(s). The parties shall not be assessed more than $600 in fees under this paragraph in any arbitration proceeding. The honorarium shall not be paid for cases administered under Rules 10203 or 10302.

(2) For purposes of paragraph (f)(1), a contested motion requesting the issuance of a subpoena shall include a motion requesting the issuance of a subpoena, the draft subpoena, a written objection from the party opposing the issuance of the subpoena, and any other documents supporting a party's position.

(3) The panel will allocate the cost of the honorarium under paragraph (f)(1) to the parties pursuant to Rules 10205(c) and 10332(c).

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASD has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to provide for the payment of a $200 honorarium per case for each arbitrator who considers contested motions for the issuance of subpoenas. Last year, NASD amended IM–10104 of the NASD Code of Arbitration Procedure (''Code''), to provide arbitrators with an honorarium of $200 to decide discovery-related motions without a hearing session.[5] The revised rule, however, does not address whether a contested motion concerning a subpoena constitutes a discovery-related motion. As a result, NASD has received questions regarding the appropriate payment, if any, for arbitrators who decide subpoena issues. These questions have focused on whether, under the rule, arbitrators should be paid to decide contested motions requesting the issuance of a subpoena.

The issue of whether arbitrators should receive an honorarium for deciding contested subpoena motions will become even more significant if the Commission approves amendments to Rule 10322 as proposed by NASD.[6] The proposed changes to Rule 10322 would permit only arbitrators to issue subpoenas in arbitration disputes.[7] If the proposed changes to Rule 10322 are approved by the Commission, attorneys would no longer have the authority to issue subpoenas. NASD anticipates that this would result in a significant increase in the number of subpoena requests considered by arbitrators.

NASD recognizes that arbitrators may spend a considerable amount of time and effort deciding contested subpoena motions and believes that arbitrators should be compensated for this work. Therefore, NASD proposes to provide a $200 honorarium to each arbitrator who decides contested motions for subpoenas.[8] NASD anticipates that if its proposed changes to Rule 10322 are approved, under most circumstances, the chairperson will be the only arbitrator considering subpoena requests based on the documents supplied by the parties. If the entire panel decides a contested motion, each arbitrator who participates in the subpoena ruling will receive an honorarium of $200. The $200 honorarium paid to an arbitrator would provide payment for all contested subpoena motions in a case (*i.e.*, the honorarium would be paid on a per case basis, regardless of the number of contested subpoena motions considered by an arbitrator or panel during the case).[9] Furthermore, the maximum amount that would be paid by the parties, collectively, for any one case would be $600, irrespective of any changes to the composition of the panel.[10] NASD believes that structuring the honorarium in this manner will limit the arbitration costs for parties while at the same time compensating arbitrators for the time that they spend considering contested subpoena requests.

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of Sections 15A(b)(5)[11] and 15A(b)(6)[12] of the Act, which require, among other things, that NASD's rules provide for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility or system that the NASD operates or controls, and that NASD's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. NASD believes that the proposed rule change is consistent with the provisions of the Act noted above because the panel will allocate the honorarium for deciding a discovery-related motion equitably among the parties. Moreover, NASD believes the proposed rule change will encourage arbitrators to decide contested subpoena requests without scheduling a prehearing conference, thereby expediting the arbitration process for parties.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

[5] *See* Securities Exchange Act Release No. 51931 (June 28, 2005) (File No. SR–NASD–2005–052), 70 FR 38989 (July 6, 2005).

[6] *See* Securities Exchange Act Release No. 54134 (July 12, 2006) (File No. SR–NASD–2005–079), 71 FR 40762 (July 18, 2006).

[7] Currently, Rule 10322 allows arbitrators and any counsel of record to the proceedings to issue subpoenas as provided by law.

[8] For purposes of this rule, a contested motion is defined as a motion to issue a subpoena, the draft subpoena, a written objection from the party opposing the issuance of the subpoena, and any other documents supporting a party's position. Arbitrators will not be entitled to receive the honorarium if a motion for a subpoena is uncontested.

[9] This differs from other discovery-related motions, for which an arbitrator receives an honorarium for each motion considered. *See* IM–10104(e). If the panel has received the honorarium for considering a contested subpoena request and subsequently receives a number of new contested subpoena requests, however, the chairperson may call a prehearing conference to hear and decide these maters, for which the participating arbitrator(s) would receive the normal prehearing honorarium. *See* IM–10104(a) and (b).

[10] In situations where more than three different arbitrators consider contested subpoena requests, NASD will pay the additional honorarium. For example, if all three members of a panel have decided a contested subpoena request and the chairperson is thereafter replaced by another arbitrator, NASD would pay the $200 honorarium to the replacement chairperson for deciding any later contested subpoena requests, because the parties already would have incurred $600 in costs relating to the requests. Likewise, if there have been three different chairpersons in the same proceeding, each of whom has considered a contested subpoena request, NASD would pay the $200 honorarium should a fourth chairperson consider a contested subpoena request. NASD does not anticipate that either of these situations will occur frequently.

[11] 15 U.S.C. 78o–3(b)(5).

[12] 15 U.S.C. 78o–3(b)(6).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NASD–2006–101 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–NASD–2006–101. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of NASD.

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASD–2006–101 and should be submitted on or before December 29, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E6–20873 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54856; File No. SR–NYSE–2006–106]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Fees Charged to Member Organizations for Transactions in Equity Securities

December 1, 2006.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 30, 2006, the New York Stock Exchange LLC (''Exchange'' or ''NYSE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. NYSE has designated this proposal as one establishing or changing a due, fee, or other charge imposed by NYSE under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective 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 revise the fees it charges to its member organizations for transactions in equity securities by eliminating the $750,000 monthly fee cap and establishing a flat fee of $0.000275 per share. The Exchange will also begin charging the standard Exchange Traded Fund (''ETF'') fee of $0.0030 per share on transactions in ETFs traded on an unlisted trading privilege basis. The Exchange also is eliminating the specialist trading privilege fee and the specialist allocation fee. In addition, simultaneously with the implementation of the revised trading fees, the Exchange intends, by means of a separate filing (the ''Commission Elimination Filing''), to eliminate specialist commissions.[5] The proposed rule changes will take effect as of December 1, 2006.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

The text of the proposed rule change is available on the Exchange's Web site (*http://www.nyse.com*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to revise the fees it charges to its member organizations for transactions in equity securities by eliminating the $750,000 monthly fee cap and establishing a flat fee of $0.000275 per share. The Exchange will also begin charging the standard ETF fee of $0.0030 per share on transactions in ETFs traded on an unlisted trading privileges basis. In addition, simultaneously with the implementation of the revised trading fees, the Exchange proposes in the Commission Elimination Filing to eliminate specialist commissions. The proposed fee changes will take effect as of December 1, 2006. The Exchange has requested that the Commission make the

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] *See* Securities Exchange Act Release No. 54850 (November 30, 2006) (notice of filing and immediate effectiveness of SR–NYSE–2006–105).

effectiveness of the Commission Elimination Filing operative on December 1, 2006, the same day the changes contained in this filing take effect.

The Exchange currently charges a fee of $0.00025 per share on equity transactions, subject to a monthly fee cap of $750,000 per member organization. The Exchange proposes to eliminate the monthly fee cap and raise the equity transaction fee to $0.000275 per share. Under the current fee structure, the member organizations with the highest trading volume on the Exchange benefit from a lower effective fee level than member organizations sending smaller volumes to the Exchange, because they benefit from the monthly cap. After the elimination of the monthly cap, the effective fee rate will be the same for all member organizations regardless of how much volume they send to the Exchange.[6] Moreover, while the transaction fee is increasing from $0.00025 to $0.000275, the prohibition of specialist commissions referenced above will lead to a lower effective trading cost when compared to the combined costs of transaction fees and specialist commissions under the current structure. As such, the Exchange believes that the combined effect of the fee change and the prohibition of specialist commissions will be to make its pricing structure more competitive, more equitable, more transparent and easier to understand.

Unlike transactions in listed ETFs, on which the Exchange charges a $0.0030 per share fee, the Exchange does not currently charge fees on transactions in ETFs traded on an unlisted trading privileges basis. As of December 1, 2006, the Exchange proposes to charge the same fee on transactions in ETF securities traded on a UTP basis as it charges on listed ETFs.

In order to partially offset the specialists' loss of commissions, the Exchange is eliminating the specialist trading privilege fee and the specialist allocation fee. The specialist allocation fee is charged to the specialist allocated a new equity listing and for any specific allocation the fee payable is an amount equal to the difference between the initial listing fee the company is required to pay subject to the Exchange's $250,000 cap on initial listing fees and the amount the company would have to pay if the listing fee cap was $500,000.[7] Initial listing fees payable by companies will continue to be capped at $250,000, notwithstanding the elimination of the specialist allocation fee.

The Exchange is also instituting a program of revenue sharing with Exchange specialists. Revenue sharing payments to specialists will be made from the Exchange's general revenues and will not be limited to a particular revenue source. Given the uncertainties faced by specialists in light of the complete implementation of the Exchange's hybrid market initiative over the next several months coupled with the loss of commission income, in order to provide to the specialist firms a source of payments in lieu of commissions for a transitional period, the Exchange will distribute a fixed amount of $53 million among the specialists with respect to the six-month period commencing on December 1, 2006. This fixed amount will be allocated among the specialist firms based on their performance in October 2006, and will be allocated in proportion to the rebates each of the specialist firms would be entitled to under the formulas set forth in items (2) and (3) (but not item (1)) of the next paragraph. The transitional rebate will be paid in six equal monthly installments.

Commencing June 1, 2007, the Exchange intends to institute a revenue sharing program that will provide variable payments to the specialist firms depending on performance. The Exchange will file a rule filing with the Commission pursuant to the Act and the rules thereunder in relation to such revenue sharing program prior to its implementation. While the nature of the revenue sharing program that the Exchange will ultimately propose may change depending on market conditions in the intervening period, it is currently anticipated that the revenue sharing program will have the following three components:

(1) Specialists would receive a rebate (calculated on a monthly basis) of $0.000275 per share for each share of their specialty securities they either buy or sell on the Exchange.

(2) Specialists would receive a rebate each month relating to their absolute market share in each of their specialty stocks if that market share exceeds 35%. A market share in a stock that is equal to or exceeds 35% would entitle a specialist to a rebate of (i) $15 for each percentage point above or equal to 35% up to and including 50%, (ii) $25 for each percentage point above 50% up to and including 65%, (iii) $35 for each percentage point above 65% up to and including 80%, and (iv) $45 for each percentage point above 80%. The following are examples of how this rebate would be paid:

- If Specialist X trades XYZ stock in which the Exchange has a 50% market share, it would receive $225 per month, which is 15% multiplied by $15.
- If Specialist X trades XYZ stock in which the Exchange has a 65% market share, it would receive $600 per month, which is 15% multiplied by $15, plus 15% multiplied by $25.

(3) Specialists would receive a volume-weighted rebate each month for every share traded in a stock in which the Exchange has a greater than 35% market share. If the Exchange has a market share:

- Equal to or greater than 35% up to and including 50%, the rebate would be $0.00013 per share.
- Greater than 50% up to and including 65%, the rebate would be $0.00014 per share.
- Greater than 65% up to and including 80%, the rebate would be $0.00015 per share.
- Greater than 80% the rebate would be $0.00016 per share.

The following are examples of how the volume-weighted rebate would be paid:

- If Specialist X trades XYZ stock in which the Exchange has a 50% market share, it would receive a rebate of $0.00013 for every share traded above the 35% market share threshold.
- If Specialist X trades XYZ stock in which the Exchange has a 65% market share, it would receive a rebate of $0.00013 per share for every share traded above the 35% market share threshold up to and including a 50% market share, and then would receive $0.00014 for every share above the 50% level.

The Exchange may alter the provisions of the revenue sharing program in the future in response to its experience with its application over time, in particular in light of the Exchange's full implementation of its hybrid market initiative.[8]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act[9] in general and furthers the objectives of

[6] The Exchange's $80 per transaction cap on fees will continue to be applied.

[7] *See* Exchange Act Release No. 34–43700 (December 11, 2000); 65 FR 79147 (December 18, 2000) (SR–NYSE–00–48).

[8] The Exchange will file a rule filing with the Commission pursuant to the Act and the rules thereunder in relation to any such changes prior to their implementation.

[9] 15 U.S.C. 78f.

Section 6(b)(4) [10] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective upon filing pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(2) [12] thereunder because it establishes or changes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File No. SR–NYSE–2006–106 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2006–106. 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 Commissions Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the NYSE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2006–106 and should be submitted on or before December 29, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E6–20872 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 19b–4(f)(2).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54850; File No. SR–NYSE–2006–105]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Prohibit Specialists From Charging Commissions on Transactions in Their Specialty Securities

November 30, 2006.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 30, 2006, the New York Stock Exchange LLC (''Exchange'' or ''NYSE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been substantially prepared by the Exchange. The Exchange has designated this proposal as non-controversial under Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposed rule change 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 adopt new Rule 104B prohibiting specialist firms from charging commissions on transactions in their specialty securities, including exchange traded fund (''ETF'') securities, and to make changes to Rules 104 and 123B to reflect the fact that specialists will no longer be able to charge commissions. In connection with the elimination of specialist commissions, the Exchange proposes in a separate filing (the ''Fee Filing'') [5] to institute a program of revenue sharing for the specialists. The proposed rule changes will take effect as of December 1, 2006. The amendments to the Exchange's Rules are included in Exhibit 5 to the Exchange's filing.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NYSE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NYSE has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

The text of the proposed rule change is available on the Exchange's Web site (*http://www.nyse.com*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] *See* SR–NYSE–2006–106 (filed on November 30, 2006).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt new Rule 104B prohibiting specialist firms from charging commissions on transactions in their specialty securities, including ETF securities, and to make changes to Rules 104 and 123B to reflect the fact that specialists will no longer be able to charge commissions. In connection with the elimination of specialist commissions, the Exchange proposes, in the separate Fee Filing, to: (i) Eliminate the specialist trading privilege fee and the specialist allocation fee, and (ii) institute a program of revenue sharing for the specialists. In the Fee Filing, the Exchange is also: (i) Eliminating its $750,000 monthly fee cap on equity transactions, (ii) adopting a flat equity transaction fee of $0.000275 per share, and (iii) applying the $0.0030 per share ETF fee to ETFs traded on an unlisted trading privilege basis. We are requesting that the Commission make the effectiveness of this filing operative on December 1, 2006, the same day the changes contained in the Fee Filing take effect.

The Exchange proposes to implement new Rule 104B prohibiting specialist firms from charging commissions on transactions in their specialty securities, including ETFs, and to make technical conforming changes to Rules 104 and 123B to reflect the fact that specialists will no longer be able to charge commissions on equity or ETF transactions.[6] The elimination of specialist commissions will take effect on December 1, 2006, and will not have retroactive effect. Therefore, specialist firms will not be prohibited from collecting commissions owed on transactions completed before that date.

Subsection (4) of Supplementary Material .20 of Rule 104 (''Dealings by Specialists'') provides that, for those members registered as a regular specialist subject to the Commission's Net Capital Rule,[7] the term ''net liquid assets'' refers to excess net capital computed in accordance with the provisions of Rule 325 (''Capital Requirements'') with certain adjustments, including deductions for floor brokerage and/or commissions receivable. Similarly, Rule 123B(b)(1) and Supplementary Material .10 to Rule 123B provide that a specialist may not charge floor brokerage (*i.e.*, a commission) for the execution of an order which he or she receives by means of the Exchange's automated order routing system, known as SuperDot, if such order is executed within five minutes of receipt by the specialist. As, under new Rule 104B, specialists will be prohibited from charging any commissions in relation to trades in their specialty securities, the foregoing provisions will cease to be relevant and the Exchange proposes to delete them upon adoption of new Rule 104B.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6[8] of the Securities Exchange Act of 1934 in general and furthers the objectives of Section 6(b)(5)[9] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments, and to perfect the mechanism of, a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[10] and subparagraph (f)(6) of Rule 19b–4 thereunder.[11] Because the Exchange has designated the foregoing proposed rule change as one that: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[12]

The Exchange requests that the Commission waive the 30-day operative delay specified in Rule 19b–4(f)(6)(iii) with respect to the proposed rule change.[13] The Exchange represents that the specialist firms affected by the proposal have all agreed to the elimination of commissions contingent upon the Exchange's implementation of the revenue sharing program proposed in the Fee Filing. As the proposal and the revision to the Exchange's trading fees are both parts of an integrated plan in which (i) the revenues generated from the revised fees will partially offset the cost to the Exchange of the payments the Exchange will make to the specialists under the revenue sharing program, and (ii) the cost to customers of the increased transaction fees will be offset at least partially by the elimination of commissions, it is essential that the proposals in this filing takes effect at the same time as the fee change. Therefore, the Exchange believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest.

The Commission has determined to waive the 30-day delay and allow the proposed rule change to become operative on December 1, 2006.[14] The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the Exchange has represented that the elimination of specialist commissions will benefit investors by helping to offset their increased transaction fees under the Fee Filing.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public

[6] The ETF transactions with respect to which specialists will be prohibited from charging commissions will include transactions in Investment Company Units pursuant to Exchange Rule 1100, Trust Issued Receipts pursuant to Exchange Rule 1200, and streetTRACKS® Gold Shares pursuant to Exchange Rule 1300, Currency Trust Shares pursuant to Exchange Rule 1300A, Commodity Trust Shares pursuant to Exchange Rule 1300B or any security governed by Exchange Rule series 1100, 1200, 1300, 1300A or 1300B.

[7] *See* 17 CFR 240.15c3–1.

[8] 15 U.S.C. 78f.

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] The Exchange provided written notice to the Commission of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to filing, as required by Rule 19b–4(f)(6)(iii).

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes only of waiving the operative delay of this proposal, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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 No. SR–NYSE–2006–105 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2006–105. 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 Commissions Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2006–105 and should be submitted on or before December 29, 2006.

[15] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E6–20874 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54849; File No. SR–NYSE–2006–104]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Waive Initial Listing Fee and One-Time Special Charge in Connection With Listing New Class of Common Shares Payable by Any Company Listed on Another National Securities Exchange That Transfers the Listing of Its Primary Class of Common Shares to the NYSE

November 30, 2006.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 29, 2006, The New York Stock Exchange LLC (''Exchange'' or ''NYSE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared substantially by NYSE. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A) of the Act,[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission.[5] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NYSE proposes to amend Section 902.03 of its Listed Company Manual to provide that there shall be no initial listing fee payable by any company listed on another national securities exchange that transfers the listing of its primary class of common shares to the Exchange. The Exchange will eliminate initial listing fees for issuers listed on other national securities exchanges that transfer their listing to the Exchange on or after November 29, 2006. In addition, the Exchange will waive with respect to such issuers the special one-time charge of $37,500 payable in connection with the initial listing of any class of common shares. The text of the proposed rule change is available at *www.nyse.com*, at the NYSE, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NYSE 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. NYSE has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NYSE proposes to amend Section 902.03 of its Listed Company Manual to provide that there shall be no initial listing fee payable by any company listed on another national securities exchange that transfers the listing of its primary class of common shares to the Exchange. NYSE will eliminate entry and application fees for exchange issuers that transfer their listing to the Exchange on or after November 29, 2006. In addition, the Exchange will waive with respect to such issuers the special one-time charge of $37,500 payable in connection with the initial listing of any class of common shares. For issuers that have paid these fees, the Exchange will refund the money. Companies transferring from other national securities exchanges will still be required to pay the annual listing fee payable by all companies, prorated for the first portion of a calendar year after the listing date.

Companies transferring from other national securities exchanges will be subject to the same level of annual fees and listing of additional shares fees as other NYSE issuers. The proposed rule change will not affect the Exchange's commitment of resources to its regulatory oversight of the listing

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] NYSE gave the Commission written notice of its intention to file the proposed rule change on November 29, 2006. The Commission reviewed the proposed rule change and gave NYSE permission to file the proposed rule change on the same day. NYSE has asked the Commission to waive the 30-day operative delay. *See* Rule 19b–4(f)(6)(iii). 17 CFR 240.19b–4(f)(6)(iii).

process or its regulatory programs. Specifically, companies that switch their listing will be reviewed for compliance with Exchange listing standards in the same manner as any other company that applies to be listed on the Exchange. The Exchange will conduct a full and independent review of each issuer's compliance with the Exchange's listing standards.

The Exchange believes that the elimination of such fees is justified on several grounds. An issuer that already paid initial listing fees to an exchange when it became a publicly traded company is reluctant to pay a second initial listing fee to another listing venue, even if it concludes that the Exchange offers the issuer and its investors superior services and market quality. Even if an issuer concludes that the Exchange would provide a superior market for its stock, the benefits of the switch must currently be weighed against the cost of initial inclusion, which can be as much as $250,000. Since the expected benefits of the switch would be diffused among the issuers' investors and realized over time, but the initial listing fees must be paid by the issuer immediately, the Exchange is concerned that issuers that stand to benefit may nevertheless opt to forgo a switch. As such, the Exchange believes that assessing the initial fees against issuers that have already paid fees to list on another market imposes a burden on the competition between exchange markets and markets other than exchange markets, a competition that the Exchange believes is one of the central goals of the national market system. This concern is particularly great in light of the fact that the Commission has approved the waiver of initial listing fees by Nasdaq with respect to companies transferring from other national securities exchanges.[6]

The Exchange understands that the effect of this proposed rule change will be to impose a lower level of listing fees on switching issuers than on some other issuers. In light of the fact that the Exchange will collect the same level of annual fees and listing of additional shares fees from such issuers, however, the Exchange believes that the difference does not constitute an inequitable allocation of fees. In light of a switching issuer's prior payment to another market, the Exchange believes that eliminating initial fees for switching issuers is entirely consistent with an equitable allocation of listing fees.

The Exchange does not expect the financial impact of this proposed rule change to be material, either in terms of increased levels of annual fees from switching issuers or in terms of diminished entry fees. Quite simply, even with the proposed rule change in place, the Exchange understands that a change in listing venue is a major step for an issuer, and therefore the Exchange does not expect that the number of switching issuers in a given time frame will be sufficient to have a material effect on financial resources. Accordingly, the proposed rule change will not impact the Exchange's resource commitment to its regulatory oversight of the listing process or its regulatory programs.

2. Statutory Basis

NYSE believes the proposed rule change is consistent with the requirement under Section 6(b)(4)[7] of the Act that an exchange have rules that provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities, and the requirement under Section 6(b)(5)[8] of the Act that an exchange have rules that are designed to remove impediments to and perfect the mechanism of a free and open market and a national market system and are not designed to permit unfair discrimination between issuers. In light of a switching issuer's prior payment to another market, the Exchange believes that the proposed fee waiver does not render the allocation of its listing fees inequitable or unfairly discriminatory because the Exchange expects that, on average, the review of companies transferring from other national securities exchanges to the Exchange will be less costly than the review of a previously unlisted company, as the issuer will have previously been subject to corporate governance requirements very similar to those of the Exchange. The Exchange believes that the fee waiver will make it easier for companies to transfer among national securities exchanges and will remove a competitive disadvantage the Exchange currently has vis a vis Nasdaq and is therefore designed to perfect the mechanism of a free and open market.

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 purpose of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10]

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.

NYSE has asked that the Commission waive the 30-day operative delay contained in Rule 19b–4(f)(6)(iii) under the Act.[11] Because waiver of these fees will enable NYSE to compete for listings with Nasdaq, the Commission believes waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission designates the proposal to be effective and operative upon filing with the Commission.[12]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[6] *See* Securities Exchange Act Release Nos. 50740 (November 29, 2004), 69 FR 70299 (December 3, 2004) (SR–NASD–2004–140) (notice) and 51004 (January 10, 2005), 70 FR 2917 (January 18, 2005) (approval order).

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] For purposes only of waiving the 30-day operative delay of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

Electronic Comments

• Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

• Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2006–104 on the subject line.

Paper Comments

• Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2006–104. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of NYSE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2006–104 and should be submitted on or before December 29, 2006.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E6–20885 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–54860; File No. SR NYSE–2006–76]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Order Granting Accelerated Approval to Proposed Rule Change, as Amended, Relating to Exchange Rule 104.10 (''Dealings by Specialists'')

December 1, 2006.

I. Introduction

On September 22, 2006, the New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend specialist stabilization requirements set forth in NYSE Rule 104.10 (''Dealings by Specialists''). The proposed rule change was published for comment in the **Federal Register** on September 28, 2006.[3] The Commission received five comment letters[4] from one commenter and two comment response letters from NYSE.[5] On October 25, 2006, NYSE filed Amendment No. 1 to the proposed rule change.[6] This notice and order approves the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.[7]

II. Description of the Proposal

NYSE Rule 104 governs specialist dealings and includes, among other things, restrictions upon specialists' ability to trade as a dealer in the stocks in which he or she is registered. Under NYSE Rule 104(a), specialists are not permitted to effect transactions on the Exchange for their proprietary accounts in any security in which the specialist is registered, ''unless such dealings are reasonably necessary to permit such specialist to maintain a fair and orderly market * * *'' This restriction is known as the ''negative obligation.'' In particular, NYSE Rules 104.10(5) and (6) expand upon the negative obligation with regard to specific types of proprietary transactions. These sections further define the instances when a specialist is restricted in his or her ability to trade in relation to the direction of the market.

A. Current Specialist Stabilization Rules

Specifically, current NYSE Rule 104.10(5)(i) provides that specialist proprietary transactions are to be effected in a reasonable and orderly manner in relation to the general market, the market in a particular stock, and the adequacy of the specialist's position to the immediate and reasonably anticipated needs of the market. The rule further provides that, unless it is to render the specialist's position in a stock adequate for current or reasonably anticipated needs of the market, a specialist should not effect a non-stabilizing transaction (*i.e.*, a transaction with the trend of price movement) for the specialist's account when acquiring or increasing a position. In this regard, the rule restricts specialists from purchasing stock at a price above the last sale (in the same trading session) and purchasing more than 50% of the stock offered on a ''zero plus tick,'' *i.e.*, at the same price as the last sale, when such last sale price was higher than the previous, differently priced sale in the stock on the Exchange. Specialists are, however, permitted to effect these types of transactions with Floor Official approval or in less active markets where such transactions are an essential part of a proper course of dealings and where the amount of stock involved and the price change, if any, are normal in relation to the market.

NYSE Rule 104.10(6) sets forth the specialist's stabilization requirements when liquidating or reducing a position. This rule provides that such trades should be effected in a reasonable and orderly manner in relation to the condition of the general market, the market in the particular security, and the adequacy of the specialist's position to meet the immediate and anticipated needs of the market in the security. Specialists are permitted to liquidate or reduce a position by selling stock on a ''direct minus tick,'' *i.e.*, selling stock at a price lower than the price of the last sale on the Exchange, or by purchasing stock on a ''direct plus tick,'' *i.e.*, at a price higher than the price of the last

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 54504 (September 26, 2006), 71 FR 57011 (''Stabilization Proposal'').

[4] *See* letters from George Rutherfurd to the Commission, dated October 11, 2006 (''Rutherfurd Letter I''); October 20, 2006 (''Rutherfurd Letter II''); October 26, 2006 (''Rutherfurd Letter III''); November 2, 2006 (''Rutherfurd Letter IV''); and November 14, 2006 (''Rutherfurd Letter V'').

[5] *See* letters from Mary Yeager, Assistant Secretary, NYSE, to Nancy M. Morris, Secretary, Commission, dated November 6, 2006 (''NYSE Letter I'') and November 29, 2006 (''NYSE Letter II'').

[6] For a description of Amendment No. 1, *see* Section II.D., *infra*.

[7] The proposed rule change, as amended by Amendment No. 1, was approved on a temporary, pilot basis in File No. SR–NYSE–2006–82. *See* Securities Exchange Release No. 54578 (October 5, 2006), 71 FR 60216 (October 12, 2006) (''Phase 3 Pilot'').

sale on the Exchange, if such transaction is reasonably necessary and the specialist has obtained Floor Official approval. After such direct tick liquidating transactions and after proprietary liquidating sales on ''zero minus ticks'' and proprietary liquidating purchases on ''zero plus ticks,'' specialists are required to re-enter the market on the opposite side in an appropriate amount, where the imbalance of supply and demand indicates that immediately succeeding transactions may result in lower (following specialist's sale) or higher (following specialist's purchase) prices.[8]

Pursuant to NYSE Rule 104.10(b)(7), specialists are permitted to effect proprietary transactions in investment company units and Trust issued receipts (securities commonly referred to as exchange-traded funds or ETFs) without Floor Official approval for the purpose of bringing the ETF price into parity with the underlying index value. These transactions, however, must be effected in a manner that is consistent with the maintenance of a fair and orderly market.

B. Proposed Specialist Stabilization Rules

NYSE proposes to retain the negative obligation in that specialist dealings must be reasonably necessary for the maintenance of a fair and orderly market and that transactions with the trend of the market be accompanied by appropriate re-entry on the opposite side of the market. NYSE proposes to amend its stabilization rules to reflect four types of specialist dealer transactions—''Neutral,'' ''Non-Conditional,'' ''Conditional,'' and ''Prohibited.''

1. Neutral Transactions [9]

NYSE proposes to define Neutral Transactions as purchases or sales by which a specialist liquidates or decreases a position. NYSE proposes that Neutral Transactions must be effected in a reasonable and orderly manner in relation to the condition of the general market, the market in the particular stock, and the adequacy of the specialist's position to the immediate and reasonably anticipated needs of the round-lot and odd-lot market. Neutral Transactions may be made without restriction as to price but must be reasonably necessary to render the specialist's position adequate to the market's needs. This is similar to what the current rule permits today,[10] but eliminates the requirement for Floor Official approval in situations where the transaction is a sale on a direct minus tick or a purchase on a direct plus tick. The specialist's obligation to maintain a fair and orderly market may require re-entry on the opposite side of the market after effecting one or more Neutral Transactions and should be in accordance with the immediate and anticipated needs of the market. Re-entry on the opposite side of the market is not required merely as a result of the specialist engaging in one or more Neutral Transactions, but may be necessary in order for the specialist to meet his or her affirmative obligation to maintain a fair and orderly market.

2. Non-Conditional Transactions [11]

Non-Conditional Transactions are defined as certain specialist bids or purchases and offers or sales that establish or increase the specialist's position other than reaching across the market to trade with the Exchange quote. Like Neutral Transactions, Non-Conditional Transactions must be effected in a reasonable and orderly manner in relation to the condition of the general market, the market in the particular stock, and the adequacy of the specialist's position to the immediate and reasonably anticipated needs of the round-lot and odd-lot market. Proposed NYSE Rule 104.10(5)(i)(a)(II)(b) sets forth seven types of Non-Conditional Transactions (items (i) through (vii)), which may be effected without restriction as to price or the need for Floor Official approval. The first two types of Non-Conditional Transactions (items (i) and (ii)) are allowed without restriction under the current rule and have not been changed.[12] The following is a list of Non-Conditional Transactions:

(i) Matching another market's better bid or offer;[13]

(ii) Bringing the price of a security into parity with an underlying or related security or asset; [14]

(iii) Adding size to an independently established bid or offer on the Exchange;

(iv) Purchasing at the published bid on the Exchange;

(v) Selling at the published offer on the Exchange;

(vi) Purchasing or selling at a price between the Exchange published bid and published offer; or

(vii) Purchasing below the published bid or selling above the published offer on the Exchange (*e.g.*, during a ''sweep'').

Re-entry on the opposite side of the market is not required as a result of the specialist engaging in one or more Non-Conditional Transactions, but may be required in order for the specialist to meet its affirmative obligation to maintain a fair and orderly market. Where such re-entry is necessary, it should be commensurate with the size of the specialist's Non-Conditional Transactions and the immediate and anticipated needs of the market.

3. Specialist Trades To Increase Its Position by Trading With the Exchange Quote [15]

Transactions in which the specialist is increasing or establishing a position in his or her registered securities by reaching across the market to trade with the Exchange bid or offer are governed by proposed NYSE Rule 104.10(5)(i)(b) for inactive securities and proposed NYSE Rule 104.10(6) for active securities. NYSE proposes to define Active Securities as: [16]

(a) Securities comprising the S&P 500® Stock Index;

(b) Securities trading on the Exchange during the first five trading days following their initial public offering; and

(c) Securities that have been designated as ''active'' by a Floor Official.[17]

''Inactive securities'' are securities that do not fall within the definition of ''Active'' securities.

[8] This rule provides that, during any period of volatile or unusual market conditions resulting in a significant price movement in the subject security, the specialist's transaction in reentering the market should reflect, at a minimum, the specialist's usual level of dealer participation. Further, any series of specialist destabilizing transactions during periods of volatile or unusual market conditions should be accompanied by the specialist's re-entry in the market and effecting transactions which reflect a significant degree of dealer participation. *See* NYSE Rule 104.10(6)(i)(B).

[9] Proposed NYSE Rule 104.10(5)(i)(a)(I).

[10] NYSE Rule 104.10(6)(i)(A).

[11] Proposed NYSE Rule 104.10(5)(i)(a)(II).

[12] NYSE Rules 104.10(5)(iv) and 104.10(7).

[13] *See* Securities Exchange Release No. 54362 (August 25, 2006), 71 FR 52201 (September 1, 2006) (SR–NYSE–2006–07).

[14] *See* Securities Exchange Release No. 37016 (March 22, 1996), 61 FR 14185 (March 29, 1996) (SR–NYSE–96–04).

[15] Proposed NYSE Rule 104.10(6).

[16] Proposed NYSE Rule 104.10(6)(i).

[17] A governing Floor Official may designate a security as ''active'' by determining, among other things, that the security in question has exhibited substantially greater than normal trading volume and is likely to continue to sustain such higher volume during the remainder of the trading session. The Floor Official's determination that a security should be considered ''active'' lasts only for the trading session on the particular day it is determined. While the security may be designated ''active'' on subsequent days, such determinations must be made based on its trading characteristics that day. Floor Officials would also be required to notify the Market Surveillance Division of New York Stock Exchange Regulation (''NYSER'') whenever he or she designates a security as ''active.'' Both the specialist and Floor Official would be required to create and maintain such documentation regarding the security as the Exchange may require.

a. Conditional Transactions in Active Securities

NYSE proposes a pilot program until June 30, 2007 (''Pilot'') that would allow Conditional Transactions, which are specialist trades in Active Securities that establish or increase a position by reaching across the market to trade with the Exchange's published bid (in the case of a specialist's sale) or offer (in the case of a specialist's purchase) when such bid (offer) is priced below (above) the last differently-priced trade and the last differently-priced published bid (offer) on the Exchange.

NYSE proposes to allow a specialist to execute Conditional Transactions without restriction as to price or Floor Official approval, provided that the specialist appropriately re-enters on the opposite side of the market in a size commensurate with the specialist's Conditional Transaction. NYSE proposes to issue guidelines that specialists should follow, called ''Price Participation Points'' (''PPPs''), that would identify the price at or before which a specialist is expected to re-enter the market after effecting one or more Conditional Transactions. The Exchange noted that PPPs are minimum guidelines only and compliance with them does not guarantee that a specialist is meeting its obligations.[18]

NYSE proposes that certain Conditional Transactions would require the specialist to immediately re-enter, or re-enter as the specialist's next available quoting or trading action, regardless of the PPP. For example, immediate re-entry may be required based on the price and/or volume of the specialist's Conditional Transaction(s) in reference to the market in the security at the time of such trading. The fact that there may have been one or more independent trades following the specialist's Conditional Transaction does not, by itself, eliminate the need for immediate re-entry, when otherwise appropriate. In addition, immediate re-entry is required after a Conditional Transaction: (a) Of 10,000 shares or more or a quantity of stock with a market value of $200,000 or more; and (b) which exceeds 50% of the published bid or offer size (as relevant).[19]

b. Inactive Securities

Specialist transactions in Inactive Securities that reach across the market to trade with the existing bid or offer when the specialist is establishing or increasing a position would continue to be governed by the requirements of current NYSE rules.[20] A specialist would not be permitted to establish or increase its position by reaching across the market to purchase the offer at a price that is above the last sale price on the Exchange or sell to the bid at a price below the last sale price on the Exchange, unless such specialist trade is reasonably necessary to render the specialist's position adequate to the immediate and reasonably anticipated needs of the market and approved by a Floor Official. Further, specialists would not be permitted to purchase more than 50% of the stock offered at a price that is equal to the last sale price when the last sale price was higher than the last differently priced regular way sale, unless such trade is approved by a Floor Official. Specialists must reenter the market when reasonably necessary after effecting such trades.

4. Prohibited Transactions [21]

NYSE proposes that, during the last ten minutes of trading, (1) A specialist with a long position in a security would be prohibited from making a purchase in such security that results in a new Exchange high for the day at the time of the specialist's transaction, and (2) a specialist with a short position in a security would be prohibited from making a sale in such security, including securities subject to the Regulation SHO Pilot,[22] that results in a new Exchange low for the day at the time of the specialist's transaction. However, the specialist would be permitted to effect such a transaction in order to match another market's better bid or offer or to bring the price of the security into parity with an underlying or related security or asset.

C. Other Changes

The Exchange proposes to delete current NYSE Rule 104.10(9). This rule states that if a specialist has sell orders on the limit order book (''Book'') at two or more different prices, the specialist should not, as a dealer, purchase all of the stock from the Book at the lowest limit price and then immediately purchase stock from the Book at a higher limit price. This rule currently requires the specialist to cross the entire amount of stock he or she is purchasing at one price. The same principle applies when a specialist sells to orders on the Book.

The Exchange also proposes to make conforming changes such as re-numbering certain provisions and other non-substantive language changes. For example, current NYSE Rule 104.10(6)(i)(D) which governs the ability of the crowd to prevent the specialist, when liquidating or decreasing a position, from trading on parity with the crowd during a manual transaction has been re-numbered NYSE Rule 104.10(5)(i)(a)(I)(d). NYSE Rules 70 and 123 have been amended to reflect this provision's new rule number.

D. Description of Amendment No. 1

In Amendment No. 1, the Exchange proposes to clarify that the transactions discussed in proposed NYSE Rule 104.10(5)(i)(b)(I) regarding transactions by a specialist for the specialist's account to establish or increase a position apply to transactions that reach across the market to trade with the Exchange bid or offer.

In addition, in the original filing, the Exchange proposed to rescind NYSE Rule 104.10(7), which provides that the requirement to obtain Floor Official approval for transactions for a specialist's own account contained in NYSE Rule 104.10 does not apply to transactions effected in ETFs when the specialist transactions are for the purpose of bringing the ETF into parity with the underlying index value. Amendment No. 1 proposes to retain NYSE Rule 104.10(7) and include that the provisions therein should not apply to streetTRACKS® Gold Shares, as the term is defined in NYSE Rule 1300 or Currency Trust Shares, as the term is defined in NYSE Rule 1301A.

In Amendment No. 1, the Exchange further requests that the Commission re-interpret the specialist's negative obligation to eliminate the requirement that each trade by the specialist for the dealer account meet a test of reasonable necessity. The Exchange believes that such an interpretation is appropriate in view of the development of the national market system over the past seventy years since the interpretation was initially issued.

According to the Exchange, the Commission has been granted specific authority by Congress to reinterpret the negative obligation. Specifically, in 1975, in connection with the 1975 amendments [23] to the Act, Congress eliminated the negative obligation clause from Section 11(b) of the Act and gave the Commission the flexibility to define dealer obligations for both exchange members and over-the-counter market makers. In making the changes,

[18] *See* proposed NYSE Rule 104.10(6)(iv)(a).

[19] *See* proposed NYSE Rule 104.10(6)(iv)(c)(I) and (II).

[20] The current requirements under NYSE Rule 104.10(5)(i) and NYSE Rule 104.10(6)(i) are reflected in proposed NYSE Rule 104.10(5)(i)(b)(I). *See also* Amendment No. 1.

[21] Proposed NYSE Rule 104.10(5)(i)(c).

[22] 17 CFR 240.202T.

[23] Securities Acts Amendments of 1975 (''1975 Amendments''), Pub. L. No. 94–29, 89 Stat. 97 (June 4, 1975).

Congress noted that changes in the marketplace might warrant changes in the scope of the dealer obligation.[24]

In Amendment No. 1, the Exchange stated that it believes that the conditions for change that were identified by Congress have largely come to pass and that, as a result, it is appropriate to redefine the scope of the specialist's negative obligation. For example, the Exchange argued that the institutionalization of the market, increased competition, and increased application of computer and communication technology has significantly diminished the time-and-place advantages of specialists. As a result, markets have seen increases in the average daily trading volume and the movement off the Floor of the decision making that affects the direction and extent of movements in the specialty stocks. The Exchange stated that there has also been a dramatic increase in transparency with respect to the specialist's Book through, among other things, Exchange initiatives like Exchange OPENBOOK.™ The Exchange stated that it believes that this increased transparency gives all market participants, both on and off the Floor, a greater ability to see and react to market changes.

The Exchange stated that there has also been a significant increase in competition in Exchange-listed securities. For example, unlike in previous years, Exchange specialists must now compete with upstairs liquidity providers and with multiple over-the-counter dealers, crossing networks and Alternative Trading Systems. As a result of unlisted trading privileges (''UTP'') and dual listings, the Exchange stated that specialists also face competition from other national and regional exchanges. For all of these reasons, the Exchange stated that it believes that it is appropriate for the Commission to reinterpret the negative obligation away from an emphasis on trade-by-trade necessity, and toward a more general evaluation of the reasonable necessity of trading activity in specialty securities for the dealer account.

The Exchange stated that NYSER has appropriate surveillance procedures in place to surveil for compliance with the negative obligation by specialists. For example, NYSER would monitor, on a patterns and practices basis, specialist activity that appears to cause or exacerbate an excessive price movement in the market, as such transactions would appear to be in violation of a specialist's negative obligation. Additionally, the Division of Market Surveillance of NYSER would monitor for all subsequent action taken by the specialist, or lack thereof, to cushion such price movement. As today, the Exchange would, in the context of price volatility alerts, monitor for excessive price movements that may involve a failure to comply with either the affirmative or negative obligation. The Exchange represented that, as it gains experience with its new market structure, it would enhance existing surveillances and/or create new surveillances where necessary and appropriate to monitor for compliance with the specialist negative obligation.

III. Comments

Commission received five comment letters from one commenter[25] and two letters from the Exchange responding to the commenter.[26] The commenter opposed NYSE's proposal. The commenter argued that the negative obligation and current stabilization rules support public order interaction and that the Exchange's proposal would result in the displacement of public orders by specialists. The commenter argued that, as a result, NYSE's proposal is inconsistent with Section 11A of the Act, which promotes the opportunity for investors' orders to be executed without the participation of a dealer.

A. Stabilization Rules

The commenter argued that NYSE's proposal to amend its Rule 104.10 to allow specialists to trade in a destabilizing manner was a ''de facto abandonment of the specialist's historic mandate to stabilize the market by trading counter to the price trend.''[27]

The commenter stated that the specialist's role is, in essence, to act as the ''trader of last resort'' and expressed concern that the proposed changes to the Exchange's stabilization rules allowing specialists to trade for their own account in instances in which they are currently not permitted would displace public orders that would otherwise be capable of execution.[28] The commenter argued that specialists would be unconstrained by whether a particular trade is ''necessary'' or not and whether the trade had an impact on the market's price direction.[29] The commenter argued that NYSE's proposal provides specialists with proprietary trading privileges that are unrelated to the specialist's market making function.[30]

The commenter stated that active stocks, in particular, trade well in terms of depth and liquidity without unnecessary dealer intervention. He also noted that the stocks in which specialists are least needed are the stocks in which they would be allowed to most freely effect non-stabilizing transactions. The commenter further argued that the maintenance of the stabilization requirements for inactive stocks is meaningless because they rarely, if ever, trade.

In addition, the commenter believed that the proposed PPPs would be ineffective in regulating specialists and, in fact, would allow a specialist to increase profits by trading on the opposite side of the market from its previous trade.[31] In the commenter's opinion, specialists would act as risk adverse intra-day ''flip traders'' who do not seek to hold positions. The Exchange disagreed with the commenter, and stated that it believed that its specialists would continue to assume risk by committing capital to cushion market volatility when other market participants are trading with the trend and destabilizing the price of the security.[32] The Exchange believed that, in order for specialists to continue in this role, they must have the appropriate tools to compete.

The Exchange argued that specialists are increasingly unable to compete in a tick-based rules environment given the significant changes in competitive forces, customer expectations, technology, and automation that have impacted the NYSE market in recent years and reduced the specialist's ability to direct or influence trading or control the quote. Notwithstanding the changes in the market place, NYSE's specialists will continue in the Hybrid Market to be required to commit capital and add liquidity in order to bridge gaps in supply and demand, reduce volatility,

[24] S. Rep. No. 94–75, at 100 (1975) (''It might well be that with active competition among market makers and the elimination of trading advantages specialists now enjoy, such a restriction on specialists' dealings would become unnecessary. Because trading patterns and market making behavior in the context of a national market system cannot now be predicted, it appears appropriate to expand the Commission's rulemaking authority in this area so that the Commission may define responsibilities and restrict activities of specialists in response to changing market conditions.'').

[25] *See supra* note 4.

[26] *See supra* note 5.

[27] *See* Rutherfurd Letter II. The commenter described NYSE's proposal as permitting ''direct and unnecessary specialist intervention in determining market price direction,'' which the commenter argued cannot serve the public interest, and would have an adverse impact on many public investor trading strategies.

[28] *Id.*

[29] *Id.*

[30] *See* Rutherfurd Letter IV.

[31] *See*Rutherfurd Letter II.

[32] *See*NYSE Letter I, *supra* note 5, at 9.

and encourage stable prices.[33] The Exchange believed that the current tick-based rules were ''appropriate for and worked well in a market where substantially all trading was conducted manually, at a pace that enabled individuals to discern 'tick' changes easily and which tolerated the time it took to call a Floor Official into the Crowd to approve a specialist's proposed destabilizing transaction.'' [34] The Exchange argued, however, that the current rules hinder the specialists from operating in the Hybrid Market, where trading is substantially electronic and the speed and frequency of executions and quote changes preclude individuals from being able to accurately track ''ticks'' or stop trading to allow for Floor Official involvement.[35] The Exchange, therefore, believes that keeping the current tick-based rule would be inconsistent with Section 11A(a)(i)(C)(ii) of the Act, which promotes fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets.

The Exchange also disagreed with the commenter's suggestion that specialists have a monopoly on algorithmic trading or have access to electronic trading that creates an ''unlevel competitive playing field.'' [36] The Exchange argued that its rules do not prevent market participants from employing algorithmic-based trading strategies in connection with round-lot trading and stated that, in fact, customers benefit from the use of e-Quotes and d-Quotes via their floor brokers and can create or purchase their own algorithmic systems to generate orders that can be entered via NYSE SuperDot®.[37] The Exchange stated that the Hybrid Market provides all market participants with the ability to trade electronically and that all orders entered on the Exchange would be executed, consistent with their instructions, in accordance with Exchange rules. The Exchange represented that no class of customers would be advantaged or disadvantaged by these rules because all market participants are afforded an opportunity to interact with published trading interest.[38]

While the Exchange acknowledged that specialists occupy a unique position in relation to other market participants, the Exchange disagreed with the commenter that specialists continue to enjoy a time and place advantage.[39] It noted that, for example, last sale prices and quotations are immediately available to all market participants and that the growth of internalization has allowed ''upstairs'' trading firms to have comparable informational advantages as the specialists but the firms are able to trade on their information instantaneously without restrictions.[40] Also, NYSE argued that, while the specialists' algorithms have a slight informational advantage by having knowledge of orders as they enter NYSE systems, such knowledge does not deny other market participants an opportunity to interact with incoming orders. NYSE further notes that specialists' algorithmic ability to trade with incoming marketable orders is limited to providing price improvement or matching a better price posted by another market center. These trading opportunities are subject to competition by floor brokers who have a similar opportunity to interact with incoming orders via d-Quotes.[41] NYSE also noted that marketable CAP–DI orders automatically convert and trade along with specialist principal transactions.[42] Accordingly, the Exchange argued that specialists' algorithms do not act as an impediment to competition among market participants. The Exchange, therefore, believes that the Stabilization Proposal and the amended interpretation of the negative obligations of specialists present an appropriately flexible approach that will allow specialists to continue to add value to the marketplace.

Moreover, the Exchange argued that the current marketplace is dominated by professional traders—program traders, hedge funds, day traders, and institutions—employing algorithmic trading and smart order routers.[43] Unlike in the past, NYSE specialists must now compete with upstairs liquidity providers, with multiple over-the-counter dealers, crossing networks, and ECNs, as well as with NYSE floor brokers empowered with new, more effective, electronic order types.[44] These market participants have the ability to trade on alternative systems while actively participating in trading on the Exchange. The Exchange stated that, unlike the Exchange specialists, none of these market participants have similar restrictions on their trading.

B. Negative Obligation

The commenter argued that the transaction-by-transaction approach to determining the reasonable necessity of a specialist's proprietary trade is the only consistent interpretation of the negative obligation. According to the commenter, the negative obligation limits a specialist's ability to trade to those situations when there is a disparity in supply and demand and the specialist is needed to ensure appropriate trade-to-trade price continuity. In these situations, the commenter argued that the specialist is not restricted by the negative obligation and, in fact, is required to trade pursuant to the affirmative obligation. The commenter argued that supply and demand assessments arise in each particular trade, and thus the trade-by-trade approach should be maintained in its current form.[45] The commenter believed that NYSE's proposal to reinterpret the negative obligation so that specialist trading is surveilled on a ''patterns and practices,'' rather than on a trade-by-trade basis, effectively results in a *de facto* rescission of the negative obligation.[46] The commenter disagreed with the Exchange's assertions that specialists' trading privileges have been reduced, and that increased competition and automation support a new interpretation of the negative obligation. The commenter believed that specialists will enjoy a time and place advantage in the Hybrid Market ''far in excess of any that the specialist may have enjoyed in the physical auction.'' [47] For example, the commenter stated that the specialist alone has knowledge of floor broker hidden public orders and can trade algorithmically to take advantage of material, non-public market information. For this reason, the commenter believed that the negative obligation in its current form will still be relevant and should be maintained. The NYSE responded that the specialists do not have the time and place advantage they once possessed. The Exchange argued that the dissemination of the consolidated quote and trade information and NYSE limit orders via OpenBook provide all investors with market information.[48] In

[33] *Id.*

[34] *Id. at 3–4.*

[35] *Id.* at 4.

[36] *Id.* at 11 (referencing Rutherfurd Letter II); *see also* Rutherfurd Letter III.

[37] *See* NYSE Letter I, *supra* note 5, at 11.

[38] *Id.*

[39] *Id.* at 8.

[40] *Id.*

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] The commenter also argued that NYSE should propose to amend its Rule 104 and petition the Commission to amend Rule 11b–1 under the Act so that the rule text would clearly express NYSE's proposal.

[46] *See* Rutherfurd Letters I, II, III, IV, and V.

[47] *See* Rutherfurd Letters II and V.

[48] *See* NYSE Letter II, at 2.

addition, NYSE argued that the expansion of Direct+® and technology available to floor brokers have diminished the size and significance of the Crowd, and allows orders to be entered and executed at the best bid (offer) without human intervention.[49] Further, the Exchange noted that quoting in pennies had reduced concentration of volume and average trade size.[50] Finally, NYSE stated that the national market system order routing requirements have resulted in orders being executed on markets other than the market on which they were entered.[51]

The commenter also challenged the Exchange's arguments based on the legislative history of Section 11(b) of the Act.[52] The commenter stated that NYSE ''continues to be the dominant, primary market in its stocks by a huge measure'' and believed that the Exchange's competitive position is much stronger today than it was in 1975, when Congress and the Commission declined to act on specialists' negative obligations.[53] The NYSE disagreed with the commenter's argument. NYSE stated that competition has increased and that competition has, consequently, effected its market share.[54] NYSE argued that increased internalization, the existence of alternative trading venues, and the ability of floor brokers to compete directly with specialists has resulted in increased competition to the specialist.[55]

The commenter also expressed concern about how the negative obligations would be measured and enforced. Further, the commenter believed that, even in a fast-moving Hybrid Market, a specialist's algorithm could easily be programmed to conform to the current trade-by-trade negative obligation requirements. The commenter stated that NYSE's proposal to surveil compliance with the negative obligation on a patterns or practices basis is vague and questioned the effectiveness of looking at whether specialist trading causes or exacerbates excessive price movements. The commenter argued that a ''specialist cannot know whether subsequent trades that may be part of a 'pattern' are necessary because subsequent order flow will dictate pricing, market direction, and, on a case-by-case basis, whether specialist intervention is appropriate as to any particular trade.'' [56] According to the commenter, the ''problem with commingling 'necessity' and 'pattern' is that the broad pattern may arguably be okay if there is no unusual price movement, but many individual trades within the pattern may not be 'necessary' at all. * * *'' [57] In addition, the commenter believed that the ''patterns and practices'' surveillance standard was flawed in that each specialist would establish his or her own such standard, which the commenter believed could lead a specialist to trade more aggressively. The commenter also questioned NYSE's plan to monitor price movements as part of its surveillance of the negative obligation, because such examinations had historically been performed to measure the specialist's compliance with the affirmative obligation by looking at whether a specialist had failed to trade to counter the market trend.

The Exchange believes that the trade-by-trade interpretation established seventy years ago no longer addresses the realities of the modern market. The Exchange emphasized that it is not proposing to eliminate the negative obligation or its reasonable necessity test. The Exchange noted that it is, instead, proposing to reinterpret the negative obligation's reasonable necessity test to eliminate the requirement that each trade must meet the test of reasonable necessity.

The Exchange disagreed with the commenter's suggestion that a non-trade-by-trade approach is unworkable, and will ultimately lead to customer disadvantage because specialists would engage in ''in and out profit taking that interferes with direct public interaction.'' [58] The Exchange argued that such a pattern of trading would continue to violate the specialist's negative obligation, and that its revised approach will provide an appropriate regulatory check on specialists.[59]

C. Public Notice

The commenter argued that the proposed rule change, as amended by Amendment No. 1 regarding the reinterpretation of the negative obligation of specialists, should be republished and the public comment period should be reset.[60] In addition, the commenter urged the Commission to consider the proposal at a public hearing.[61]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the proposed rule change as modified by Amendment No. 1, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File No. SR–NYSE–2006–76 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2006–76. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of NYSE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2006–76 and should be submitted on or before December 29, 2006.

[49] *Id.* at 3.

[50] *Id.*

[51] *Id.*

[52] *See* Rutherfurd Letter II (referring to NYSE's excerpt of a Senate Report in SR–NYSE–2006–82: ''It might well be that with active competition among market makers and the elimination of trading advantages specialists now enjoy, such a restriction on specialists' dealings would become unnecessary.'' S. Rep. No. 94–75, at 100 (1975)).

[53] *Id. See also* Rutherfurd Letters III and V.

[54] *See* NYSE Letter II, at 2

[55] *Id.* at 3.

[56] *See* Rutherfurd Letter II.

[57] *Id.*

[58] *See* NYSE Letter I, *supra* note 5, at 10 (citing Rutherfurd Letter II).

[59] *Id.*

[60] *See* Rutherfurd Letters I, II, III, IV, and V.

[61] *See* Rutherfurd Letters I, II, and III.

V. Discussion and Commission Findings

After careful consideration, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange[62] and, in particular, the requirements of Section 6 of the Act.[63] Specifically, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[64] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, and processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Finally, the Commission believes that the proposal is consistent with the principles set forth in Section 11A of the Act and the requirements of Rule 11b–1 under the Act.[65]

Specialists' dealer activities are governed, in part, by the negative and affirmative trading obligations. Rule 11b–1 under the Act requires exchanges that permit members to register as specialists to have rules governing specialists' dealer transactions so that their proprietary trades conform to the negative and affirmative obligations. The negative obligation as set forth in Rule 11b–1 under the Act requires that a specialist's dealings be restricted, so far as practicable, to those reasonably necessary to permit the specialist to maintain a fair and orderly market.[66] The affirmative obligation as set forth in Rule 11b–1 under the Act requires a specialist to engage in a course of dealings for its own account to assist in the maintenance, so far as practicable, of a fair and orderly market.[67] NYSE has adopted these obligations in its Rule 104.[68]

When debating the adoption of the Act, Congress considered barring the ability of exchange members to trade for their own accounts.[69] Instead, pursuant to Section 11(e) of the Act, Congress directed the Commission to make a study of the feasibility and advisability of the completely segregating the functions of brokers and dealers.[70] In 1935, soon after the adoption of the Act, the Commission recommended that the national securities exchanges adopt sixteen rules to regulate trading on exchanges in order to eliminate some of the undesirable consequences of dealer activities.[71] These rules were adopted by all the exchanges. The tenth rule (''Tenth Rule'') prohibited specialists from effecting purchases or sales for their registered securities unless such dealings were reasonably necessary to permit specialists to maintain a fair and orderly market.[72]

''This rule * * * represents an attempt to eliminate the dealer activities of specialists except insofar as such activities allegedly perform a useful service to the market. In view of the specialist's fiduciary obligation to buyers and sellers whose orders he has accepted for execution; in view of his special knowledge and superior bargaining power in trading for his own account; in view of his peculiar opportunities and motives for attracting public interest to the stock in which he specializes; and in view of the undesirable effect which his trading may exert upon the market; it was deemed essential by the Commission that the dealer functions of the specialist be subjected to stringent control. The rule was intended to allow him only sufficient latitude in his personal trading to enable him to maintain a fair and orderly market in the securities in which he is registered.''[73]

In 1937, the Commission issued an interpretation (''Saperstein Interpretation'') to clarify various aspects of the Tenth Rule, which the exchanges believed to be unnecessary because of other, more general rules regarding specialists that the exchanges had already adopted.[74] In the interpretation, the Commission emphasized that ''a mere showing that a transaction by a specialist for his own account had no undesirable effect, or even no discernible effect, upon the market'' was not enough to evidence compliance with the rule.[75] The Saperstein Interpretation stated that the ''rule leaves no doubt that it prohibits all transactions for the account of a specialist, excepting only such transactions as are properly a part of a course of dealings reasonably necessary to permit the specialist to maintain a fair and orderly market * * *''[76] The Saperstein Interpretation thereafter stated that *each transaction* by a specialist for his own account must meet the test of reasonable necessity.[77] The interpretation made clear that a specialist would be required to comply with the rule on a transaction-by-transaction basis.

The Saperstein Interpretation also provided the basis for some of the current stabilization rules. Specifically, in the Interpretation, the Commission noted that certain transactions effected by a specialist when increasing or establishing a position tend to have a detrimental effect on the market and therefore would be commonly unjustifiable. These transactions included: (1) A purchase above the last sale price; (2) the purchase of all or substantially all the stock offered on the book at the last sale price; (3) the supplying of all or substantially all the stock bid for on the book at the last sale price; and (4) transactions that clean up the market in a manner that is similar to cleaning up the book. The Saperstein Interpretation noted that these transactions may be justifiable ''but only when they are an essential part of a course of dealings designed to promote the continuity and stability of the market and effected in an orderly manner.''[78]

NYSE has proposed to amend its rules that restrict the ability of specialists to

---

[62] In approving this proposed rule change, as amended, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[63] 15 U.S.C. 78f.

[64] 15 U.S.C. 78f(b)(5).

[65] 17 CFR 240.11b–1.

[66] 17 CFR 240.11b–1(a)(2)(iii).

[67] 17 CFR 240.11b–1(a)(2)(ii).

[68] NYSE Rule 104(a) reflects NYSE's adoption of the negative obligation and states that ''no specialist shall effect on the Exchange purchases or sales of any security in which such specialist is registered, for any account in which he or his member organization * * * is directly or indirectly interested, unless such dealings are reasonably necessary to permit such specialist to maintain a fair and orderly market * * *''

[69] Report of the Committee on Banking and Currency, Stock Exchange Practices, S. Rep. No. 1455 (1934), reprinted in 5 J.S. Ellenberger and Ellen P. Mahar, Legislative History of the Securities Act of 1933 and Securities Exchange Act of 1934 (2001), at 19–30.

[70] Commission, Report on the Feasibility and Advisability of the Complete Segregation of the Functions of Dealer and Broker (June 20, 1936) (''Segregation Study'').

[71] The text of the recommended rules can be found at Appendix O–1 of the Segregation Study. *See also* Segregation Study at 60–64 for a summary of the rules.

[72] The Tenth Rule stated: ''No specialist shall effect on the exchange purchases or sales of any security in which such specialist is registered, for any account in which he, or the firm of which he is a partner, or any partner of such firm, is directly or indirectly interested, unless such dealings are reasonably necessary to permit such specialist to maintain a fair and orderly market, or to act as an odd-lot dealer in such security.'' *See* Segregation Study Appendix O–1 at 169. *See also* NYSE Rule 104(a).

[73] *Id.* at 63.

[74] Securities Exchange Act Release No. 1117, 1937 SEC LEXIS 357 (March 30, 1937). The Saperstein Interpretation took the form of an interpretation by David Saperstein, then-Director of the Commission's Trading and Exchange Division, and was contained in a letter sent to the Presidents of the various exchanges having a specialist system, including NYSE and a predecessor to the American Stock Exchange.

[75] Saperstein Interpretation at 3–4.

[76] *Id.* at 4.

[77] *Id.*

[78] *Id.* at 5.

trade with the trend of the market. NYSE has also asked the Commission to reinterpret the negative obligation to eliminate the requirement that *each* trade be measured against the reasonable necessity test. NYSE believes that specialists are an integral part of its market structure and that they perform important functions in the marketplace. NYSE believes that specialists will continue to contribute vitally to the Hybrid Market by committing capital and adding liquidity in order to bridge gaps in supply and demand, which can help to keep the market fair and orderly and reduce volatility. However, NYSE argues that with the anticipated increase in the volume of orders and speed of market activity as a result of the Hybrid Market and the implementation of Regulation NMS, its current rules restricting the ability of specialists to trade for their own account based upon the tick in relation to the last sale on the Exchange, as set forth in NYSE Rules 104.10(5) and (6), are both unworkable and less relevant in determining whether a specialist's trading is consistent with the negative obligation. Instead, NYSE believes these rules may in fact hinder specialists' ability to maintain fair and orderly markets in the Hybrid environment.

In addition, NYSE argues that the time and place and informational advantages traditionally enjoyed by specialists have been diminished. Prior to the Hybrid Market, the majority of orders that were executed on the Exchange were handled by the specialist. Specialists would have unique knowledge at the point of sale as to the extent of interest available in the market for execution. Under the Hybrid Market, all investors have access to the depth of the NYSE Book and will be able to access NYSE liquidity without the involvement of a specialist. Floor brokers and their customers also will be able to interact with incoming orders directly without the involvement of the specialist. This increased transparency and access gives all market participants, both on and off the floor, a greater ability to see and react to market changes.

The Commission believes that these combined factors significantly change the market in which the NYSE specialist operates and justifies a new approach to regulating specialists' dealer trades so that they will be able to effectively perform their obligation to maintain a fair and orderly market. The Commission notes that specialists remain constrained by the negative obligation and that their proprietary trading must be limited to that reasonably necessary to maintain a fair and orderly market. Therefore, for the reasons discussed below, the Commission believes that NYSE's proposal to amend its stabilization rules is consistent with the Act. In addition, the Commission has decided to reinterpret the negative obligation to remove the obligation to measure each individual specialist trade against the test of reasonable necessity.

A. Negative Obligation

In Amendment No. 1, the Exchange requested that the Commission reinterpret the reasonable necessity test found in the negative obligation to eliminate the trade-by-trade analysis that measures whether a specialist's proprietary trade is consistent with the negative obligation. As noted above, the negative obligation as set forth in Rule 11b–1 under the Act requires that a specialist's dealings be restricted, so far as practicable, to those reasonably necessary to permit the specialist to maintain a fair and orderly market.[79]

The commenter argued that the trade-by-trade requirement of the Saperstein Interpretation was the only consistent reading of reasonable necessity test. In addition, the commenter believed that, in the Hybrid Market, specialists will not experience a reduction in their advantages, but rather would enjoy advantages far in excess of those available to them in the floor-based auction environment.[80] NYSE disagrees with the commenter's assertion and argues that specialists do not have the informational advantages they once possessed. Specifically, NYSE argues that market information is ''ubiquitous, readily available to all market participants as a result of consolidated quote and trade streams'' and OpenBook.[81] NYSE also argued that ''the expansion of NYSE Direct+® and technology available to floor brokers has diminished the size and significance of the Crowd and enables orders entered into the Exchange system to execute at the best bid and offer without the need for human intervention.'' [82]

The Commission agrees with NYSE that the national market system has changed greatly in the nearly seventy years since the Saperstein Interpretation was issued. The Commission believes that the trade-by-trade standard that was established seventy years ago is unworkable in the current market environment. The high speed and volume of trading in today's market make impracticable a trade-by-trade determination by the specialist of whether a particular trade is reasonably necessary. Further, the Commission believes that the informational advantages that specialists once enjoyed have been diminished.

The Commission believes that eliminating the trade-by-trade standard with respect to the negative obligation should enhance the specialist's ability to fulfill its obligation to maintain a fair and orderly market. The Commission believes that increased automation and competition—both within the Hybrid Market and in the markets generally—are significant factors, among others, that affect the ability of specialists to make a trade-by-trade analysis regarding their negative obligations. The Commission finds that permitting specialists to consider the reasonable necessity of their transactions under the negative obligation without a transaction-by-transaction test, is appropriate and consistent with the Act.[83] The Commission emphasizes that it is not eliminating the negative obligation. Therefore, specialists must continue to assess their need to trade and limit their proprietary trades to those reasonably necessary to allow the specialist to maintain a fair and orderly market.

The commenter expressed concern that eliminating the trade-by-trade test could lead to more aggressive trading by specialists. The Commission notes that the new interpretation does not relieve specialists of their obligations under federal securities laws or NYSE Rules. A specialist's ability to effect proprietary transactions remains limited under the Act and NYSE Rules and a specialist must still determine whether their transactions are reasonably necessary. The Commission notes that the Exchange is obligated to surveil its specialists to ensure their compliance with the Act and the Exchange's Rules, and the Exchange has represented that it will conduct surveillance of specialist

[79] 17 CFR 240.11b–1(a)(2)(iii).

[80] The Commission notes that the commenter's assertion that specialists have the exclusive ability to trade with incoming marketable orders is incorrect. Floor brokers are permitted to execute against incoming marketable orders via d-Quotes. *See* NYSE Rule 70.25(b)(i). In addition, the commenter asserted that specialists have access to floor broker agency interest data. This statement is likewise inaccurate. Specialists' algorithms will not have access to such data. *See* NYSE Rule 104(c)(ii). Further, a floor broker may exclude its interest from aggregate floor broker interest that is disclosed to the specialist on the floor. *See* Rule 70.20(g).

[81] *See* NYSE Letter II, *supra* note 5.

[82] *Id.*

[83] The commenter believed that this ''reinterpretation'' of the Saperstein Interpretation should be done through a change to the text of NYSE Rules. The Commission believes this to be unnecessary, as the original Saperstein Interpretation, was communicated through a letter from then-Director Saperstein to the presidents of the various exchanges.

trading for compliance with the negative obligation.

B. Stabilization Rules

NYSE proposes to amend its rules that specifically restrict certain specialist transactions that are effected with the trend of the market. As noted above, these rules supplement the negative obligation.

1. Neutral Transactions

NYSE proposes to allow a specialist to liquidate or reduce a position regardless of the tick and without the need to receive Floor Official approval. Currently, NYSE rules are less restrictive regarding liquidating trades because these transactions do not create as great a potential conflict of interest for specialists. For example, if a specialist wanted to inappropriately influence the trend of the market in a security in which the specialist held a position, that specialist would have an incentive to increase the value of his or her position in the security by inflating the price. When liquidating a position, the specialist would not have a comparable incentive to cause the price to move downward. Importantly, however, specialists' liquidating trades remain subject to the negative obligation and, therefore, specialists remain constrained by reasonable necessity when engaging in liquidating transactions. Therefore, the Commission finds that it is consistent with the Act for NYSE to eliminate the need for specialists to obtain Floor Official approval when liquidating or reducing a position.

2. Non-Conditional Transactions

NYSE proposed to allow a specialist to increase or establish a position in transactions other than transactions that reach across the market to trade with the Exchange bid or offer, without the need for Floor Official approval and regardless of the tick. The Commission believes that these Non-Conditional Transactions do not create a significant potential conflict of interest for specialists. Non-Conditional Transactions reflect instances where an independent source establishes the price of the transaction, thereby addressing concerns that a specialist may be ''leading the market.'' In addition, the proposed rule would allow specialists to buy at the published bid or sell at the published offer without Floor Official approval. While in this circumstance the specialist may establish the bid/offer, the trade itself is initiated by other market participants and not the specialist.

NYSE argues that requiring Floor Official approval is impractical in the Hybrid Market, where trading is substantially electronic and the speed and frequency of executions and quote changes preclude specialists from being able to accurately track ticks or stop trading to allow for Floor Official involvement. The Commission also believes that the proposal to remove specific restrictions on Non-Conditional Transactions could enhance the specialist's ability to maintain fair and orderly markets. Finally, the Commission notes that Non-Conditional Transactions remain subject to the negative obligation. Accordingly, the Commission believes the proposed rule change regarding Non-Conditional Transactions is consistent with the Act.

3. Prohibited Transactions

NYSE has proposed to prohibit certain transactions during the last ten minutes of the trading day. The Commission finds that the proposed rules for Prohibited Transactions are consistent with the Act because they restrict trades that may inappropriately influence the price of a security to advantage a specialist's proprietary position. The Commission also believes exempting specialist transactions that match another market's better bid or offer or that bring the price of the security into parity with an underlying or related security asset is appropriate because in these situations, an independent party, not the specialist, has set the price.

4. Conditional Transactions in Active Securities

NYSE proposes to allow specialists to trade with the NYSE quote without the need for Floor Official approval and regardless of the tick when increasing or establishing a position in certain Active Securities.[84] As proposed, NYSE specialists will remain subject to the negative obligation and will be required to appropriately reenter the market after a Conditional Trade is executed. NYSE will issue guidelines known as PPPs to provide specialists with a price at which they should reenter. For certain Conditional Trades, specialist reentry must immediately follow the Conditional Trade.

The Commission believes that the provisions governing Conditional Transactions in Active Securities may reflect an appropriate balance between the needs of specialists and other market participants in today's fast moving markets. The Commission recognizes the potential conflicts of interest presented when a specialist engages in aggressive trading activity such as reaching across the market to trade with the NYSE Quote while increasing its position. The concern is lessened with Active Securities, however, because the specialist likely will be less able to unilaterally cause a price movement. Accordingly, the Commission is approving this proposed provision on a pilot basis until June 30, 2007. Before the Commission decides whether to extend the operation of this rule or to approve this rule on a permanent basis, NYSE must provide data and analysis on the impact of this rule change.

Specifically, during the Pilot, NYSE must provide to the Commission on a regular, ongoing basis, statistics relating to market quality and specialist trading activity under the Pilot. These statistics should include general market quality measures, in addition to specific measures aggregated up from a trade-by-trade analysis of market activity and specialist activity during periods immediately following a specialist's Conditional Trade. After the initiation of the Pilot, NYSE must continue to work with Commission staff to ensure that these statistics are sufficiently informative to allow NYSE and the Commission to evaluate (i) the degree to which the trading activity of specialists under the Pilot affects execution quality for orders arriving on the same side of the market immediately after Conditional Trades, (ii) whether specialist Conditional Trades tend to be immediately followed by market price movements in the same direction as the specialist Conditional Trades, and (iii) the extent to which specialists provide liquidity on the opposite side of the market immediately after a Conditional Trade. These statistics should reflect all relevant aspects of the specialist trading and quoting activity immediately following Conditional Trades, including the frequency and speed of re-entry, the re-entry price relative to the take-out price, and the size of the re-entry quote relative to the size taken.

The Commission recognizes that the national market system is changing in considerable ways. Technological advancements and market forces, as well as regulatory changes such as the

[84] Transactions that increase or establish a specialist's position in securities that do not satisfy the definition of Active Security would remain subject to the current NYSE rule, which requires that a specialist receive Floor Official approval before executing a transaction on a destabilizing tick. *See* proposed NYSE Rule 104.10(5)(i)(b). NYSE has proposed some clarifying changes to the rule text of this provision and the Commission finds that these changes better reflect the operation of this rule and therefore are consistent with the Act.

Commission's Regulation NMS, have spurred trading centers to become even more automated, with trading volume and intermarket competition expected to continue to increase. Although it is difficult to forecast at this time the precise effect of such changes on the Exchange generally and specialists in particular, the Commission believes that the Exchange has made a case for modifying the rules relating to Conditional Transactions in Active Securities in anticipation of such changes. At the same time, the Commission recognizes that the proposed rule change represents a significant shift in the roles and obligations of specialists at the Exchange. Therefore, the Commission has required that, for Conditional Transactions, the Exchange implement this proposed rule change only for Active Securities and only as a Pilot.

5. Other Changes

The Commission finds that the proposal to delete current NYSE Rule 104.10(9) is appropriate because it is no longer applicable given the proposed changes to the stabilization rules as described above. In addition, the Commission also believes that the deletion of section (9) is consistent with the proposed re-definition of a Sweep Transaction [85] and notes that NYSE Rule 104.10(6)(c)(III) makes clear that each specialist trade at a separate price in a Sweep is viewed as a transaction with the published bid or offer for the purposes of the transactions that require immediate re-entry pursuant to proposed NYSE Rule 104.10(6)(iv)(c).

Further, the Commission believes that retaining NYSE Rule 104.10(7) and including streetTRACKS® Gold Shares (as defined in NYSE Rule 1300) and Currency Trust Shares (as defined in NYSE Rule 1301A) are appropriate because these are derivative products in which there is limited risk for the specialist to assert price control.

C. Accelerated Approval of Amendment No. 1

The Commission finds good cause to approve Amendment No. 1 to the proposed rule change prior to the thirtieth day after Amendment No. 1 is published for comment in the **Federal Register** pursuant to Section 19(b)(2) of the Act.[86] The commenter requested that the Commission publish the Exchange's proposal as amended in Amendment No. 1 for public comment. The Commission has authority under Section 19(b)(2) of the Act to approve the proposed rule change prior to the thirtieth day after it is published for comment.[87] The Commission notes that the Exchange's request that the Commission issue a new interpretation of the negative obligation described in Amendment No. 1 was published for a 21-day comment period in an earlier proposed rule change.[88] In that order, the Commission specifically requested comment on NYSE's request to reinterpret the negative obligation. The Commission received comment letters from the commenter himself in response to that request, which were fully considered by the Commission. Therefore, the Commission believes that the public has had appropriate notice of the Exchange's request to re-interpret the negative obligation of specialists.

The remaining modifications in Amendment No. 1 were clarifications and/or technical corrections to the originally proposed rule change. For these reasons, the Commission believes that good cause exists to accelerate approval of the proposed rule change as amended by Amendment No. 1.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[89] that the proposed rule change (File No. SR–NYSE–2006–76), as modified by Amendment No. 1, be, and hereby is, approved, on an accelerated basis and the Pilot is approved on a temporary basis until June 30, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[90]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E6–20886 Filed 12–7–06; 8:45 am]

BILLING CODE 8011–01–P

[85] *See* Securities Exchange Act Release No. 54820 (November 27, 2006).

[86] 15 U.S.C 78s(b)(2).

[87] *Id.*

[88] *See* Securities Exchange Act Release No. 54578 (October 5, 2006), 71 FR 60216 (October 12, 2006). *See also* Securities Exchange Act Release No. 54685 (November 1, 2006), 71 FR 65559 (November 8, 2006).

[89] 15 U.S.C. 78s(b)(2).

[90] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 5635]

Bureau of Near Eastern Affairs; Notice of New Information Collection Under Emergency Review: Iran Democracy Program Grants Vetting; Form DS–4100, OMB Control Number 1405–xxxx

AGENCY: Department of State, Bureau of Near Eastern Affairs.

ACTION: Notice of request for Emergency OMB approval.

SUMMARY: The Department of State has submitted the following new information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the emergency review procedures of the Paperwork Reduction Act of 1995.

Type of Request: Emergency Review.

Originating Office: Bureau of Near Eastern Affairs, Middle East Partnership Initiative.

Title of Information Collection: Iran Democracy Program Grants Vetting.

Frequency: On occasion.

Form Number: DS–4100.

Respondents: Potential Grantees for Iran Democracy Program.

Estimated Number of Respondents: 200.

Average Hours per Response: 1 hour per response.

Total Estimated Burden: 200 hours.

The proposed information collection is published to obtain comments from the public and affected agencies. Emergency review and approval of this collection has been requested from OMB by December 8, 2006. If granted, the emergency approval is only valid for 180 days. Comments should be directed to Katherine Astrich, State Department Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20530, who may be reached on 202–395–4718.

During the first 60 days of this same period a regular review of this information collection is also being undertaken. Comments are encouraged and will be accepted until 60 days from the date that this notice is published in the **Federal Register**. The agency requests written comments and suggestions from the public and affected agencies concerning the proposed collection of information. Your comments are being solicited to permit the agency to:

• 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, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including

through the use of automated collection techniques or other forms of technology.

For Additional Information: Requests for additional information, regarding the collection listed in this notice should be directed to David Denehy, Bureau of Near Eastern Affairs, U.S. Department of State, Washington, DC 20520, who may be reached on 202–647–2519, or via e-mail at *DenehyDM@state.gov*.

Abstract of Proposed Collection:

A critical component of the Administration's Iran policy is the support for indigenous Iranian voices calling for freedom. President Bush himself has pledged this support and the State Department has made the awarding of grants for this purpose a key component of its Iran policy. As a condition of licensing these activities, the Office of Foreign Assets Control (OFAC) has requested the Department of State to follow certain procedures to effectuate the goals of Sections 481(b), 531(a), 571, 582, and 635(b) of the Foreign Assistance Act of 1961 (as amended); 18 U.S.C. §§ 2339A and 2339B; Executive Order 13224; and Homeland Security Presidential Directive 6. These licensing conditions mandate that the Department conduct a vetting of potential Iran democracy grantees and sub-grantees for counter-terrorism purposes. To conduct this vetting the Department envisions collecting information from grantees and sub-grantees regarding the identity and background of their key employees and Boards of Directors.

Methodology: The State Department (Bureau of Near Eastern Affairs, Bureau of Democracy Human Rights and Labor, and Bureau of Educational and Cultural Affairs) will collect this information via electronic submission.

Dated: December 4, 2006.

David M. Denehy,

Senior Advisor, Bureau of Near Eastern Affairs, Department of State.

[FR Doc. E6–20917 Filed 12–7–06; 8:45 am]

BILLING CODE 4710–31–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

[Docket Nos. OST–2006–26266, FHWA–2006–26270, FTA–2006–26269, RITA–2006–26271]

Applications for Urban Partnership Agreements as Part of Congestion Initiative

AGENCIES: Office of the Secretary of Transportation (''OST''), Federal Highway Administration (''FHWA''), Federal Transit Administration (''FTA''), Research and Innovative Technology Administration (''RITA'')

ACTION: Notice of solicitation for applications to enter into urban partnership agreements with the U.S. Department of Transportation.

SUMMARY: In May 2006, the U.S. Department of Transportation (the ''Department'') announced its *National Strategy to Reduce Congestion on America's Transportation Network* (the ''Congestion Initiative''), a bold and comprehensive national program to reduce congestion on the Nation's roads, rails, runways, and waterways. One major component of the Congestion Initiative is the Urban Partnership Agreement (''UPA''). The purpose of this Notice is to solicit proposals by metropolitan areas to enter into UPAs with the Department in order to demonstrate strategies with a combined track record of effectiveness in reducing traffic congestion. To support congestion-reducing strategies adopted by the Department's urban partners (''Urban Partners''), the Department expects to utilize discretionary funding available under the Department's Intelligent Transportation System Operational Testing to Mitigate Congestion Program (the ''ITS–OTMC Program''), its Value Pricing Pilot Program (the ''VPP Program''), and other discretionary grant, lending and credit support programs administered by the Department. In addition, to the maximum extent possible, the Department will support its Urban Partners with regulatory flexibility and dedicated expertise and personnel.

This Notice is the first of three solicitations to be issued by the Department in connection with the Congestion Initiative. *See below* **SUPPLEMENTARY INFORMATION**: Coordination with Other Congestion Initiative Solicitations.''

The Department reserves the right to solicit, and is actively soliciting, by means other than this Notice, certain metropolitan areas that the Department has determined, on a preliminary basis, to be candidates for UPAs. Neither the procedures nor the criteria set forth in this Notice shall be binding on the Department.

DATES: Applicants wishing to become Urban Partners must submit their application on or before April 30, 2007. Applicants wishing to become Urban Partners who intend to apply for funding under the VPP and ITS–OTMC Programs must submit separate applications to the VPP and ITS–OTMC Programs on or before April 30, 2007, in accordance with the requests for proposals for those programs to be published by the Department in the **Federal Register** this month. *See* **SUPPLEMENTARY INFORMATION**: Coordination with Other Congestion Initiative Solicitations.'' Late-filed applications for designation as an Urban Partner and for funding under the VPP and ITS–OTMC Programs will be considered to the extent practical.

ADDRESSES: Applicants wishing to become Urban Partners may send three copies of their application by U.S. Post or express mail to: Thomas M. McNamara, Office of the Assistant Secretary for Transportation Policy, U.S. Department of Transportation, Room 10305 (P–20), 400 7th Street, SW., Washington, DC 20590. Alternatively, applicants may file applications via e-mail to Thomas M. McNamara at *thomas.mcnamara@dot.gov*.

Only applications received via U.S. Post, express mail or e-mail, in each case as provided above, shall be deemed properly filed.

FOR FURTHER INFORMATION CONTACT: Please address questions concerning this Notice to David B. Horner, Esq., Chief Counsel, Federal Transit Administration, U.S. Department of Transportation, via e-mail at *david.horner@dot.gov*. Please address technical questions concerning project development to either Thomas M. McNamara at 202–366–4462 (or by e-mail at *thomas.mcnamara@dot.gov*) or Patrick DeCorla-Souza at 202–366–4076 (or by e-mail at *patrick.decorla-souza@dot.gov*).

SUPPLEMENTARY INFORMATION:

A. Background

Crisis of Congestion. Traffic congestion affects virtually every aspect of peoples' lives—where people live, where they work, where they shop, and how much they pay for goods and services. According to 2003 figures, in certain metropolitan areas the average rush hour driver loses as many as 93 hours per year to travel delay—equivalent to more than two weeks of work, amounting annually to a virtual ''congestion tax'' as high as $1,598 per traveler in wasted time and fuel.[1] Nationwide, congestion imposes costs on the economy of over $65 billion per year,[2] a figure that has more than doubled since 1993, and that would be even higher if it accounted for the

[1] Texas Transportation Institute (''TTI''), 2005 Urban Mobility Report, May 2005 (*http://tti.tamu.edu/documents/mobility_report_2005.pdf*), Tables 1 and 2.

[2] TTI, 2005 Urban Mobility Report, p. 1.

significant cost of unreliability to drivers and businesses, the environmental impacts of idle-related auto emissions, or increased gasoline prices.

Traffic congestion also has a substantial negative impact upon the quality of life of many American families. In a 2005 survey, for example, 52% of Northern Virginia commuters reported that their travel times to work had increased in the past year,[3] leading 70% of working parents to report having insufficient time to spend with their children and 63% of respondents to report having insufficient time to spend with their spouses.[4] Nationally, in a 2005 survey conducted by the National League of Cities, 35% of U.S. citizens reported traffic congestion as the most deteriorated living condition in their city over the past five years; 85% responded that traffic congestion was as bad or worse than the previous year.[5] Similarly, in a 2001 survey conducted by the U.S. Conference of Mayors, 79% of Americans from 10 metropolitan areas reported that congestion has worsened over the past five years; 50% believe it has become ''much worse.'' [6]

The Urban Partnership Agreement. In May 2006, the Department announced its National Strategy to Reduce Congestion on America's Transportation Network (the ''Congestion Initiative''), a bold and comprehensive national program to reduce congestion on the nation's roads, rails, runways, and waterways. One major component of the Congestion Initiative is the Urban Partnership Agreement (''UPA''), through which the Department plans to partner with certain metropolitan areas or ''Urban Partners'' in order to demonstrate strategies with proven effectiveness in reducing traffic congestion. Under UPAs, the Department and its Urban Partners would agree to pursue four strategies with a combined track record of effectiveness in reducing traffic congestion, known as the ''Four Ts:''

1. *Tolling:* Implementing a broad congestion pricing or variable toll demonstration;

2. *Transit:* Creating or expanding express bus services, bus rapid transit (''BRT'') or other innovative commuter transit services, which would benefit from the free-flow traffic conditions generated by pricing;

3. *Telecommuting:* Securing agreements from major area employers to establish or expand telecommuting and flex scheduling programs; and

4. *Technology & operations:* Utilizing cutting edge technological and operational approaches to improve transportation system performance.

In return for their commitment to adopt innovative, system-wide solutions to traffic congestion, the Department, to the maximum extent possible, would support its Urban Partners with the Department's financial resources (including a combination of grants, loans, and borrowing authority), regulatory flexibility and dedicated expertise and personnel.

Congestion Pricing. The most innovative—and often misunderstood—component of the UPA is congestion pricing. Congestion pricing leverages the principles of supply and demand to manage traffic. It does this by charging drivers a user fee that varies by traffic volumes or time of day, thus managing highway resources in a manner that promotes free-flow traffic conditions on highways at all times. Congestion pricing achieves free-flow conditions by shifting purely discretionary rush hour highway travel to other transportation modes or to off-peak periods, taking advantage of the fact that many rush hour drivers on a typical urban highway are not commuters. By removing a fraction of the vehicles from a congested rush hour roadway, pricing enables the system to flow much more efficiently, allowing more cars to move through the same physical space. Similar variable charges have been successfully utilized in other industries (airline tickets, cell phone rates, and electricity, for example), and there is a consensus among economists that congestion pricing represents the single most viable approach to reducing traffic congestion.

Congestion pricing benefits drivers and businesses by reducing delays and stress, increasing the predictability of trip times, and allowing for more deliveries per hour. It benefits mass transit by improving transit speeds and the reliability of transit service, increasing transit ridership, and lowering costs for transit providers. It benefits State and local government by improving the quality of transportation services without tax increases or large capital expenditures, providing additional revenues for funding transportation, retaining businesses and expanding the tax base. It saves lives by shortening incident response times for emergency responders. And it benefits society as a whole by reducing fuel consumption and vehicle emissions, allowing for more efficient land use decisions, reducing housing market distortions, and expanding opportunities for civic participation.

Congestion pricing is no longer simply a theory; it has demonstrated positive results both here in the U.S. and around the world. Successful American applications of congestion pricing include California's SR–91 between Anaheim and Riverside, portions of I–15 outside of San Diego, and Express Lanes on I–394 between downtown Minneapolis and the western suburbs, all of which have enabled congestion-free rush hour commuting and proven popular with drivers of all income levels. Internationally, congestion pricing has yielded dramatic reductions in traffic congestion and increases in travel speeds in Singapore, London, and Stockholm. Notably, a small reduction in vehicles can yield dramatic improvements in traffic, as demonstrated by a British study, which projected that a 9% drop in traffic could yield a 52% drop in congestion delay.[7] This same dynamic plays out in metropolitan areas every August, as family vacations lead to a minor decrease in rush hour drivers, which substantially reduces area traffic congestion.

Transit. Another critical congestion-reducing strategy to be incorporated into UPAs is increasing the quality and capacity of peak-period transit service in order to offer a more attractive alternative to automobile travel and to accommodate peak-period commuters who elect to switch to transit in response to the imposition of congestion pricing.

Congestion pricing and public transportation convey mutual benefits-road pricing benefits public transportation by improving transit speeds and the reliability of transit service, increasing transit ridership, lowering costs per rider for transit providers, and expanding the source of revenue that may be used for transit, while public transportation benefits road pricing by absorbing commuters who shift their travel from automobile to bus or rail. By replacing congested traffic with free-flowing conditions on major routes, congestion pricing will improve the speed and productivity of current express bus services, making them more attractive to commuters while reducing their operating costs. Reducing congestion will also facilitate rapid deployment of innovative, high-performance BRT operations in major

[3] Northern Virginia Transportation Alliance 2005 Survey (*http://www.nvta.org/content.asp?contentid=1774*).

[4] Virginia Department of Transportation.

[5] National League of Cities survey of cities (2005).

[6] U.S. Conference of Mayors survey on traffic congestion (2001).

[7] Department of Transport, U.K., Feasibility Study of Road Pricing in the U.K.: A Report to the Secretary of State for Transport, Road Price Steering Group, Chapter 4, Figure 3.

corridors, which require only modest investments in new vehicles and passenger facilities that may be eligible for financial support through the Department's various funding mechanisms. Improving the performance and variety of peak-period transit commuting options through a combination of congestion pricing and limited capital investment will provide significant benefits to current transit riders, while improving transit's effectiveness in reducing peak-period auto travel and providing the expanded passenger-carrying capacity necessary to accommodate shifts to transit commuting induced by the imposition of congestion pricing.

Telecommuting. The third critical congestion-reducing strategy for Urban Partners to adopt is promoting increased use of telecommuting and flexible work scheduling, in order to reduce peak-period commuting and shift some commuting travel to ''shoulder'' or off-peak hours. Telecommuting can eliminate some peak-period commuting travel by using computer and electronic communications technology to enable certain employees to work from their homes or nearby telecommuting centers on predetermined (often regularly scheduled) workdays, or in some cases on a full-time basis. Flexible work schedules allow employees to shift their commute trips from the peak period to less congested hours. The most promising means to achieve these objectives is for public officials representing Urban Partners to secure agreements from major employers in their metropolitan areas to establish or expand telecommuting programs, and to offer flexible work schedules to the maximum number of their employees. The Department and local transportation planning agencies can offer technical and logistical support to employers for designing, implementing, and monitoring the effectiveness of telecommuting programs and flexible work scheduling.

Technology. Technology makes possible congestion pricing, which differs from traditional tolling in two material respects: (1) Instead of charging a fixed fee, congestion pricing manages traffic by charging drivers a user fee that varies by traffic volumes or time of day, thus balancing supply and demand; and (2) unlike traditional tolling, congestion fees are collected electronically at highway speeds. With variable pricing, technology affords highway managers the flexibility of setting user fees by time of day or ''dynamically''—by increasing or decreasing fees depending on traffic volumes to maximize throughput and the free flow of traffic. Technology facilitates this variability by enabling the collection of user fees at highway speeds through the use of transponders, Global Positioning Systems (''GPS''), or cameras. With transponders, or ''tags,'' tolls may be collected as vehicles pass under overhead antennae. With GPS technology, like that used on Germany's autobahns, an in-vehicle device records charges based on the vehicle's location, and periodically uploads a summary of charges to a processing center along with payments. And with cameras, highway managers can record the identity of vehicles that are not equipped with a transponder or GPS unit.

In addition, technological advancements may enhance the quality of transit service deployed to reduce urban congestion. These technology-based improvements may include lane-keeping devices or longitudinal control designed to enhance spatial efficiency on existing highways, precision docking, signal priority systems for buses, contactless fare collection, real-time travel information (bus arrival times, schedules, etc.), advanced traveler information systems, parking alerts and automatic vehicle locator systems.

Other technological innovations that may help reduce congestion include:

- *Telecommuting* technology, including high-speed wireless internet service to allow download of large files, called ''WiMax.''
- *Traffic management* technology, including adaptive traffic signal control systems and the use of cameras to provide real-time information to first responders that will help them determine what equipment they will need before they arrive at the site of an accident or incident.
- *Advanced traveler information systems* that include web or wireless access to route-specific travel time and toll information; route planning assistance using historical records of congestion by time of day; and communications technologies that gather traffic- and incident-related data from a few vehicles traveling on a roadway and then publish that information to drivers via mobile phones, in-car units or dynamic message signs.

B. Funding Urban Partnership Agreements

The Department proposes to support UPAs with some or all of the resources listed below. Please note, however, that the Department does not intend for UPAs to replace the VPP or ITS–OTMC Programs; instead, applicants wishing to become Urban Partners who intend to pursue grants, loans or credit support under the programs below should apply separately to such programs on or before April 30, 2007. With respect to the ITS–OTMC and VPP Programs, the Department will publish separate requests for proposals in the **Federal Register** this month. *See below* **SUPPLEMENTARY INFORMATION** Coordination with Other Congestion Initiative Solicitations.''

1. *Intelligent Transportation Systems Funding:* Since enactment of the Intermodal Surface Transportation Efficiency Act of 1991 (''ISTEA''), the Department has been administering the Intelligent Transportation Systems (''ITS'') Program. In its discretion, the Department may provide Urban Partnerships up to $100 million of ITS research and development funds over three years through the ITS–OTMC Program to be established by the Department as part of the ITS Program. The Department may also continue or modify existing or currently proposed programs or initiatives under the ITS Program to support the Department's Urban Partners.

A primary objective of the ITS Program has been the development and operational testing of systems and strategies to reduce congestion in urban areas. As a result, the program has focused considerable attention on the development of various products oriented towards congestion mitigation, such as electronic toll collection, advanced real-time adaptive traffic signals, transit signal priority systems, innovative surveillance systems, improved incident detection and response systems, advanced transit management systems, and multi-modal traveler information systems. These and other congestion-mitigation strategies have been shown to be very effective in improving overall traffic operations and reducing congestion. In reauthorizing the ITS Program, section 5306 of the recently-enacted Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (''SAFETEA–LU'') requires the Department to continue to invest in technologies and systems that can aid in reducing congestion by five percent by 2010. Given the increasing demand on the Nation's surface transportation system, this ambitious goal will require bold, innovative approaches. Projects the Department will consider for funding through the ITS-OTMC Program would incorporate strategies comprised of the ''Four Ts.'' Such projects could also include: Advanced traffic signal control, innovative incident detection and management strategies, integrated

corridor management, real-time traveler information, parking management tied to transit service, innovative traveler information services, managed lanes, ramp control, technology enhanced bus rapid transit systems, freight management, or other innovative and aggressive technology-based congestion mitigation strategies.

2. *Value Pricing Pilot Program Grants:* Since the enactment of ISTEA, the Department has also been administering the VPP Program, a specific congestion-related deployment and evaluation program, formerly known as the Congestion Pricing Pilot Program. The VPP Program provides grants and tolling authority to up to 15 States or other jurisdictions. It provides crucial support for pre-implementation and implementation activities aimed at demonstrating how pricing improves transportation services, specifically for highway and transit related travel. The Department may award a significant portion of the discretionary funding available under the VPP Program to support its Urban Partners.

3. *Small Starts Funding:* The Small Starts program administered by the Federal Transit Administration (''FTA'') provides up to $75 million per project for qualifying transit projects, with a focus on less-capital intensive projects such as bus rapid transit. In its recently issued guidance on Small Starts, the Department noted that because congestion is one of the Nation's most daunting transportation challenges, FTA will facilitate worthy projects that are a significant element of a comprehensive congestion reduction strategy, especially when such projects incorporate pricing strategies. Final funding decisions are made by Congress in response to recommendations by FTA. Projects sponsored by the Department's Urban Partners would be candidates for Small Starts funding.

4. *Private Activity Bonds:* The Department has the authority to issue Private Activity Bonds to qualifying projects, lowering the cost of capital required to construct transportation facilities. The overall program allows for the issuance of up to $15 billion in bonds, some of which could be applied toward projects sponsored by the Department's Urban Partners.

5. *TIFIA Loans and Credit Assistance:* The Department's program administered under the Transportation Infrastructure Finance and Innovation Act (''TIFIA'') can issue direct loans, loan guarantees, and standby lines of credit to qualifying projects. The overall program allows for the support of approximately $10 billion in credit assistance, some of which could be applied toward projects sponsored by the Department's Urban Partners.

6. *Other Assistance.* The Department may also provide its Urban Partners with the authority to institute tolls on portions of their respective Interstate systems [8] and expedite project delivery by waiving certain FHWA regulations (in accordance with FHWA's Special Experimental Project (or ''SEP–15'') program or as otherwise permitted by law), and placing key projects on the Environmental Stewardship Executive Order, allowing for the streamlining of some aspects of the environmental review process. Finally, the Department may offer extensive technical expertise and advice from world class engineers and economists.

Please note that designation as an Urban Partner does not, by itself, qualify a party for any grant or funding amount. However, Urban Partners will receive preferential treatment under the ITS–OTMC and VPP Programs in accordance with their terms and certain other discretionary programs administered by the Department. An Urban Partner will also receive the commitment of the Department's leadership to work directly with the Urban Partner in solving its congestion problems.

C. Coordination With Other Congestion Initiative Solicitations

This solicitation is one of three related solicitations being issued by the Department in connection with the Congestion Initiative. To be published separately in the **Federal Register** this month, the other two solicitations are:

1. *Solicitation for the VPP Program.* The VPP Program, as reauthorized in SAFETEA–LU, supports implementation of a variety of pricing-based approaches for managing congestion on highways. The forthcoming solicitation for the VPP Program will align the program with the Congestion Initiative to support metropolitan areas in implementing broad congestion pricing strategies in the near term.

2. *Solicitation for the Intelligent Transportation System Operational Testing to Mitigate Congestion Program.* The ITS Research and Development program, as reauthorized in SAFETEA–LU, supports the research, development and testing of ITS for a variety of purposes. The forthcoming solicitation for the ITS–OTMC Program will support the operational testing and evaluation of advanced technologies to reduce metropolitan congestion.

Please note: If an applicant wishing to become an Urban Partner intends to apply for funding under both the VPP and ITS–OTMC Programs, the applicant must apply to each program by submitting to each program identical copies of a single application that is responsive to both programs' requests for proposals. The Department will publish both programs' requests for proposals in the **Federal Register** this month.

D. Preliminary Urban Partner Designation; Urban Partner Designation

Step One. Applications to become Urban Partners must be submitted on or before April 30, 2007 (with late-filed applications being considered to the extent practical). *See below* **SUPPLEMENTARY INFORMATION**: ''Contents of UPA Application'' for instructions concerning the content of applications to become an Urban Partner.

Step Two. The Department will designate certain applicants as Preliminary Urban Partners on or before June 8, 2007. The Department expects to select up to 10 Preliminary Urban Partners. Please note that designation as a Preliminary Urban Partner does not, by itself, qualify a party for any grant or funding amount. However, it will qualify the designee to continue discussions with the Department to become an Urban Partner.

Step Three. The Department will work towards selecting Urban Partners by continuing discussions with its Preliminary Urban Partners to determine whether an Urban Partnership is feasible.

Step Four. Following negotiations, the Department will announce its Urban Partners by August 8, 2007, along with funding decisions under the VPP and ITS–OTMC Programs. Please note that designation as an Urban Partner does not, by itself, qualify a party for any

[8] As enacted by SAFETEA–LU, the High Occupancy Vehicle (''HOV'') Facilities Program (23 U.S.C. 166) allows States and localities to convert HOV lanes to high occupancy toll (''HOT'') lanes which allow low-occupant vehicle users to pay for the chance to travel on underutilized HOV lanes, shifting traffic from congested regular lanes to HOV lanes, while maintaining free-flowing travel speeds and vehicle throughput performance for all vehicles on the HOV lanes. When operated in parallel with general purpose lanes, HOT lanes offer drivers an option to pay for congestion-free predictable trips when they need it the most, while improving the performance of general purpose lanes. In coordination with 23 U.S.C. 166, FTA has recently published proposed guidance that, once adopted as final, would eliminate certain existing disincentives to jurisdictions to convert their HOV lanes to HOT lanes. In particular the proposed guidance describes the terms and conditions on which FTA would classify HOV lanes that are converted to HOT lanes as ''fixed guideway miles'' for purposes of the transit funding formulas administered by FTA. See ''Policy Statement on When High-Occupancy Vehicle Lanes Converted to High-Occupancy/Toll Lanes Shall Be Classified as Fixed Guideway Miles for FTA's Funding Formulas and When HOT Lanes Shall Not Be Classified as Fixed Guideway Miles for FTA's Funding Formulas'' (*http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/E6-14796.pdf*).

grant or funding amount. However, the designation will afford Urban Partners preferential treatment under certain of the Department's discretionary grant funding programs, such as the ITS–OTMC and VPP Programs, in accordance with their terms. Designation as an Urban Partner will also provide the designee with the commitment of the Department's leadership to work directly with the Urban Partner in solving its congestion problems.

Step Five. The Department will sign UPAs as soon as possible after selecting its Urban Partners. The Department expects implementation or pre-implementation efforts for the proposed congestion reduction activities to commence shortly after the UPA is signed.

Signatories to UPAs may include city and county governments, metropolitan planning organizations, State transportation departments, chambers of commerce, academic institutions, citizen advisory groups, or other responsible organizations that seek to resolve major congestion problems (any of whom may apply to become an Urban Partner).

E. Contents of UPA Application

An application to become an Urban Partner should briefly describe, with respect to the metropolitan area proposed, (i) Why its traffic congestion is severe, (ii) the local public's acknowledgement of the problem, (iii) the readiness of area's political leadership to solve the problem and (iv) a solution to congestion that incorporates the Four Ts. In addition, an application should be responsive to the specifications and criteria set forth below. The Department recognizes that information provided in an application to become an Urban Partner may be preliminary and incomplete. If the Department selects an applicant to be a Preliminary Urban Partner, the Department may ask the Preliminary Urban Partner to supplement the data in its application to the extent practical.

1. *Length of Applications:* An application should not exceed 25 pages in length, including both the proposal details and appendix materials. Appendix materials may include maps of roadways and other affected facilities (such as bridges and parallel routes), maps of BRT routes and other transit services or facilities that are directly involved and a list of possible local employers that might endorse new or expanded telecommuting and flextime policies for its employees.

2. *Participating Parties:* An application should provide a preliminary, non-binding list of the parties likely to participate in the Urban Partnership.

3. *Comprehensive Congestion Reduction Strategy:* An application should generally describe the metropolitan area's proposed comprehensive congestion reduction strategy, and explain how different parts of that strategy, if any, would interact to reduce congestion.

4. *Congestion Pricing Measures and Affected Areas:* An application should describe the role pricing would play in the congestion reduction strategy. To the extent practical, an application should indicate, in specific terms, how traffic would be affected, what areas or routes would be priced, how congestion prices would be determined, and which vehicle categories would be affected (*e.g.*, single occupant vehicles or all vehicles). If the proposed congestion pricing configuration contemplates a cordon pricing system, then the application should specify the approximate area (*e.g.*, 10 square miles surrounded by certain highways or natural boundaries).

5. *Transit Services:* An application should describe transit services, including BRT and other commuter transit services that are to be provided or supplemented, and the expected impacts of the expanded transit services on congestion. The application should also describe transit fare pricing policies to be adopted with the objective of increasing traveler throughput during peak traffic periods, while avoiding excessive congestion in the transit system.

6. *Telecommuting:* An application should indicate telecommuting, flex-time, and various related employer-employee policies to be adopted, including likely employer participants and the number and location of employees affected. These proposed non-pricing demand management activities need not be limited to telecommuting or flex-time schedules, and they may include activities like parking cash-outs or other suitable incentives that seek to reduce peak-hour, drive-alone travel.

7. *Expedited Project Completion:* An application should indicate any major transportation projects or project components that are sought to be expedited through an UPA. The application should also indicate the expected effects on congestion from early completion of these projects.

8. *Travelers Affected Daily:* An application should indicate the estimated number of daily travelers that will be directly affected by priced facilities and by other measures expected to be adopted by the Urban Partner. This should include the estimated number of persons (vehicles) that will pay congestion charges, as well as the likely number diverted to other travel times, routes, or other transportation services, such as transit. Similarly, if telecommuting is to be adopted, the application should indicate the estimated number of daily employee participants.

9. *Use of Technology:* An application should clearly indicate the extent to which a locality plans to operationally test innovative technology in achieving its congestion reduction targets.

10. *Research, Planning, and Experience To Date:* An application should indicate the prior work that participating parties (*e.g.*, the candidate city or other jurisdictions) have already done to reduce congestion, including research, planning, and actual implementation of congestion related activities in the metropolitan area.

11. *Other Time-Frame Considerations:* An application should indicate the dates during which applicants expect to conduct congestion reduction activities (*e.g.*, a seven-month trial from June 1, 2008 until December 31, 2008). If the applicant expects the activities to continue indefinitely, the application should indicate this fact. Similarly, if the pricing activity is adopted on a temporary, experimental basis and the applicant expects it to be voted on by citizens of the jurisdictions participating in an Urban Partnership or otherwise considered for continuation, the application should provide this information.

12. *Funding Support:* An application should indicate the estimated cost to implement the overall congestion reduction strategy. An application should also indicate the anticipated sources of those funds, including the amount requested to be covered by Federal sources.

13. *Contact Information:* An application should clearly indicate contact information, including name, organization, address, phone number, and e-mail address. The Department will use this information to inform parties of the Department's decision regarding selection of interested parties, as well as to contact parties in the event that the Department needs additional information about an application.

F. Consideration of Applications

The Department will review and consider applications upon receipt. The Department will consider a variety of factors in reviewing applications seeking designations an Urban Partner, including whether proposals:

- Are likely to be successfully implemented;
- Affect the most daily surface transportation travelers;
- Produce the greatest potential reduction in overall traffic congestion;
- Provide the greatest congestion-reduction benefits per dollar of Federal support;
- Provide the most cost-effective means of reducing traffic congestion; and
- Demonstrate innovative and potentially far-reaching technology applications.

This Notice is not the sole means by which the Department is soliciting candidates for UPAs. The Department reserves the right to solicit, and is actively soliciting, by means other than this Notice, certain metropolitan areas that the Department has determined, on a preliminary basis, to be candidates for UPAs. Neither the procedures nor the criteria set forth in this Notice shall be binding on the Department.

Issued On: November 7, 2006.

Maria Cino,

Deputy Secretary.

[FR Doc. E6–20924 Filed 12–7–06; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Availability of Draft Advisory Circulars, Other Policy Documents and Proposed Technical Standard Orders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: This is a recurring Notice of Availability, and request for comments, on draft advisory circulars (ACs), other policy documents, and proposed technical standard orders (TSOs) currently offered by Aviation Safety.

SUMMARY: The FAA's Aviation Safety, an organization responsible for the certification, production approval, and continued airworthiness of aircraft, and certification of pilots, mechanics, and others in safety related positions, publishes proposed non-regulatory documents that are available for public comment on the Internet at *http://www.faa.gov/aircraft/draft_docs/*.

DATES: We must receive comments on or before the due date for each document as specified on the Web site.

ADDRESSES: Sent comments on proposed documents to the Federal Aviation Administration at the address specified on the Web site for the document being commented on, to the attention of the individual and office identified as point of contact for the document.

FOR FURTHER INFORMATION CONTACT: See the individual or FAA office identified on the Web site for the specified document.

SUPPLEMENTARY INFORMATION: Final advisory circulars, other policy documents, and technical standard orders (TSOs) are available on FAA's Web site, including final documents published by the Aircraft Certification Service on FAA's Regulatory and Guidance Library (RGL) at *http://rgl.faa.gov/*.

Comments Invited

When commenting on draft ACs, other policy documents or proposed TSOs, you should identify the document by its number. The Aviation Safety organization, will consider all comments received on or before the closing date before issuing a final document. You can obtain a paper copy of the draft document or proposed TSO by contacting the individual or FAA office responsible for the document as identified on the Web site. You will find the draft ACs, other policy documents and proposed TSOs on the ''Aviation Safety Draft Documents Open for Comment'' Web site at *http://www.faa.gov/aircraft/draft_docs/*. For Internet retrieval assistance, contact the AIR Internet Content Program Manager at 202–267–8361.

Background

We do not publish an individual **Federal Register** Notice for each document we make available for public comment. On the Web site, you may subscribe to our service for e-mail notification when new draft documents are made available. Persons wishing to comment on our draft ACs, other policy documents and proposed TSOs can find them by using the FAA's Internet address listed above. This notice of availability and request for comments on documents produced by Aviation Safety will appear again in 30 days.

Issued in Washington, DC on December 4, 2006.

Terry Allen,

Acting Manager, Production and Airworthiness Division, Aircraft Certification Service.

[FR Doc. 06–9605 Filed 12–7–06; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2006–25652]

Agency Information Collection Activities; Request for Comments; Notice of Intent To Survey Motor Carriers Operating Small Passenger-Carrying Commercial Motor Vehicles

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

ACTION: Notice and request for comments.

SUMMARY: The FMCSA invites comments about its plan to request the Office of Management and Budget's (OMB) approval of a new information collection (IC). FMCSA intends to sponsor this new information collection by use of a research contractor to conduct a survey of motor carriers who operate small passenger-carrying commercial motor vehicles (CMVs). The data collected would assist FMCSA with outreach initiatives to these motor carriers of passengers, some of which will be brought within the scope of FMCSA safety regulation by recent statutory changes. This notice is required by the Paperwork Reduction Act of 1995.

DATES: Comments must be submitted on or before February 6, 2007.

ADDRESSES: All comments should reference Docket Number FMCSA–2006–25652. You may mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590; telefax comments to (202) 493–2251; or submit electronically at *http://dms.dot.gov.* You may examine and copy all comments received at the above address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. If you desire your comment to be acknowledged, you must include a self-addressed stamped envelope or postcard or, if you submit your comments electronically, you may print the acknowledgment.

FOR FURTHER INFORMATION CONTACT: Mr. Peter Chandler, Federal Motor Carrier Safety Administration, Office of Enforcement and Compliance, Commercial Passenger Carrier Safety Division, Washington, DC 20590, phone (202) 366–5763, fax (202) 366–3621, e-mail *peter.chandler@dot.gov.* Office hours are from 8 a.m. to 4 p.m., ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: On August 12, 2003, FMCSA published a final rule entitled, ''Safety Requirements for Operators of Small Passenger-Carrying Commercial Motor Vehicles Used in Interstate Commerce,'' to require motor carriers operating CMVs, designed or used to transport between 9 and 15 passengers (including the driver), in interstate commerce, to comply with parts 391 through 396 of the Federal Motor Carrier Safety Regulations (FMCSRs) when they are directly compensated for such services, and the vehicle is operated beyond a 75 air-mile radius from the driver's normal work-reporting location (*see* 68 FR 47860). As a result of the 2003 rule, these motor carriers are now subject to the same safety requirements as motor coach operators, except for the commercial driver's license (CDL), and controlled substances and alcohol testing regulations. Affected motor carriers were required to be in compliance with such regulations by December 10, 2003 (*see* 68 FR 61246). The 2003 rule implemented section 212 of the Motor Carrier Safety Improvement Act of 1999 (MCSIA) [Public Law 106–159, 113 Stat. 1748, 1766 (Dec. 9, 1999)].

Section 4136 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy For Users (SAFETEA-LU) [Public Law 109–59, 119 Stat. 1144, 1745 (Aug. 10, 2005)] directed FMCSA to remove the 75 air-mile radius standard. This congressional mandate would result in a greater number of motor carriers that operate small passenger-carrying CMVs being subject to the FMCSRs. To effectively inform this segment of the motor carrier passenger industry of the regulatory requirements that they will be subject to, and to assist the agency in administering an effective educational outreach program to this entire industry segment, FMCSA intends to conduct a survey to obtain information about all of these motor passenger carrier operations.

Because certain motor carriers that operate small passenger-carrying CMVs will have new regulatory requirements as a result of the section 4136 provision, FMCSA wants to learn about the safety and/or regulatory compliance challenges of this industry segment. There is no motor carrier industry association that is comprised mostly of commercial companies that primarily operate between 9–15 passenger-carrying commercial motor vehicles. This makes obtaining information about this industry segment more difficult and necessitates the assistance of a researcher to obtain information needed by FMCSA to effectively provide outreach to these passenger carriers. FMCSA will request a research contractor to obtain information about motor carriers with small passenger-carrying CMV operations. The research contractor will collect information through approximately 50 telephone interviews and 8 site visits at places of business. A copy of the telephone survey instrument has been placed in the docket for review and comments. Information obtained from the study will provide insight into the common safety and regulatory compliance challenges facing motor carriers with small passenger-carrying CMV operations. Such information will also be utilized by FMCSA to develop educational outreach initiatives for the affected industry segment. It is appropriate that FMCSA connect with and inform this segment of the motor carrier industry of its regulatory compliance responsibilities before implementing an enforcement program. Any information obtained will help identify specific areas of regulatory compliance that are problematic for this industry segment. In addition, the questions of the telephone survey instrument address safety issues that preliminary research shows are pertinent to motor carriers with small passenger-carrying CMV operations. Useful information about these safety issues could be included in outreach materials for the benefit of the industry. The survey will also obtain needed insight about how to best provide and distribute information to the affected industry segment.

Title: Survey of Motor Carriers with Small Passenger-Carrying CMV Operations.

Type of Information Collection Request: New one-time survey/information collection.

Respondents: For-hire motor carriers that operate between 9–15 passenger-carrying commercial motor vehicles in interstate commerce.

Number of Respondents: 50 motor carriers.

Estimated Average Burden per Response: The estimated average burden per response for each telephone survey is 30 minutes.

Estimated Total Annual Burden: The estimated total annual burden is 25 hours for the information collection based upon an acceptable level of statistical significance and a confidence interval of 13.6 percent.

Total Annual Burden: 25 hours [(50 responses × 30 minutes per response) / 60 minutes = 25 hours].

Frequency: This information collection will be a single, nonrecurring event.

Public Comments Invited

Interested parties are invited to send comments regarding any aspect of this information collection, including but not limited to: (1) The necessity and utility of the information collection for the proper performance of the functions of FMCSA and specifically the regulatory oversight of small passenger-carrying commercial motor vehicle operations; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB's clearance for this information collection. For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Issued on: November 28, 2006.

John H. Hill,

Administrator.

[FR Doc. E6–20830 Filed 12–7–06; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

BNSF Railway and Norfolk Southern Railway

[Docket Number FRA–2006–26435]

The BNSF Railway (BNSF) and Norfolk Southern Railway (NS), two Class I Railroads, request relief from certain provisions of Title 49 Code of Federal Regulations (CFR) Part 232 Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment and 49 CFR Part 229 Railroad Locomotive Safety Standards to begin implementation of

Electronically Controlled Pneumatic (ECP) brakes. The petition implicitly requests, as well, exemption from certain provisions of Chapter 204, Title 49, United States Code. The petitioners believe that implementation of ECP brakes requires a substantial capital investment, and relief from certain provisions of 49 CFR Part 232 will permit them to initiate pilot train operations. In addition, BNSF and NS believe that this relief will permit them to implement this pilot program on an expedited basis, allow FRA and the industry to identify definable savings with ECP brake equipped train operations, and evaluate changes to the CFR to accommodate these operations on a permanent basis.

BNSF and NS specifically request relief from the following subsections of 49 CFR Part 232: 232.207 Class IA Brake Test, 232.15(a)(7) Movement of defective equipment, 232.103 (d) and 232.103(g) General requirement for train braking system, 232.109 Dynamic brake requirements, 232.111(b)(3) and (4) Train handling information, 232.205 Class I brake test, 232.205(c)(3), (c)(4) and (c)(5), 232.209(a)(1) Class II brake inspection, 232.211 Class III brake inspection, 232.217(c)(3) Train brake tests conducted using yard air, 232.305 Single car airbrake tests, 232.505(e) Pre-revenue service acceptance testing plan, and elimination of all Subpart E—End of train devices. In addition, the petitioners request relief from the requirements to perform daily inspections for locomotives (49 CFR 229.21) in service on ECP brake equipped trains, performing only a trip inspection. Petitioners also represent that this requested relief should provide a framework for an expedited rulemaking by FRA which will encourage further investment in ECP brake technology throughout the railroad industry.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA anticipates scheduling a public hearing in connection with these proceedings in the near future, at a time and place yet to be determined, as the facts appear to warrant a hearing. Interested parties are advised that the petition appears to present issues that would require findings under 49 U.S.C. § 20306 (Exemption for technological improvements). The petitioners should be present at the hearing and prepared to support any required findings with evidence that any requirements of Chapter 204, title 49, United States Code, sought to be waived ''preclude the development or implementation of more efficient railroad transportation equipment or other transportation innovations under existing law.''

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number FRA–2006–26435) and must be submitted in triplicate to the Docket Clerk, DOT Central Docket Management Facility, Room Pl–401, Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at DOT Central Docket Management Facility, Room Pl–401 (Plaza Level), 400 Seventh Street, SW., Washington. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at *http://dms.dot.gov.*

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 19377–78). The statement may also be found at *http://dms.dot.gov.*

Issued in Washington, DC, on December 4, 2006.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. E6–20831 Filed 12–7–06; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[DOT Docket No. NHTSA–06–26554]

Reports, Forms, and Recordkeeping Requirements

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

ACTION: Request for public comment on proposed collection of information.

SUMMARY: This notice solicits public comment on continuation of the requirements for the collection of information on safety standards. Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections.

This document describes a collection of information associated with 49 CFR Part 574, Tire Identification and Recordkeeping.

DATES: Comments must be received on or before February 6, 2007.

ADDRESSES: Comments must refer to the docket notice number cited at the beginning of this notice and be submitted to Docket Management, Room PL–401, 400 Seventh St., SW., Washington, DC 20590. It is requested, but not required, that 2 copies of the comment be provided. The Docket Section is open on weekdays from 10 am to 5 pm except for Federal holidays.

FOR FURTHER INFORMATION CONTACT: Complete copies of each request for collection of information may be obtained from Mr. George Soodoo, NVS–122, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. Mr. Soodoo's telephone number is: (202) 366–5274.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before a proposed collection of information is submitted to OMB for approval, Federal agencies msut first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) 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;

(ii) 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;

(iii) How to enhance the quality, utility, and clarity of the information to be collected; and

(iv) How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks for public comment on the following proposed collection of information:

Title: 49 CFR Part 574, Tire Identification and Recordkeeping.

OMB Control Number: 2127–0050.

Form Number: None.

Requested Expiration Date of Approval: Three years from the approval date.

Type of Request: Extension of a currently approved collection.

Summary of the Collection of Information: 49 U.S.C. 30117(b) requires each tire manufacturer to collect and maintain records of the names and addresses of the first purchasers of new tires. To carry out this mandate, 49 CFR Part 574 requires tire dealers and distributors to record the names and addresses of retail purchasers of new tires and the identification number(s) of the tires sold. A specific form is provided to tire dealers and distributors by tire manufacturers for recording this information. The completed forms are returned to the tire manufacturers where they are to remain for three years after the date received by the manufacturer. Additionally, motor vehicle manufacturers are required to record the names and addresses of the first purchasers of new motor vehicles, together with the identification numbers of the tires on the new vehicles.

The Motor Vehicle Safety and Cost Savings Authorization Act of 1982 (P.L. 97–311) prohibited NHTSA from enforcing the mandatory tire registration provisions in 49 CFR Part 574 against dealers and distributors whose business is not owned or controlled by a tire manufacturer (hereinafter referred to as ''independent dealers''). For independent dealers, Congress specified that a voluntary registration system would take effect as soon as this agency specified the format and content of the voluntary tire registration forms and standardized the information for all independent dealers.

The previously specified mandatory tire registration requirements remain applicable to all dealers and distributors other than independent dealers and that the requirements for tire and vehicle manufacturers are unchanged.

Description of the Need for the Information and the Proposed Use of the Information: The information is used by a tire manufacturer, when it determines that some of its tires either fail to comply with an applicable safety standard or contain a safety related defect. With the information, the tire manufacturer can notify the first purchaser of the tire and provide the purchaser with any necessary information or instructions.

Description of the Likely Respondents (Including Estimated Number and Proposed Frequency of Response to the Collection of Information): It is estimated that this collection of information affects 10 million respondents annually. This group consists of approximately 8 tire manufacturers, 12,000 new tire dealers and distributors, and 10 million consumers who choose to register their tire purchasers with the tire manufacturers. A response is required by motor vehicle manufacturers upon each sale of a new vehicle and by non-independent tire dealers with each sale of a new tire. A consumer may elect to respond when purchasing a new tire from an independent dealer.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting from the Collection of Information: The estimated burden is as follows:

New tire dealers and distributors	12,000.
Consumers	10,000,000.
Total tire registrations (manually)	54,000,000.
Total registration hours (manual)	225,000 hours.
Recordkeeping hours (manual)	25,000 hours.
Total annual tire registration and recordkeeping hours	250,000 hours.

In addition, before this collection of information is approved, OMB has asked NHTSA to respond to the following questions:

1. Solicit public comment on how NHTSA can cost-effectively reduce the collection of information burden and enhance the practical utility of this information collection.

2. Estimate the percentage of individual purchasers of replacement tires for which contact information is maintained that is adequate to contact them, for two recent years of tire purchases. For comparison, similarly estimate the percentage of new vehicles for which there is adequate contact information maintained for tire recalls, for two recent years of vehicle purchases.

3. Provide each NHTSA evaluation of the success of procedures for keeping records on first purchasers of tires, under 49 U.S.C. 30117(b)(3), including ''the extent to which distributors and dealers have encouraged first purchasers of tires to register the tires'' and a ''detailed statement of the decision and an explanation of the reasons for the decision.'' Also, estimate the extent to which such mandated recordkeeping is or is not cost-effective.

4. Respond to the following: Does 49 CFR 574.7 specify a form to be used? Why is a form set in a final rule? If that form is actually required or offered, provide it to OMB. It should include a currently valid control number and the consequences of failure to provide a valid number. Include any such form in the notices—which should specify collecting information for tire recalls—and solicit comment on: (a) Whether that is an efficient and effective way to collect the information needed for recalls; (b) whether electronic or telephonic collection of information would be more efficient; and (c) generally, what form(s) of information collection would most efficiently and effectively encourage tire sellers and purchasers to provide recall information.

5. Determine whether or not, under 49 U.S.C. 3017(b) or otherwise, the DOT Secretary has the authority by rule or otherwise to allow electronic (*e.g.*, via the Internet) or telephonic collection—in lieu of paper-based collection—of the information pertinent to that provision. In the opinion of DOT/NHTSA can such information collection procedures change without a change in this rule? Please explain why or why not. If new rulemaking is needed, shouldn't that occur to better achieve the goals of both the authorizing statute and the PRA?

6. Clarify whether, under the statute and regulation, this collection of information is voluntary or mandatory for the tire dealer and similarly, for the tire purchaser.

7. Refer to the letter of July 18, 2003 from the NHTSA Chief Counsel to Ann Wilson of the Rubber Manufacturers Association. Kindly explain why telephone or electronic registration may be a supplement to the required mail-in form, but not in lieu of it Since burden is properly estimated by the actual time taken, not by whether any approach is voluntary or not, wouldn't registration that only supplements a paper form lead to additional burdens? At the same time

couldn't an alternative—not a supplementary—approach reduce total burden and be more effective?

8. Verify whether or not the statute and rule require the contact/registration information be kept for at least five years, not three years.

Comments on these issues raised by OMB are solicited. NHTSA will take these comments into consideration in its submission to OMB asking for an extension of OMB Clearance No. 2127–0050.

Authority: 44 U.S.C.3506(c); delegation of authority at 49 CFR 1.50.

Issued on: December 5, 2006.

H. Keith Brewer,

Director, Crash Avoidance Standards.

[FR Doc. E6–20936 Filed 12–7–06; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34938]

Stillwater Central Railroad—Trackage Rights Exemption—BNSF Railway Company

Pursuant to a written trackage rights agreement, Stillwater Central Railroad (SLWC) has agreed to grant overhead trackage rights to BNSF Railway Company (BNSF) over SLWC's rail line extending between milepost 668.73 at Long, OK, and milepost 438.9 at Sapulpa, OK, a distance of approximately 229.83 miles.

The transaction is scheduled to be consummated on or before January 1, 2007.[1] The purpose of the trackage rights is to allow for the movement of BNSF's trains overhead between (a) Long, OK, and Oklahoma City, OK, and (b) Long, OK, and Sapulpa, OK.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

[1] The trackage rights agreement provides for an initial term of 15 years. The parties must seek appropriate Board authority for the trackage rights to expire at the end of that time period.

This notice is filed under 49 CFR 1180.2(d)(7). If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34938, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Sidney L. Strickland Jr., Sidney Strickland and Associates, PLLC, 3050 K Street, NW., Suite 101, Washington, DC 20007.

Board decisions and notices are available on our Web site at ''*http://www.stb.dot.gov.*''

Decided: December 1, 2006.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E6–20903 Filed 12–7–06; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–33 (Sub–No. 238X)]

Union Pacific Railroad Company—Discontinuance of Service Exemption—in Yuba County, CA

On November 20, 2006, Union Pacific Railroad Company (UP) filed with the Board a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to discontinue service over an approximately 4.77-mile line of railroad known as the Pearson Industrial Lead, extending from milepost 133.29, near Alicia, to milepost 129.91, near Pearson, and milepost 0.00 to milepost 1.39, near Pearson, in Yuba County, CA. The line traverses U.S. Postal Service Zip Code 95901, and serves stations at Pearson and Reed.

The line does not contain federally granted rights-of-way. Any documentation in the possession of the railroad will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

By issuing this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by March 9, 2007.

Any offer of financial assistance (OFA) to subsidize continued rail service under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each OFA must be accompanied by a $1,300 filing fee. *See* 49 CFR 1002.2(f)(25).[1]

All filings in response to this notice must refer to STB Docket No. AB–33 (Sub-No. 238X) and must be sent to: (1) Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001; and (2) Mack H. Shumate, Jr., Senior General Attorney, 101 North Wacker Drive, Room 1920, Chicago, IL 60606. Replies to the petition are due on or before December 28, 2006.

Persons seeking further information concerning discontinuance procedures may contact the Board's Office of Public Services at (202) 565–1592 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis at (202) 565–1539. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: December 1, 2006.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E6–20789 Filed 12–7–06; 8:45 am]

BILLING CODE 4915–01–P

[1] Because this is a discontinuance of service proceeding and not an abandonment, trail use/rail banking and public use conditions are not appropriate. Similarly, no environmental or historic documentation is required under 49 CFR 1105.6(c)(2) and 1105.8(e).

Corrections

Federal Register

Vol. 71, No. 236

Friday, December 8, 2006

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 239 and 258

[EPA–R07–RCRA–2006–0878; FRL–8242–6]

Adequacy of Nebraska Municipal Solid Waste Landfill Program

Correction

In rule document E6–19388 beginning on page 66686 in the issue of Thursday, November 16, 2006, make the following correction:

On page 66686, in the third column, under the **DATES** heading, in the fourth line, ''January 16, 2007'' should read ''December 18, 2006''.

[FR Doc. Z6–19388 Filed 12–7–06; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-141901-05]

RIN 1545-BE92

Exhanges of Property for an Annuity

Correction

In proposed rule document E6–17301 beginning on page 61441 in the issue of Wednesday, October 18, 2006, make the following correction:

§ 1.1001-1 [Corrected]

On page 61445, in the first column, in § 1.1001-1(J)(2)(ii), in the next to last line, ''April 18, 2006'' should read ''April 18, 2007.''

[FR Doc. Z6–17301 Filed 12–7–06; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Friday,

December 8, 2006

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 460, 462, 466, 473, and 476

Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 460, 462, 466, 473, and 476

[CMS–1201–F]

RIN 0938–AN83

Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions

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

ACTION: Final rule.

SUMMARY: This rule finalizes the interim final rule with comment period published in the **Federal Register** November 24, 1999 (64 FR 66234) and the interim final rule with comment period published in the **Federal Register** on October 1, 2002 (67 FR 61496). The November 1999 interim final rule implemented sections 4801 through 4803 of the Balanced Budget Act of 1997 (Pub. L. 105–33) and established requirements for Programs of All-inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The interim final rule with comment period published on October 1, 2002 (67 FR 61496) implemented section 903 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554).

DATES: *Effective Date:* These regulations are effective on January 8, 2007.

FOR FURTHER INFORMATION CONTACT: Jana Petze, (410) 786–4533, or Carrie Smith, for State technical assistance, (410) 786–4485.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
A. Program Description
B. Legislative History
1. Demonstration Project
2. Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33)
a. Use of the PACE Protocol
b. Consultation With States
c. Consultation With State Agency on Aging
d. State Medicaid Plan Requirement
e. Interaction with Medicare + Choice (Now Medicare Advantage)
f. Flexibility Under the BBA
3. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)
a. Background
b. Contracting for IDT Members and Administrative Staff
c. Contracting With Another Entity to Furnish PACE Center Services
d. Oversight of Direct Patient Care Services
e. Waiver Process
4. Medicare Prescription Drug Improvement and Modernization Act of 2003, (MMA)
II. Analysis of Public Comments
A. Summary of Comments on the 1999 Interim Final Rule
B. Summary of Comments on the 2002 Interim Final Rule
III. Provisions of the 1999 Interim Final Rule With Comment and the 2002 Interim Final Rule With Comment, Analysis of and Response to Public Comments and Final Rule Actions
IV. Provisions of the Final Rule
V. Collection of Information Requirements
VI. Regulatory Impact Statement
Regulation Text
Addendum—PACE Protocol (1999)

ACRONYMS for the PACE Final Rule

ADLs Activities of Daily Living
BBA Balanced Budget Act of 1997
BIPA Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000
CAP Corrective Action Plan
CBRR Consumer Bill of Rights and Responsibilities
CMS Centers for Medicare & Medicaid Services
COBRA Consolidated Omnibus Budget Reconciliation Act of 1985
COP Condition of Participation
CHSPR Center for Health Services and Policy Research
CMS–HCC CMS Hierarchical Conditions Category
ESRD End-Stage Renal Disease
FFP Federal Financial Participation
HOS Health Outcomes Survey
HPMS Health Plan Management System
IDT Interdisciplinary Team
IRE Independent Review Entity
LCS Life Safety Code
MA Medicare Advantage (formerly Medicare + Choice(M + C))
MA–PDP Medicare Advantage—Prescription Drug Plan
M + C Medicare + Choice (now Medicare Advantage (MA))
MMA Medicare Prescription Drug Improvement andModernization Act of 2003
NF Nursing Facility
NPA National PACE Association
OBCQI Outcome-Based Continuous Quality Improvement
PACE Programs of All-inclusive Care for the Elderly
PCA Personal Care Attendant
PCP Primary Care Physician
PHS PACE Health Survey
PO PACE Organization
QAPI Quality Assessment and Performance Improvement
RAI Request for Additional Information
SAA State Administering Agency
SFH State Fair Hearing
SPA State Plan Amendment
SSA Social Security Administration

Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173 enacted on December 8, 2003, amended section 1871(a) of the Social Security Act (the Act)) requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA states that the timelines for these regulations may vary among different regulations but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances. Section 902 also directs the Secretary to establish an appropriate period for finalizing those interim final regulations that were published before the enactment of MMA on December 8, 2003. Pursuant to this requirement, we published a notice in the **Federal Register** (69 FR 78442) establishing a publication deadline of 3 years from MMA enactment, that is December 8, 2006, for finalizing interim final rules published prior to MMA enactment.

This final rule finalizes provisions set forth in the November 24, 1999 and October 1, 2002 interim final rules with comment. These interim final regulations will be finalized within the 3-year period after MMA enactment that was established under section of the MMA 902. Therefore, we believe that this final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

I. Background

A. Program Description

The Program of All-inclusive Care for the Elderly (PACE) program is a unique model of managed care service delivery for the frail community-dwelling elderly, most of whom are dually eligible for Medicare and Medicaid benefits, and all of whom are assessed as being eligible for nursing home placement according to the standards established by their respective States.

B. Legislative History

1. Demonstration Project

Section 603(c) of the Social Security Amendments of 1983 (Pub. L. 98–21), as extended by section 9220 of the Consolidated Omnibus Budget

Reconciliation Act of 1985 (COBRA) (Pub. L. 99–272) authorized the original demonstration PACE program for On Lok Senior Health Services (On Lok) in San Francisco. Section 9412(b) of Pub. L. 99–509, the Omnibus Budget Reconciliation Act of 1986 (OBRA, 1986), authorized us to conduct a PACE demonstration program to determine whether the model of care developed by On Lok could be replicated across the country. The number of sites was originally limited to 10, but the Omnibus Budget Reconciliation Act of l990 (Pub. L. 101–508) authorized an increase to 15 PACE demonstration programs.

The PACE model of care includes as core services the provision of adult day health care and interdisciplinary team (IDT) care management, through which access to and allocation of all health services is managed. Physician, therapeutic, ancillary, and social support services are furnished in the participant's residence or on-site at a PACE center. Hospital, nursing home, home health, and other specialized services are generally furnished under contract. Financing of the PACE demonstration model was accomplished through prospective capitation of both Medicare and Medicaid. PACE demonstration programs had been permitted by section 4118(g) of Pub. L. 100–203 (OBRA 1987) to assume full financial risk progressively over the initial three years. As such authority was removed by section 4803(b)(1)(B) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), PACE demonstration programs approved after August 5, 1997 had to assume full financial risk at start-up.

The PACE demonstration program was operated under a Protocol established and published by On Lok, Inc. on April 4, 1995.

2. Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33)

The BBA built on the success of the PACE demonstration program. Section 4801 of the BBA, authorized coverage of PACE under the Medicare program. It amended title XVIII of the Act by adding section 1894, which addresses Medicare payments and coverage of benefits under PACE. Section 4802 of the BBA authorized the establishment of PACE as a State option under Medicaid. It amended title XIX of the Act by adding section 1934, which directly parallels the provisions of section 1894. Section 4803 of the BBA addresses implementation of PACE under both Medicare and Medicaid, the effective date, timely issuance of regulations, priority and special consideration in processing applications, and transition from PACE demonstration program status.

As directed by section 4803 of BBA, we published an interim final rule on November 24, 1999, permitting entities to establish and operate PACE programs under section 1894 and 1934 of the Act (64 FR 66234).

The 1999 interim final rule was a comprehensive rule that addressed eligibility, administrative requirements, application procedures, services, payment, participant rights, and quality assurance.

a. Use of the PACE Protocol

Throughout the 1999 interim final rule, when we referred to ''the Protocol'' we meant the PACE Protocol, as published by On Lok, Inc., the parent company of On Lok Senior Health Services. A copy of the Protocol was included as an attachment to the 1999 interim final rule with comment period.

We were directed by sections 1894(f)(2) and 1934(f)(2) of the Act to incorporate into regulation the requirements applied to PACE demonstration programs under the Protocol, to the extent consistent with the provisions of sections 1894 and 1934 of the Act. We also were authorized to modify or waive certain provisions of the Protocol in the development of the regulation, if the modification or waiver were not inconsistent with and would not impair the essential elements, objectives, and requirements of sections 1894 and 1934 of the Act.

b. Consultation With States

Sections 4801 and 4802 of Pub. L. 105–33 clearly dictate a cooperative relationship between the Secretary and the States in the development, implementation and administration of the PACE program. In order to fulfill these requirements, we utilized the American Public Human Services (formerly, the American Public Welfare Association) as the conduit to solicit States for volunteers to consult with CMS staff. The participating State staff members represented States with a range of PACE experience. Each State staff volunteer selected a specific target area to provide information.

In order to efficiently and effectively obtain a large amount of feedback in a short period of time, CMS staff arranged a series of conference calls to discuss a wide range of issues pertaining to PACE including requirements on the application process, enrollment, and payment and related financial data collection. Each subject area discussion included CMS staff and two to three State representatives. The feedback obtained during these meetings was an invaluable source of information in understanding State operational concerns and in constructing the regulation. We believed that this approach would minimize operational barriers that are frequently inherent when new programs are initiated. For this reason, CMS continues to regularly consult and receive feedback from States regarding PACE policy by means of teleconferences and forums.

c. Consultation With State Agency on Aging

Under the Older Americans Act, State Agencies on Aging were charged with the responsibility of promoting comprehensive and coordinated service systems for older persons in their States. Consistent with this responsibility, State Agencies on Aging oversee important programs for home and community-based services which are funded through title III of the Older Americans Act, State revenues, and the Medicaid home and community-based waiver program.

The State agencies also implement and oversee important planning, referral, case management, and quality assurance functions. In addition, State agencies are responsible for administering the State Long Term Care Ombudsman Program through which service quality in nursing homes and board and care homes are monitored in every State.

Each State agency that administers the PACE program should regularly consult with their respective State Agency on Aging in order to avoid service duplication in the PACE service areas and to assure the delivery and quality of services to PACE participants. In our 1999 interim final rule, we indicated we were considering the extent to which the State Long Term Care Ombudsman Program would be useful in promoting the rights of PACE participants and in monitoring the quality of care provided by PACE organizations (POs). We received a number of comments on this issue that we discuss in Subpart G ''Participant Rights'' of this final rule.

d. State Medicaid Plan Requirement

The State Medicaid plan is a comprehensive written statement submitted by the State and approved by CMS describing the nature and scope of the Medicaid program and giving assurance that the Medicaid program will be administered according to Federal law and policy. The State plan preprint sets forth the scope of the Medicaid program, including groups covered, services furnished, and

payment policy. When a State completes a new State plan preprint page because of changes in its Medicaid program (called a ''State plan amendment (SPA)''), the preprint page must be approved by CMS in order for the State to receive Federal matching funds.

Section 1905(a)(26) of the Act, as added by section 4802(a)(1) of the BBA, provided authority for States to elect PACE as an optional Medicaid benefit. The State plan electing the optional PACE program must be approved before CMS and the State enter into a program agreement with a PO. To aid States in modifying their State plans, the CMS Center for Medicaid and State Operations developed an interim State plan preprint for PACE. A State Medicaid letter dated March 23, 1998, provided information and guidance to State Medicaid agencies on how to satisfy the State plan amendment requirement. Additional directions for completing the State plan amendment were provided in a State Medicaid Director letter that was issued November 9, 2000. The most current version of the State Plan preprint is available on the CMS PACE homepage, *http://www.cms.hhs.gov/PACE/04_InformationforStateAgencies.asp.*

e. Interaction With Medicare+Choice (Now Medicare Advantage)

The BBA also established the Medicare+Choice (M+C) program, which expanded the health care options available to Medicare beneficiaries. Under the M+C program, beneficiaries could elect to receive Medicare benefits through enrollment in one of several private health plan choices beyond the original (fee-for-service) Medicare program or choose a plan previously available through managed care organizations under section 1876 of the Act.

The BBA set forth the requirements for M+C organizations in a new Part C of title XVIII of the Act. The interim final rule that implemented the M+C program was published June 26, 1998 (63 FR 34968). The final regulation addressing comments was published on February 17, 1999 (64 FR 7968).

Significant changes were made to the M+C program by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003). The two final regulations that implemented the MMA were published January 28, 2005 (70 FR 4194 and 4588). The first regulation established the Medicare Prescription Drug Benefit or Medicare Part D and the second regulation established the Medicare Advantage (MA) program which replaced the M+C program.

In this final rule, we are finalizing our regulations that implement the PACE provisions of the BBA and BIPA statutes. We are limiting our discussion of the effects of MMA provisions to those issues that have been addressed in other MMA rulemaking. We think our regulations on Part D and MA provide sufficient and appropriate guidance to all affected entities, including POs. However, we believe it is essential to highlight the impact of MMA, particularly with respect to how Medicare Part D relates to a PO. Specifically, the MMA provides that POs electing to provide Part D coverage to their enrollees shall be treated in a manner similar to Medicare Advantage Prescription Drug Plans (MA–PDPs). A more detailed discussion of the relevant MMA provisions is provided later in this section.

Although the PACE program has certain fundamental similarities to M+C (now MA), PACE is not a M+C plan. The BBA established separate and distinct requirements for the PACE program. PACE is similar to some M+C options in these ways: it is capitated; it is risk-based; it provides managed care; and it is an elective option. However, PACE differs significantly from M+C plans in other ways such as: it is not available nationwide (only in a limited number of sites); statutory waivers expand the scope of Medicare covered services; it is not available to all beneficiaries (only to a defined subset of frail elderly); and it is a joint Medicare/Medicaid program. However, the BBA directed us to consider some of the requirements established for the M+C program as we developed regulations for POs in certain areas common to both programs, for example, beneficiary protections, payment rates, and sanctions.

f. Flexibility Under the BBA

As noted above, the PACE demonstration program was operated pursuant to a Protocol developed by On Lok, Inc. The Protocol provided authority for CMS and the State Administering Agency (SAA) (that is, the State Agency designated to administer the PACE program) to waive specific requirements of the Protocol, if, in their judgment, the following criteria were met:

- The intent of the requirements was met by the proposed alternative and
- Safe and quality care would be provided.

In addition, written requests for waivers were required to be approved by CMS and the SAA before implementation of the proposed alternative.

Flexibility was limited to the requirements in the section on service coverage and arrangement. That section includes the following requirements:

- POs must provide all Medicare and Medicaid services and provide care 7 days per week, 365 days per year;
- A listing of required and excluded services and minimum services;
- Each participant be assigned to an IDT;
- The composition and duties of the IDT;
- The assessment and reassessment requirements.

Flexibility was not authorized for other sections of the Protocol, such as participant rights, enrollment and disenrollment, and administration.

Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act give the Secretary the authority to waive regulatory provisions as follows:

> In order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas or those that may determine it appropriate to use non-staff physicians according to State licensing law requirements) * * * the Secretary (in close consultation with State administering agencies) may modify or waive provisions of the PACE protocol as long as the modification or waiver is consistent with and would not impair the essential elements, objectives, and requirements of this section * * *.

The statute also specifies the following essential elements that may not be waived:

- The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.
- The delivery of comprehensive, integrated acute and long-term care services.
- The multidisciplinary team approach to care management and service delivery.
- Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals.
- The assumption by the provider of full financial risk.

To implement sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, in the 1999 interim final rule, we identified specific waivers that were intended to encourage the development of PACE programs in rural and Tribal areas. The waivers included the following three requirements:

- A prohibition on members of the governing body and their family members from having a direct or indirect interest in contracts with the organization (see § 460.68(c));

• A requirement that members of the IDT primarily serve PACE participants (see § 460.102(g)); and

• A requirement that the primary care physician (PCP) must be employed by the PO (see § 460.102(g)).

The regulation included specific criteria for each waiver related to whether the PO's service area is rural or Tribal, the accessibility of individuals who meet the three regulatory requirements listed above, and a requirement that the proposed alternative does not adversely affect the availability or quality of care furnished to PACE participants.

Our rationale for this initial, limited view of the flexibility provision was based on our belief that all PACE demonstration programs were in compliance with the Protocol, necessitating only minor changes in their operations to meet the PACE regulatory requirements. Our intention was to allow some flexibility to promote PACE in rural and Tribal areas while maintaining consistency of the requirements for other PACE programs. We intended to provide more flexibility to all POs once we had gained sufficient experience in administering the PACE program.

However, after publication of the 1999 interim final rule, we learned that although the early PACE demonstration programs initially complied with the Protocol, most of them modified the Protocol requirements as they expanded, using the flexibility authorized in the Protocol. While many of these modifications were related to the allowable areas of service coverage and arrangement provisions, many others were not authorized by the flexibility clause in the Protocol. Furthermore, many of the later PACE demonstration programs also inappropriately exercised the flexibility clause in the Protocol, especially with regard to direct employment of staff. Finally, very few of the waivers were requested in writing or approved by CMS or the SAA before implementation.

We subsequently revised our regulations on the waiver process in response to comments on the 1999 interim final rule and in accordance with the requirements of section 903 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted on December 21, 2000), as discussed below. A detailed discussion of waivers and the waiver process is located in section III, subpart B of this final rule.

3. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)

a. Background

BIPA modified the PACE program in the following three ways:

• Section 901 extended the transition period for the PACE demonstration programs to allow an additional year for these organizations to transition to the permanent PACE program.

• Section 902 gave the Secretary the authority to grandfather in the modifications these programs had implemented as of July 1, 2000. This provision allowed the PACE demonstration programs to continue program modifications they had implemented and avoid disruptions in participant care where these modifications were determined to be consistent with the PACE model. These sections were implemented administratively.

• Section 903 specifically addressed flexibility in exercising the waiver authority provided under sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act. It authorized CMS to modify or waive PACE regulatory provisions in a manner that responds promptly to the needs of POs relating to the areas of employment and the use of community-based PCPs. Section 903 of BIPA also established a 90-day review period for waiver requests. As the flexibility language is part of the statutory section dealing with regulations (sections 1894(f) and 1934(f) of the Act), we believed it was intended that waiver requirements be incorporated into the PACE regulations. In order to implement section 903 of BIPA, we published the 2002 PACE interim final rule.

b. Contracting for IDT Members and Administrative Staff

In the 2002 interim final rule, we amended the PACE regulations to replace the term ''multidisciplinary'' with ''interdisciplinary'' to more accurately reflect the interactive and collaborative approach of the PACE care team.

In the 2002 interim final rule, we responded to public comments regarding flexibility, including comments on § 460.102(f) of the 1999 interim final rule, which required that the PACE IDT members be employees of the PO or PACE center. In the 2002 interim final rule, we deleted § 460.102(f) and revised § 460.60 to allow the PO to employ or contract with the program director and the medical director. We also added requirements at § 460.70 that must be met when the PO is contracting for services.

A more detailed discussion of § 460.60 and § 460.70 is located in section III, subpart E of this final rule.

c. Contracting With Another Entity To Furnish PACE Center Services

After publication of the 1999 interim final rule, we learned that in 1995, On Lok, Inc. had changed the Protocol to reflect a contractual arrangement they entered into with another organization to provide all PACE center services. Under this arrangement, the IDT was employed and managed by the contracting organization but On Lok retained responsibility for all care provided to and all risk entailed in meeting the healthcare needs of the participants attending the center. Through this contractual relationship, On Lok was able to expand PACE services within their service area. As this approach was reflected in the PACE Protocol, we amended the PACE regulations in the 2002 interim final rule to allow POs to provide PACE center services through contractual arrangements. We also revised § 460.70 to identify the criteria that a PO must meet to contract out PACE center services. A more detailed discussion of § 460.70 is located in section at IV.B. of this final rule.

d. Oversight of Direct Patient Care Services

As discussed above, in the 2002 interim final rule, we revised the requirements of the 1999 interim final rule to allow for the contracting of IDT members, program director, medical director, and all PACE center services. For this reason, we believed it was essential to establish oversight criteria that POs must implement for all employees and contracted staff who furnish direct patient care. This was accomplished with the addition of § 460.71. A more detailed description of § 460.71 is located in section IV, subpart E of this final rule.

e. Waiver Process

To implement section 903 of BIPA, we established a process for submission and approval of waiver requests. The 2002 interim final rule amended the 1999 interim final rule by adding § 460.26, which specifies the requirements for submission and evaluation of waiver requests and § 460.28, which addresses requirements related to CMS review of waiver requests. In the 2002 interim final rule, we also removed the restrictive waiver provisions for rural and Tribal

organizations that were included in the 1999 interim final rule.

A more detailed description of § 460.26 and § 460.28 is located in section III, subpart B of this final rule.

4. Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA)

On December 8, 2003, the Congress enacted the MMA of 2003 (Pub. L. 108–173). Several sections of the MMA impact POs. Most notably, section 101 of the MMA affected the way in which POs are paid for providing certain outpatient prescription drugs to any Part D eligible participant. As specified in sections 1894 and 1934 of the Act, POs shall provide all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, co-payments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. Up until January 1, 2006, payment for drugs covered under Medicare parts A and B was included in the monthly Medicare capitation rate paid to POs for Medicare beneficiaries, while payment for outpatient prescription drugs was included in the monthly Medicaid capitation rate paid to POs for Medicaid recipients, or as a portion of the amount equal to the Medicaid premium paid by non-Medicaid recipients.

Consequently, in order for POs to continue to meet the statutory requirement of providing prescription drug coverage to their enrollees, and to ensure that they receive adequate payment for the provision of Part D drugs, beginning January 1, 2006, POs could begin to offer qualified prescription drug coverage to their enrollees who are Part D eligible individuals. The MMA did not impact the manner in which POs are paid for the provision of outpatient prescription drugs to non-part D eligible PACE participants.

Section 1860D–21(f) of the Act, added by section 101 of the MMA, provides that POs may elect to provide qualified prescription drug coverage to enrollees who are Part D eligible individuals.

This section also provides that in the case of a PACE program that elects to provide qualified Part D prescription drug coverage, the requirements under Part D apply to the provision of such coverage in a manner that is similar to the manner in which those requirements apply to the provision of such coverage under an MA–PD local plan. However, because we did not believe that Congress intended for the MMA to alter the way in which PACE services, including outpatient prescription drugs are provided to PACE enrollees, we indicated in the final rule that implements Part D (70 FR 4194) that POs would not be deemed to be MA–PD local plans, but rather, would be treated in a manner similar to an MA–PD local plan for purposes of payment under Part D. We stated that this approach is consistent with section 1894(d)(1) of the Act, which provides that payments will be made to POs ''in the same manner and from the same sources'' as payments are made to a MA organization.

The MMA allows CMS the flexibility to deem POs as MA–PD plans or to treat POs that elect to provide qualified drug coverage in a manner similar to MA–PD plans. Due to inconsistencies in the PACE and MMA statutes, we chose to treat POs in a similar manner as MA–PD plans avoiding conflicting requirements. The requirements that apply to POs that elect to provide qualified prescription drug coverage to Part D eligible enrollees are set forth in subpart T of the preamble to the Part D final rule (70 FR 4194). To the extent that we need to address additional issues regarding Part D as it applies to POs, we will do so in a future rulemaking.

In addition, section 236 of the MMA amended the Act to extend to POs the existing statutory Medicare and Medicaid balance billing protections that had previously applied to POs under PACE demonstration program authority. Specifically, provisions of the Act that limit balance billing against MA organizations by non-contract physicians, providers of service, and other entities with respect to services covered under title XVIII now include PACE providers. Similarly, Medicaid billing limitations specified in the Act now apply to providers participating under the State plan under title XIX that do not have a contract or other agreement with a PACE provider. Both MMA provisions apply to services furnished on or after January 1, 2004.

Section 301 of the MMA amends the Medicare Secondary Payer (MSP) provisions in section 1862(b) of the Act. These amendments clarify the obligations of primary plans and primary payers, the nature of the insurance arrangements subject to the MSP rules, the circumstances under which Medicare may make conditional payments, and the obligations of primary payers to reimburse Medicare. To implement section 301 of the MMA, we issued an interim final rule with comment period (71 FR 9466), published on February 24, 2006, revising our MSP regulations at part 411. Our PACE regulations at § 460.180(d) specify that Medicare does not pay for PACE services to the extent that Medicare is not the primary payer under part 411. The MSP interim final rule establishes our current policies regarding the obligations of other payers. If there are any provisions specific to PACE organizations that result from issuance of the final MSP rule, we will address those provisions in a future PACE rulemaking.

Finally, as discussed above, under the rulemaking requirements of section 902 of the MMA and our notice in the **Federal Register** on December 30, 2004 (69 FR 78442), interim final regulations issued before enactment of MMA on December 8, 2003 must be finalized within 3 years of the date of enactment or the regulations shall not continue in effect. This rule finalizes both the PACE interim final rule with comment period published in the **Federal Register** November 24, 1999 (64 FR 66234) and the PACE interim final rule with comment period published in the **Federal Register** on October 1, 2002 (67 FR 61496).

II. Analysis of and Response to Public Comments

This final rule responds to public comments received on both the November 24, 1999 interim final rule with comment (64 FR 66234) and the October 1, 2002 interim final rule with comment (67 FR 61496).

A. Summary of Comments on the 1999 Interim Final Rule

We received 34 items of correspondence containing more than 500 specific comments on the 1999 interim final rule. In this document, we will refer to this regulation as the 1999 interim final rule. Commenters included representatives of professional associations, State and county governments, PACE demonstration programs, potential PACE programs, various health care providers, and advocacy organizations.

Consistent with the scope of the 1999 interim final rule, most of the commenters addressed multiple issues, often in great detail. Some commenters expressed concerns about Medicare and Medicaid issues that do not pertain to the PACE program.

Numerous commenters disapproved of the limited flexibility provided in the regulation, stating that the regulation restricts programs from developing innovatively and responsively to participant preferences, community needs, and the healthcare marketplace. They asked for operational and service delivery flexibility, while permitting

liberal exceptions for established programs that have proven success in furnishing the PACE benefit. Commenters also noted the regulatory language was too prescriptive in several key areas (personnel qualifications) and too vague in others (Medicare rate-setting), saying that prescriptive language also reduces flexibility in organizational design and limits innovative strategies for service delivery.

Commenters indicated that the application of M+C requirements was often made without considering the differences between the PACE program and M+C plans and that the differences between PACE and nursing facilities should be recognized in the final requirements.

In addition, commenters indicated that the numerous written notices required by the 1999 interim final rule were unduly burdensome.

Comments also indicated that in some instances requirements from other programs (for example, the Outcome Assessment Information Set (OASIS) for home health agencies) have been applied to PACE, thereby disregarding the differences between the programs and adding the burden of information collection.

Finally, commenters opposed the prescriptive language that they thought limited State discretion and usurped traditional State regulatory activities rather than optimizing the opportunity to encourage cooperation with the States. We respond to the particular comments as they relate to specific provisions discussed in section III of this final rule.

Listed below are the six areas of the 1999 interim final rule that generated the most concern:

Subpart D: Sanctions, Enforcement Actions and Termination including civil money penalties;

Subpart E: PACE Administrative Requirements including organizational structure, personnel qualifications, contracted services and marketing;

Subpart F: PACE Services including the interdisciplinary team and participant assessment;

Subpart G: Participant Rights including the appeals process;

Subpart I: Participant Enrollment and Disenrollment which includes eligibility to enroll, enrollment process, continuation of enrollment, and involuntary disenrollment;

Subpart J: Payment including Medicare payment.

B. Summary of Comments on the 2002 Interim Final Rule

We received 4 letters of public comment on the October 1, 2002 interim final rule (67 FR 61496) containing more than 17 specific comments. Commenters included representatives of professional associations, a State government, and an advocacy organization. In this document, we will refer to this regulation as the 2002 interim final rule.

Commenters expressed opposing opinions on the flexibility permitted in the 2002 interim final rule. In general, commenters expressed concerns about flexibility related to all aspects of the program, including waivers and the waiver process, contracted services including staff and contractors, and oversight of direct participant care. Listed below are the three areas that generated the most concern:

Subpart B: PO Application and Waiver Process;

Subpart D: Sanctions, Enforcement Actions and Termination;

Subpart E: Administrative Requirements.

III. Provisions of the 1999 Interim Final Rule With Comment and the 2002 Interim Final Rule With Comment, Analysis of and Responses to Comments and Final Rule Actions

The purpose of this final rule is to respond to public comments and finalize the regulations established in the 1999 and 2002 interim final rules. Below we will list each PACE regulation, note any comments and responses, and then note our final action.

Subpart A—Basis, Scope, and Purpose

This subpart provides the basis for this regulation, the scope and purpose, and defines terms specific to the PACE benefit.

Section 460.2 Basis

As stated in the 1999 interim final rule, the regulations set forth in 42 CFR part 460 are based on Sections 1894, 1905(a), and 1934 of the Act. Section 1894 of the Act authorizes Medicare payments to and coverage of benefits under PACE. Sections 1905(a) and 1934 of the Act authorize the establishment of PACE as an option under the State Medicaid plan to provide for Medicaid coverage of services furnished by the PACE program.

No comments were received on this section.

Final rule actions:

This final rule will finalize § 460.2 as published in the 1999 interim final rule.

Section 460.4 Scope and Purpose

We stated in the 1999 interim final rule that the purpose of the regulation was to set forth the requirements that an entity must meet in order to be approved as a PO under Medicare and Medicaid. It also sets forth how individuals may qualify to enroll in PACE, how Medicare and Medicaid payment will be made for PACE services, provisions for Federal and State monitoring of PACE programs, and procedures for sanctions and termination.

We stated the purpose of a PACE program is to provide pre-paid, capitated, comprehensive health care services that are designed to:

- Enhance the quality of life and autonomy for frail, older adults;
- Maximize dignity of and respect for older adults;
- Enable frail, older adults to live in their homes and in the community as long as medically and socially feasible; and
- Preserve and support the older adult's family unit.

This philosophy is based on Part I, section A, of the Protocol. Adopting a mission or philosophy statement that includes these elements indicates that an entity is guided by a set of values that influence its structure, planning, and day-to-day operations that is consistent with the purpose of PACE.

No comments were received on this section.

Final rule actions:

This final rule will finalize § 460.4 as published in the 1999 interim final rule.

Section 460.6 Definitions

This section of the 1999 interim final rule included the following definitions based on those in sections 1894(a) and 1934(a) of the Act and other terms determined necessary by CMS.

Contract year means the term of a PACE program agreement, which is a calendar year, except that a PO's initial contract year may be from 12 to 23 months, as determined by CMS.

Medicare beneficiary means an individual who is entitled to Medicare Part A benefits or enrolled under Medicare Part B, or both.

Medicaid participant means an individual determined eligible for Medicaid who is enrolled in a PACE program.

Medicare participant means a Medicare beneficiary who is enrolled in a PACE program.

PACE stands for Programs of All-inclusive Care for the Elderly.

PACE center means a facility operated by a PO where primary care is furnished to participants.

PACE organization (PO) means an entity that has in effect a PACE program agreement to operate a PACE program under this part.

PACE program agreement means an agreement between a PO, CMS, and the State administering agency for the operation of a PACE program.

Participant means an individual who is enrolled in a PACE program.

Services include both items and services.

State administering agency means the State agency responsible for administering the PACE program agreement.

Trial period means the first 3 contract years in which a PO operates under a PACE program agreement, including any contract year during which the entity operated under a PACE demonstration program.

In developing the definition of PACE organization, we explained in the 1999 interim final rule that sections 1894(a)(3) and 1934(a)(3) of the Act defined a ''PACE provider.'' We changed that term to ''PACE organization'' (PO) because we believed that the term ''PACE provider'' would be confusing. Medicare regulations (at 42 CFR 400.202) and Medicaid regulations (at 42 CFR 400.203) define the word ''provider,'' but the definitions are different and neither applies to entities that operate PACE programs. Those definitions denote individual providers of individual services under conventional fee-for-service systems. We selected the alternative term, PO, since ''organization'' is a term used in both titles XVIII and XIX when referring to managed care organizations, which are more similar to entities under PACE. In the few places where we use the term ''provider'' in this regulation, we are using it in the broad generic sense to refer to an individual or an entity that furnishes health care services. Our use of the term is not limited to the narrower Medicare definition in § 400.202.

Also, in defining contract year, we explained that a PO's initial (start-up) contract year may be from 12 to 23 months, as determined by CMS, to enable us to adjust the length of the initial (start-up) contract year so that subsequent years are on a standard annual calendar year cycle.

Comment: One commenter suggested that we clarify the term ''center'' by replacing it with the term ''PACE center.''

Response: We agree and have replaced the term ''center'' with ''PACE center'' throughout the regulation.

Comment: We received several comments requesting that we clearly define PACE, what constitutes a PO, and what constitutes a PACE center including clarification that a PACE provider is considered a PACE program and may have more than one center.

It was also recommended that we adopt the definition of PACE center as contained in the Protocol, which explicitly addresses the full range of services and benefits available at the PACE center.

Response: In response to these comments, in this final rule, we are redefining ''PACE center'' to be more consistent with the definition provided in the Protocol and the statute by defining it as a facility which includes a primary care clinic, areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.

In addition, as noted below we are adding a definition of ''PACE program''. However, we disagree with the commenter who requested that we adopt the definition of ''PACE center'' as contained in the Protocol which explicitly identifies the full range of services and benefits available at the PACE center. We believe that our modification is more appropriate and less cumbersome than including every required service in the definition. We also believe that by expanding the definition of ''PACE center'' that was published in the 1999 interim final rule, we are clarifying that a PACE center is a facility where most PACE services are provided, not just primary care.

As noted earlier in this section, in the 1999 interim final rule, we defined *PACE center* as ''a facility operated by a PO where primary care is furnished to participants.'' This definition was based on section IV. B. 2 of the Protocol, which states: ''The PACE center is the focal point for coordination and provision of most PACE services. The PACE center is a facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal care and dining.'' The Protocol identified other requirements for a PACE center, which were included in other sections of the 1999 interim final rule. Those requirements are included in the following sections: The list of required services is at § 460.98; the requirement that POs operate at least one PACE center is in § 460.98(d)(1); the requirement that the frequency of attendance is determined by the IDT based on each participant's needs is at § 460.98(e); and the requirement that the PACE center is designed, equipped, and maintained to provide for the physical safety of participants, personnel, or visitors and to ensure a safe and sanitary environment is at § 460.72.

We believe the list of explicit services and benefits belongs in § 460.98 which relates to ''Service delivery,'' and in § 460.72, which relates to ''Physical environment.''

Comment: A commenter requested that we add a definition of a ''PACE program'' and use the following language ''all centers and service provision by an approved PACE provider in an approved service area.''

Response: ''PACE program'' is defined in the Act at sections 1894(a)(2) and 1934(a)(2) as an entity that meets the statutory requirements to be a PACE provider and provides comprehensive health care services to PACE program eligible individuals in accordance with the PACE program agreement and regulations. We have not included a definition for ''PACE program'' in our regulations at § 460.6. However, we agree with the commenter that doing so would help to clarify and standardize PACE terminology. As noted above, we changed the term ''PACE provider'' to ''PACE organization'' and defined that term in the 1999 interim final rule.

Based on sections 1894(a)(2) and 1934(a)(2) of the Act, we are defining a PACE program as a program of all-inclusive care for the elderly that is operated by an approved PACE organization and that provides comprehensive health care services to PACE enrollees in accordance with a PACE program agreement. As noted above, we are defining a PACE center as a facility which includes a primary care clinic, areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services. We do not think the commenter's language would be needed to ensure that PACE centers are included within the definition of a PACE program.

Final rule actions:

In this final rule we are:

- Replacing the term ''center'' with the term ''PACE center'' throughout the regulation.
- Redefining the term ''PACE center'' as ''a facility which includes a primary care clinic, areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.''
- Defining ''PACE program'' to mean a program of all-inclusive care for the elderly that is operated by an approved PACE organization and that provides

comprehensive health care services to PACE enrollees in accordance with a PACE program agreement.

Subpart B—PO Application and Waiver Process

Section 460.10 Purpose

We established in the 1999 interim final rule, that this subpart sets forth application requirements for an entity that seeks approval from CMS as a PO. In the 2002 interim final rule, we amended § 460.10 to clarify that subpart B also establishes a process by which a PO may request a waiver of certain regulatory requirements in order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas).

PACE Under Both Medicare and Medicaid

We require that each PO must enter into a program agreement under both sections 1894 and 1934 of the Act, that is, that each organization participate in both Medicare and Medicaid. Most of the text in those two sections is identical and our analysis indicates that key language contemplates entities acting as POs under both programs.

Sections 1894(f)(2) and 1934(f)(2) of the Act require that we incorporate in our regulations the requirements applied to PACE demonstration programs under the PACE Protocol, to the extent consistent with the provisions of sections 1894 and 1934 of the Act. Under the Protocol, PACE demonstration programs operated under both Medicare and Medicaid. We believe that the directive to incorporate the requirements in the Protocol reflected an expectation by the Congress that all POs would participate in both Medicare and Medicaid. This view is reinforced by paragraph (f)(2)(B) of these sections, which permits us to modify or waive provisions of the PACE Protocol ''so long as such modification or waiver is not inconsistent with and would not impair the essential elements, objectives, and requirements'' of sections 1894 and 1934 of the Act, but which forbids modifying or waiving, among others, the following provisions:

- Capitated, integrated financing that allows the organization to pool payments received from public and private programs and individuals; and
- The assumption by the organization of full financial risk.

We concluded that both of these provisions preclude the possibility of a Medicare-only or Medicaid-only PACE program. For example, if a program could collect capitation payments from Medicare but bill fee-for-service under Medicaid, not all financing would be capitated, nor would financing be integrated, nor would the organization assume full financial risk.

However, the law does not require that States offer the PACE benefit under Medicaid. As indicated by its title, section 4802 of BBA provides for the ''Establishment of PACE Program as Medicaid State Option.'' If an entity attempted to become a PO under Medicare in a State which has not included PACE program services as an option under its Medicaid program, it would not be possible for that entity to be both a Medicare and a Medicaid PO. While this would curtail the availability of PACE programs in those States, we have concluded that this result was intended because a Medicare-only program could not meet the fundamental concept of an all-inclusive, integrated, capitated, full-risk program.

Moreover, both sections 1894 and 1934 of the Act contemplate the active collaboration of Federal and State governments in the administration of PACE. Each State must have a SAA that is responsible for administering PACE program agreements in their State under sections 1894 and 1934 of the Act. The SAA closely cooperates with CMS in establishing procedures for entering into, extending, and terminating PACE program agreements. The SAA cooperates with CMS and the PO in the development of participant health status and quality of life outcome measures. The SAA also cooperates with us in conducting oversight reviews of PACE programs and has the authority to terminate a PACE program agreement for cause. If Medicare-only programs had been contemplated in a State that does not elect the PACE option, there would have been no reason to assign such a significant role to an SAA. We believe that a State which has not chosen PACE as an optional service would be ill-prepared or unable to perform this role.

As mentioned earlier, most of the text of section 1894 of the Act is identical to text in section 1934 of the Act. Portions of both text reflect the concept of entities acting as POs under both programs. The scope of Medicare PACE program benefits includes ''all items and services covered under this title (for individuals enrolled under this section [section 1894]) and all items and services covered under title XIX.'' Similarly, section 1934 of the Act, defines the Medicaid benefit package as ''all items and services covered under title XVIII (for individuals enrolled under section 1894) and all items and services covered under this title.'' In addition, to be eligible for PACE, an individual must require the nursing facility (NF) level of care covered under the State Medicaid plan.

Section 1894(e) of the Act provides that ''CMS, in close cooperation with the SAA'' will establish program agreements for ''entities that meet the requirements for a PO under this section, section 1934, and regulations.'' A corresponding provision is found at section 1934(e) of the Act, referring to ''entities that meet the requirements for a PO under this section, section 1894, and regulations.'' We believe that the use of the correlative ''and'' indicates that PACE entities would have to meet all three sets of requirements.

A parallel provision provides for termination of PACE program agreements (see paragraphs (e)(5) of sections 1894 and 1934 of the Act). Termination of an agreement under both sections 1894 and 1934 of the Act may be accomplished by either ''CMS or a SAA.''

Nonetheless, it is highly unlikely that any entity could be a viable PO without approval under both Medicare and Medicaid. The majority of potential participants are Medicare beneficiaries who also are eligible for Medicaid. Those who are not currently Medicaid-eligible may eventually exhaust their financial resources and become eligible. Medicare participants who are not enrolled in PACE under Medicaid must pay premiums equal to the Medicaid capitation rate. Aside from the technicality that there would not be an established Medicaid capitation rate in a State that does not elect the PACE option, most of these participants would lack the ability to pay these significant premiums.

As the above citations illustrate, some provisions of the law are conflicting and thus ambiguous. We therefore interpreted them to give effect to many of the provisions and policy objectives that they advance. Furthermore, in keeping with the congressional intent that the Protocol guide our implementation of the PACE program, we determined that POs must be approved under both Medicare and Medicaid.

Based on this interpretation, if a State should choose not to amend its State Medicaid plan to adopt PACE as an optional Medicaid service, we would not accept PACE applications from entities in that State. Also, if a State has elected the optional benefit but declines to recommend a particular entity as a PO, we would not accept an application from that entity.

We stated in the 2002 interim final rule that to implement section 903 of BIPA, we amended the PACE regulation by adding § 460.26 and § 460.28 to establish a process for a PO to request waiver of regulatory requirements. This process allows for variations while achieving the intent of the regulatory provision and responding to the needs of POs to develop and expand within their States' long-term care delivery system.

Waivers will be discussed in detail under § 460.26 and § 460.28.

Comment: Another commenter recommended that social support services and participant care be more clearly defined so beneficiaries and caregivers may make informed decisions about the type and level of care to be provided.

Response: In response to the comment regarding a more defined regulation where social services and participant care is concerned, we disagree with this commenter, as required services are participant specific. After the IDT determines a participant requires a service and it is included in their plan of care, those services become required for that participant for that specific need. Therefore, it would not truly represent the PACE model to constrain the benefit by defining it in regulatory language.

Final rule actions:

This final rule will finalize § 460.10, as published in the 2002 interim final rule.

Section 460.12 Application Requirements

We established § 460.12 to set forth the application requirements for the PACE program. In order for CMS to determine whether an entity qualifies as a PO, an individual authorized to act for the entity must submit an application that describes thoroughly how the entity meets all the requirements specified in this regulation. In recognition of the 90-day review timeframe specified in the statute and described below and the numerical limit on the number of PACE program agreements, we will review and take action to approve, deny, or request additional information only on complete applications; those applications that address all elements of the PACE program agreement. We will send a letter to each applicant indicating whether or not the application is complete and specifying when the 90-day review period ends.

We require in § 460.12(b) that applications for PO status be accompanied by an assurance from the SAA indicating that it considers the entity to be qualified to be a PO and that the State is willing to enter into a PACE program agreement with the entity. We will not accept applications from entities that have not obtained these assurances.

To enable a SAA to make these assurances, an entity would have established to the satisfaction of the State that it is committed to the PACE model of care, that there is sufficient funding for program development and facilities, that there is adequate demand for PACE services as shown by demographic analysis.

Entities that are interested in developing a PACE program agreement should contact their SAA to determine whether the State has submitted or plans to submit a SPA to elect PACE as an optional benefit under its State Medicaid plan and if the State has established additional requirements for POs. Section 1905(a)(26) of the Act provides authority for States to elect PACE as an optional Medicaid benefit. The State plan electing the optional PACE program must be approved before we can approve an application for a PO in that State. We received three comments related to application requirements.

Comment: Commenters questioned the requirement that POs must be approved by their SAA. Further, they requested that we specify an absolute role for SAA, and revise the regulatory language to reflect the SAAs' responsibility to submit the program application and the States' role in the application process.

Response: As we explained in the 1999 interim final rule, States have played a significant role in the development of the PACE demonstration program as well as other community-based alternatives to institutionalization. Most States have implemented home and community based programs that provide comprehensive coordinated services to various groups of Medicaid recipients. As a result, States have gained extensive experience in demographic analysis and contracting with entities that are capable of delivering a specified range of services.

Although the PACE statute does not specify the States' role in the application approval process, many aspects of implementing PACE in Medicare and Medicaid will necessitate extensive involvement of the SAAs and the State Medicaid Agencies. The State must elect to provide PACE services as an option under the Medicaid State plan and PACE applications must be accompanied by an assurance from the SAA that the State considers the entity to be qualified to be a PO and is willing to enter into a program agreement with them.

With regard to applications, we continue to believe the States are in the best position to work with potential organizations to develop programs that meet our requirements and are integrated into the States' overall long-term care delivery system.

Comment: One commenter asked us to clarify the regulatory provision related to the hiring requirements of non-operational programs before submission of their program application. The commenter stated that it is unreasonable to expect the applicant would have hired core staff before application submission.

Response: Although hiring requirements for non-operational PACE programs do not appear in our regulations at § 460.12, we addressed these requirements in the preamble of the 1999 interim final rule (64 FR 66238). We stated, ''To enable a State to make such assurances, an entity would have established to the satisfaction of the State that it is committed to the PACE model of care, that there is sufficient funding for program development and facilities, that there is adequate demand for PACE services as shown by demographic analysis, and that the entity has hired core PACE staff and has developed contracts for referral arrangements and other program services that the site will not furnish directly.''

When the 1999 interim final rule was developed, there were several PACE demonstration programs that needed to transition to permanent provider status. As they were operational and had key staff members in place before submitting their PACE provider applications, this requirement was not an issue.

However, as all PACE demonstration programs have transitioned to permanent provider status, applications will now be primarily from non-operational providers. We acknowledge that start-up costs are extensive and paying salaries for top management staff without a revenue stream is unrealistic. We do not believe that it is appropriate to hold non-operational applicants to the same standard as POs that had been fully operational under the PACE demonstration program. Therefore, we are not requiring that core staff be hired before application approval. However, at the time of an organization's Readiness Review, we do expect documentation that core staff have been chosen and accepted those specific key positions. Language related to staff contracts of non-operational organizations has been included on page ix of the Provider Application, which

can be found on the PACE Web site under Provider Application and Appendices at *www.cms.hhs.gov/pace/*. This signed certification guarantees us, among other things, that the SAA will verify that the PO has qualified staff employed or under contract before furnishing services. This document must be signed by the SAA and included as part the PACE provider application.

In the 2002 interim final rule, we revised § 460.12 by removing and reserving paragraph (a)(2) to clarify that although we may begin review of PO applications, we may sign a program agreement only with a PO located in a State with an approved SPA electing PACE as an optional benefit under its Medicaid State plan. We are finalizing this provision by deleting § 460.12(a)(2) entirely. For the sake of continuity we are redesignating § 460.12(a)(3) as § 460.12(a)(2).

Final rule actions:

In this final rule we are redesignating § 460.12(a)(3) to § 460.12(a)(2).

Section 460.14 Priority Consideration

Section 4803(c) of the BBA directed us to give priority in processing applications, during the 3-year period following enactment of the BBA on August 5, 1997, to PACE demonstration programs and then to entities which had applied to operate a PACE demonstration program as of May 1, 1997.

In the 1999 interim final rule, we established § 460.14 to address priority applications and stated that to give priority in processing applications from entities that met the criteria, we would accept applications only from those entities beginning on the effective date of the 1999 interim final rule and continuing for 45 days. Applications from other entities would not be accepted during this period. Moreover, during the subsequent 45 days, extending to 90 days after the effective date of that regulation, we stated we would continue to accept applications from entities that met the priority processing criteria and we would also accept applications from entities that qualify for special consideration as described in the following section.

We did not receive any requests for priority consideration.

Comments related to § 460.14 also address § 460.16 and will be addressed at the end of § 460.16.

Section 460.16 Special Consideration

Section 4803(c) of the BBA required that we give special consideration in the processing of applications during the 3 years following enactment, to any entity that, as of May 1, 1997, had indicated specific intent to become a PO through formal activities such as entering into contracts for feasibility studies.

In § 460.16, we established a process for special consideration of a PACE application. Similar to the process for priority consideration, to give special consideration in processing applications from entities that meet the criteria in the 1999 interim final rule, we indicated we would accept applications from these entities beginning 45 days after the effective date of the 1999 interim final regulation. We further noted that during the 45-day period that extends from 45 days after the effective date to 90 days after the effective date, we would accept applications only from entities that met the priority processing criteria or entities that qualified for special consideration. Applications from other entities would not be accepted during this period.

Applications from entities that believed they were entitled to special consideration were to include information regarding the formal activities they were engaged in towards becoming a PO. If we agreed that special consideration was appropriate for applications submitted after the special 45-day window, we would identify those applicants and factor in the entity's special status in the event that we had a greater number of applications under review than available capacity for PACE program agreements.

We did not receive any requests for special consideration.

Comment: Six commenters requested clarification regarding the criteria and process applied to applications under the BBA mandate providing priority and special consideration in processing PACE applications.

Response: We believe the 2002 interim final rule provided sufficient information as to the criteria and process needed for priority and special consideration for PACE applications. More importantly, however, we note that as the authority to provide these considerations expired on August 5, 2000, it is no longer necessary to retain these regulations.

Final rule actions:

In this final rule we are deleting § 460.14 and § 460.16.

Section 460.18 CMS Evaluation of Applications

We established the information used to evaluate a PO application in the 1999 interim final rule. We approve entities based upon a review of the materials submitted as part of the application, as well as information obtained from the SAA or through onsite visits.

No comments were received on § 460.18.

Final rule actions:

This final rule will finalize § 460.18 as published in the 1999 interim final rule.

Section 460.20 Notice of CMS Determination

Sections 1894(e)(8) and 1934(e)(8) of the Act require us to approve or deny an application for PO status within 90 days after the date of the submission of the application unless additional information is requested. Applications are deemed approved unless we deny PO status in writing or request additional information within the 90-day timeframe. In the 1999 interim final rule, we established procedures for implementing these requirements at § 460.20. We clarified that, for purposes of the 90-day time limit described in this section, the date that an application is considered to be submitted to CMS is the date on which the application is delivered to the address designated by CMS.

These statutory sections also provide that we may request in writing additional information as may be required in order to make a final determination regarding the application and, after the date we receive that information, the application shall be deemed approved unless, within 90 days of that date, we deny the request.

Based on this authority, we may take up to 90 days to request additional information and, once the information is received, may take an additional 90 days to complete processing of the application. It is important to note that there is no corresponding requirement that the SAA or the PO respond to our request for additional information (RAI) within a specified timeframe.

If the additional information proves insufficient to approve the application, the application will be denied. We will notify each applicant of our determination and the basis for the determination in writing. If the application is denied, we will provide the basis for the denial and the process for requesting reconsideration of the application.

No comments were received on § 460.20.

Final rule actions:

This final rule will finalize § 460.20 as published in the 1999 interim final rule.

Section 460.22 Service Area Designation

Sections 1894(e)(2(B) and 1934(e)(2)(B) of the Act permit the Secretary, in consultation with the SAA, to exclude from a service area designation an area that is already

covered under another PACE program agreement. In the 1999 interim final rule, we specified in § 460.22 that each applicant must designate the service area of the program. We stated that CMS (in consultation with the SAA) may exclude from the proposed service area designation any area that is already covered under another PACE program agreement. Consistent with the statute, we believe this was required to avoid unnecessary duplication of services and impairing the financial and service viability of an existing PO.

No comments were received on § 460.22.

Final rule actions:

This final rule will finalize § 460.22 as published in the 1999 interim final rule.

Section 460.24 Limit on Number of PACE Program Agreements

This provision implements sections 1894(e)(1)(B) and 1934(e)(1)(B) of the Act establishing a limit on the number of PACE program agreements that may be in effect on August 5 of each year, that is, the anniversary of the enactment of the PACE statute. Those sections state that we shall not permit the number of POs with which agreements are in effect under those sections or PACE demonstration programs under section 9412(b) of the OBRA of 1986 to exceed—

- Forty as of August 5, 1997, the date of the enactment of the PACE statute, or
- As of each succeeding anniversary of that date, the numerical limitation for the preceding year plus 20. The annual increase in the number of PACE program agreements is not tied to the actual number of agreements in effect as of a previous anniversary date.

Based on this statutory language, we may enter into up to 80 PACE program agreements as of August 5, 1999, and the limit on the number of PACE program agreements increases by 20 each year thereafter.

No comments were received on § 460.24.

Final rule actions:

This final rule will finalize § 460.24 as published in the 1999 interim final rule.

Section 460.26 Submission and Evaluation of Waiver Requests

Section 460.28 Notice of CMS Determination on Waiver Requests

These sections were established in the 2002 interim final rule to implement section 903 of BIPA. As we explained in that rule, we considered amending the 1999 interim final rule to identify each requirement that is eligible for waiver and provide separate waiver criteria for each requirement. However, we were concerned that amending the regulation for each waiver would: (1) Create a regulatory level of specificity that might make it difficult to apply to future requests for similar but not identical waivers; and (2) cause a significant delay between when the need for a waiver is identified and when it may be implemented.

As an alternative, we amended the PACE regulation by adding § 460.26 and § 460.28 to establish a process for a PO to request waiver of regulatory requirements.

As noted previously, the PACE Protocol and the 1999 interim final rule have been proven effective as POs grow and reach financial solvency. We have learned a great deal about variations in the model through the information we received in processing grandfathering requests under section 902 of BIPA and numerous discussions with the National PACE Association (NPA), POs, and States. Allowing for waivers provides a unique opportunity for POs, the States, and CMS to experiment with new approaches within the structure of the PACE model. This process allows for variations while achieving the intent of the regulatory provision and responding to the needs of POs to develop and expand their States' long term care delivery system. The POs will serve as an ongoing laboratory that over time will establish best practices that may ultimately replace the current regulatory requirements.

We realize that in order to foster innovation and creativity within the PACE program, POs must be granted some degree of flexibility in their operation and service delivery. However, we must balance this need for flexibility with our responsibility to ensure quality, cost effective care for all beneficiaries.

Based upon our experience and review of grandfathering requests under section 902 of BIPA, we established two types of waivers in the 2002 interim final rule, that is, general waivers and conditional waivers subject to evaluation. We discuss the waiver types below:

1. General Waivers

A general waiver may be granted to a PO that has successfully implemented a specific operating arrangement, for example, an operating arrangement approved under section 902 of BIPA. General waivers continue indefinitely; however, approval may be withdrawn for good cause if periodic monitoring of the organization's operations and policies indicates participant care is being jeopardized, there is fiscal instability, or the goals of the PACE model are not maintained.

2. Conditional Waivers

A conditional waiver, subject to evaluation, is a provisional waiver we would approve for a specific period of time to a new or experienced organization. During the conditional period, the PO would need to submit specific data, that we prescribed, that would allow us to monitor and evaluate the conditional waiver to determine whether the waiver may become permanent. This category of waiver may include the following scenarios:

(a) A request for waiver without which a PO would be prevented from entering the program. For example, if a prospective PO has been unable to hire or contract with a social worker with a Master's degree, we may consider approving a conditional waiver request to allow a social worker with a baccalaureate degree to operate in this capacity until a qualified social worker is hired. This waiver would only be in effect until the PO could hire or contract for an appropriate staff member.

(b) A request for approval of an arrangement with which a PO does not have any experience. We want to encourage creative approaches to improving the PACE model and view conditional waivers as a responsible way to balance the need of a PO with protection of participant health and safety. We need to be cautious in approving arrangements in which the PO does not have a proven record of success. In approving a conditional waiver request, we may limit the number of participants exposed to the waiver or approve the waiver for a limited period of time or at a specific PACE center until we are assured through evaluation that (1) the intent of the regulation is met; and (2) the approach is not inconsistent with nor impairs the essential elements, objectives, and requirements of PACE. At that time, we may approve a general waiver so that the PO may expand the arrangement to other PACE centers it manages without jeopardizing participant care.

Each of the conditional waivers is subject to periodic monitoring. A PO approved for a conditional waiver must submit any prescribed data at specified intervals. We have learned that, in most cases, conducting a detailed review of a waiver request allows us to implement waiver approvals without having to require data submission. This evaluation serves a dual purpose. It allows us to monitor the impact on participant care as well as enable us to determine if any permanent changes to

PACE should be implemented through regulations. In addition, it allows us to provide technical assistance to other POs requesting a similar waiver.

In the 2002 interim final rule, we discussed the process necessary to obtain any waiver. To obtain either a conditional or general waiver, a PO must provide a detailed description of how its proposed modification differs from the regulatory requirement and how it meets the intent of the regulatory provision. The burden is on the PO to explain why a waiver is needed to start up or expand their program. Where a PO has not completed the trial period, attained financial solvency, and demonstrated competence with the PACE model as evidenced by successful CMS and State onsite reviews and monitoring activities, it will be necessary for the organization to explain how the waiver is necessary to meet those objectives. For a new organization, it will be necessary for the organization to explain why a waiver is needed for the organization to begin serving participants.

Consistent with the process developed for initial PACE provider applications, all waiver requests must be submitted to the SAA for initial review. The SAA forwards the waiver request to CMS along with any concerns or conditions they may have regarding the waiver. We will not accept waiver requests directly from POs. Waiver requests submitted with an initial application process must be prepared as a separate document. These requests are reviewed simultaneously and in conjunction with the application. Where an existing PO is requesting a waiver, the request must be submitted through the State to the CMS address for BIPA 903 waiver requests indicated on the PACE home page (*http://www.cms.hhs.gov/PACE*). We intend to process waiver requests as expeditiously as possible in order to be responsive to the needs of new organizations to develop their programs and to the needs of mature organizations as they expand.

Section 903 of BIPA directs us to approve or deny a request for a modification or waiver no later than 90 days after the date of receipt. We clarified in § 460.28(b) that the date of receipt is the date the request is delivered to the address designated by CMS. We note that there is no statutory authority to stop the 90-day clock if additional information is necessary to make a determination on a waiver request. Thus, it is in the PO's best interest to provide all pertinent information relevant to their request. Where additional information is necessary, the CMS PACE Team Leader will inform the PO as early as possible in the review process. The PO will then be responsible for submitting the additional information in a timely enough manner to allow us to evaluate the additional information and make a determination on the waiver request within the allotted 90 days. If the reply from the PO is not received in a timely manner, we would have to deny the request. The PO may then reapply for the waiver, starting a new 90-day clock.

Consistent with sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, we specified in § 460.26(c) the following requirements that would not be waived:

(1) A focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility;

(2) The delivery of comprehensive, integrated acute and long-term care services;

(3) The IDT approach to care management and service delivery;

(4) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals; and

(5) The assumption by the provider of full financial risk (we note that assuming full financial risk does not preclude an organization from utilizing reinsurance, stop-loss protection, or other mechanism to meet its financial obligations).

In addition to these five provisions, we will not grant waivers that we believe are inconsistent with or would impair the essential elements, objectives, and requirements of sections 1894 and 1934 of the Act.

In addition to the requirements specified in sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, we believe there are other requirements that must not be waived. For example, health care is focused at a PACE center; the IDT is composed of certain health care professionals that manage all of the health care provided to participants; a comprehensive assessment by the IDT is conducted before admission into the PACE program; and reassessment occurs at least every 6 months or whenever there is a significant change in a participant's health status. Further, we believe that PACE participants are entitled to the same patient rights' protection available in the Medicare or Medicaid fee-for-service or managed care programs. Therefore, we will not approve waiver or significant modification of these requirements.

Two waiver issues specifically mentioned in section 903 of BIPA are requirements related to employment and the use of community-based primary care physicians (PCP). In this approach, the PCPs work out of their offices rather than from the PACE center and do not primarily serve PACE participants.

The 2002 interim final rule removed the restrictive waiver provisions at § 460.68(c) regarding direct or indirect interest in contracts, which was limited to rural and Tribal organizations. In addition, the 2002 interim final rule also removed the two waivers in § 460.102(g) related to employment of the PCP and the requirement that the IDT primarily serve PACE participants. These waivers were available if CMS and the SAA determined that there was ''insufficient availability in the PO's service area of individuals who meet the requirement, or State licensing laws make it inappropriate for the organization to employ physicians.'' Although we deleted the specific waivers that were intended to encourage development of PACE in rural or Tribal or other medically underserved areas, we continue to recognize the special need for flexibility in these areas and remain committed to allowing waivers to promote PACE in medically underserved areas. Deletion of the specific waiver language was intended to provide greater flexibility within the overall PACE regulatory structure. We remain committed to working with rural and Tribal communities to help them address the challenges of developing successful PACE programs. Organizations that seek waiver of these or any other regulatory requirements must follow the requirements specified in § 460.26.

We note that a PO requesting a waiver of the prohibition on direct or indirect interest in contracts must develop policies and procedures for disclosure of financial interest to the governing body, establish recusal restrictions, and a process to record recusal actions for review by CMS and the SAA in its waiver request.

Comment: We received two comments expressing concern about compromising the integrity of the PACE model by providing expanded flexibility.

One commenter offered assistance in evaluating PACE policy, program, and practice on a continuing basis. The second commenter was concerned that the PACE regulations lack sufficient safeguards to preserve the model as established by the Protocol. The commenter indicated that maintaining the PACE center as the focal point for delivery of services and retaining the central role of the IDT in managing the health care and other services provided to PACE participants were critical to the PACE model. The commenter also emphasized the important role of the PCP in the Protocol, stating, ''the

ultimate responsibility for managing participant medical care rests with the PCP; therefore, if this team member is not present during team meetings the ability to fulfill this obligation will be compromised.''

Response: We share the commenter's concerns regarding the integrity of the PACE model, and thank the commenter who offered assistance in evaluating the PACE program. We believe the flexibility permitted by the 2002 interim final rule has sufficient safeguards to ensure the integrity of the model. We instituted contracting and oversight requirements we believe will ensure quality of care for PACE participants. During the development of the 2002 interim final rule, we made a concerted effort to develop a waiver process that would allow modification of the model without excessive controls, while at the same time not being too burdensome for POs. We believe we achieved that balance.

The PACE model has been proven successful when the PACE center is the focal point for delivery of services and when the IDT's central role of managing the health care and other services provided to PACE participants is retained. Therefore, we believe there are few circumstances when it would be appropriate to waive these elements of the PACE model without substantial justification by a PO or potential PO, for example, the entity being a rural or Tribal organization. However, according to sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, we do not have the authority to waive the provision requiring the IDT's central role managing the health care and other services provided to PACE participants, since it is statutorily mandated.

Although we have permitted the use of community-based PCPs, we require that effective and consistent communication be maintained. Whenever we have received a request for waiver pertaining to use of community-based PCPs, the PO has had to provide in-depth justification and meet our conditions for waiver. Among other conditions for waiver approval, the community-based PCP must perform all the requirements of the staff PCP including but not limited to participation in IDT meetings related to their participants' participation in Quality Assurance and Performance Improvement (QAPI) activities and agree to PO oversight by the medical director.

Comment: One commenter submitted comments related to the submission and evaluation of waiver requests. This commenter supported reasonable waiver requests for community-based PCPs for flexibility and innovation within PACE which will allow the program to grow. The commenter also supported conditional waivers, which would allow CMS to monitor the performance of organizations utilizing community-based PCPs as well as participant outcomes. The commenter recommended that we focus on processes for integrating care while utilizing community-based PCPs.

Response: In general, we are not inclined to approve waiver requests allowing POs to utilize community-based PCPs without identifying a substantial need. However, we believe there are circumstances when the use of community-based PCPs may be appropriate. For example, it is important for a participant to have a physician that speaks their language and understands their culture's mores and traditions, which can improve participant compliance with their plans of care and, therefore, their health outcomes. We have approved a limited number of waiver requests allowing community-based PCPs contingent on their compliance with specific requirements. We plan to monitor and review the impact of the interactions between the community-based PCPs and the IDT and participant care before we alter the conditions currently applied to these waiver requests.

Comment: Commenters asked whether PACE programs which are operating under grandfathering arrangements would be required to request a waiver in order to continue operations. They believe having to request waiver of operational arrangements grandfathered under BIPA 902 will be administratively burdensome, and they recommend POs be allowed to expand grandfathering arrangements ''organization wide'' provided the expansion is ''* * * reasonably consistent with the objectives of the PACE program.'' They suggested the PO could file a notice with CMS describing the expansion arrangement and how it is consistent with program objectives.

Response: PACE demonstration program sites were granted BIPA 902 ''grandfathering'' of certain operational arrangements that did not meet the 1999 interim final rule, if the identified practice was in place before July 1, 2000. As the approved ''grandfathering'' was effective, only to the extent it existed on July 1, 2000, we believe it was not intended to cover a new or expanded site. As a result, POs need to submit BIPA 903 waiver requests of grandfathered practices for expansion sites.

Based on our experience with the waiver process, we believe there is value in CMS and SAA review and approval of waivers. The consultations involved in the waiver process allows CMS and the SAA to discuss the PO's ability to implement the requested waiver, any concerns either agency has regarding the waiver request, request further information or clarification of the PO's operations, and determine any requirements or conditions that will be included in the waiver approval. CMS and the SAA collaborate in the review and approval of waivers. We have found that the SAA generally has a better knowledge and understanding of the PO and its operations and relevant State laws and requirements.

Comment: One commenter indicated that the regulatory language fails to address entities that are not already a PO, saying that prospective POs (as well as established POs) should be eligible for waivers of regulatory requirements. The commenter requested clarification regarding whether PACE demonstration programs transitioning to permanent provider status, pre-PACE programs, and previously ''non-operational'' entities are eligible to request waivers of regulatory requirements.

Response: Any entity submitting a PACE provider application may submit a request for waiver. The PO demonstration programs had been operating in some cases for years and the implementation of the 1999 interim final rule could have disrupted operations and care to the participants as the demonstration programs transitioned to permanent provider status and were required to be in compliance with the 1999 interim final rule. BIPA provided flexibility for those transitioning demonstration programs to continue their existing operational arrangements and a waiver process for those organizations that did not meet the grandfathering criteria but were unable to comply with the 1999 interim final rule. We believe the intent of the waiver provision in BIPA was to assist organizations to participate in the Medicare and Medicaid PACE benefit program.

We believe that there may be circumstances when applicants are not able to comply with the regulations. The BIPA section 903 waiver process allows developing organizations to work with CMS and the SAA to develop an appropriate alternative rather than abandon their efforts to become a PACE program when they discover they can not meet the regulatory requirements. Therefore, we have allowed these entities to submit waiver requests. A waiver request must be submitted as a

separate document from the provider application and must contain substantial justification for the request. Pre-PACE organizations are Medicaid pre-paid health plans that provide Medicare services under Medicare fee-for-service rules and certain Medicaid services paid by Medicaid on a capitated basis. These organizations may submit a waiver request and their PACE provider application simultaneously but as separate documents.

We will accept waiver requests from non-operational entities and pre-PACE applicants, in an attempt to assist new organizations that would otherwise be unable to meet regulatory requirements. All waiver requests must be submitted through the SAA, who will review and forward to CMS. Regardless of the prior status of the entity, a request for a waiver is reviewed on a case-by-case basis.

Comment: Commenters also requested that we make information regarding approved waiver requests available to current and potential POs.

Response: At this time, we do not agree that making information on particular PACE programs available is warranted. We believe it would be more beneficial for each PO to develop their own unique waiver request and rationale. Each PO is a unique operational entity that has specific circumstances and experience that influence the appropriateness for approving a waiver. Therefore, approving all similar requests for a waiver of a specific requirement is inappropriate. Our intention is that all POs comply with the PACE regulations.

Final rule actions:

In this final rule, we are expanding the regulatory requirements of § 460.26 to permit POs and entities applying to become POs to submit waiver requests.

Section 460.28 Notice of CMS Determination on Waiver Requests

Comment: One commenter requested clarification as to whether an entity submitting a PACE application is permitted to submit a waiver request separate from the provider application, as prompt CMS determination will be important to the organization's ability to move forward with PACE development. The commenter also asked whether the CMS timeframe for responding to waiver requests is affected by the status of the request, or whether the applicant is an operational or a prospective PO.

Response: Waiver requests may accompany an application, but must be prepared and submitted as a separate document. Requests will be reviewed simultaneously and in conjunction with the application. Alternatively, waiver requests can be submitted independently of the application by POs that are currently operational.

The timeframe for our response to a waiver request is the same regardless of the operational status of the requestor. We have a statutory 90-day timeframe to approve or deny waiver requests. As a result, when we request additional information, regarding a waiver request, it is incumbent upon the organization to respond as expeditiously as possible to provide CMS and the SAA time to review their responses. We provide a written approval or denial letter to the PO or PACE applicant with the determination and any additional conditions.

Final rule actions:

In this final rule, we are amending paragraph (a)(2) by adding ''or PACE applicant,'' thereby requiring CMS to notify the PO or PACE applicant in writing of the decision to deny the submitted waiver request.

Subpart C—PACE Program Agreement

The purpose of subpart C is to establish requirements for the PACE program agreement establishing the entity as a provider of PACE benefits under Medicare and the Medicaid State plan.

Section 460.30 Program Agreement Requirements

In accordance with sections 1894(a)(4) and 1934(a)(4) of the Act, we established § 460.30 to require that each PO have an agreement with CMS and the SAA for the operation of a PACE program by the organization under Medicare and Medicaid. This three-party agreement must be signed by an authorized official of the organization, as well as by an authorized CMS official and an authorized State official.

We received no public comments on § 460.30 of the 1999 interim final rule.

In the 2002 interim final rule, we revised the regulatory language to reflect that the PACE program agreement is a three-party agreement that is signed by CMS, the SAA, and the PO. Also, we added regulatory language to clarify that CMS may sign a program agreement only with a PO that is located in a State with an approved SPA electing PACE as an optional benefit under its Medicaid State plan.

We received no comments on this section of the 2002 interim final rule.

Final rule actions:

This final rule will finalize § 460.30 as published in the 1999 and 2002 interim final rules.

Section 460.32 Content and Terms of PACE Program Agreement

In § 460.32(a), we stipulate the required content of a PACE program agreement.

We require that each PACE program agreement designate the service area of the program, specifically identifying the area by county, zip code, street boundaries, census tract, block, or tribal jurisdictional area, to the extent that those identifiers are appropriate. Any changes in the designated service area would require advance approval by CMS and the SAA. This requirement implements the provisions of sections 1894(e)(2)(A)(i) and 1934(e)(2)(A)(i) of the Act and reflects Part I, section D of the Protocol.

Each PO must agree to meet all applicable requirements under Federal, State, and local laws and regulations, including provisions of the Civil Rights Act, the Age Discrimination Act, and the Americans with Disabilities Act. These requirements include, but are not limited to, all requirements contained in the regulations implementing those Acts. This requirement implements in part the provisions of sections 1894(e)(2)(A)(iv) and 1934(e)(2)(A)(iv) of the Act.

We require that the program agreement indicate the effective date and term of the agreement as well as information related to: Organizational structure of the PO; participant rights; processes for grievances and appeals; eligibility; enrollment and disenrollment policies; service description; QAPI; capitation rates; names and numbers of administrative contacts in the organization; and program agreement termination procedures. These requirements are based on sections 1894(b)(2) and 1934(b)(2) of the Act and on Part X, section A of the Protocol.

Each PACE program agreement includes a statement of the levels of performance that we require the organization to achieve on standard quality measures and the data and information on participant care that CMS and the State require the organization to collect. A detailed discussion of the levels of performance and the standard quality measures are contained in the preamble discussions for § 460.134 and § 460.202(b) in the 1999 interim final rule.

In § 460.32(b), we specify that a PACE program agreement may provide additional requirements for individuals to qualify as PACE program eligible individuals. This provision implements sections 1894(e)(2)(A)(ii) and 1934(e)(2)(A)(ii) of the Act. However,

the eligibility criteria in § 460.150(b)(1)–(3) cannot be modified. In addition, a PACE program agreement may contain additional terms and conditions as the parties agree to, if the terms and conditions are consistent with sections 1894 and 1934 of the Act and with these regulations. This provision implements sections 1894(e)(2)(A)(v) and 1934(e)(2)(A)(v) of the Act.

We received five comments on the 1999 interim final rule related to the program agreement, which are listed below.

Comment: One commenter requested that we clarify whether the program agreement content is meant as a substitute for all provisions or only some of the provisions of the State Medicaid contract requirements in 42 CFR part 434. The commenter also asked whether additional terms and conditions could be included in the PACE program agreement to meet specific State law requirements.

Response: The PACE program agreement is a three-way contract between the PO, the SAA and CMS, and contains the PACE requirements from the Federal statute and regulations. If the SAA has requirements beyond those in the three-way PACE program agreement, those requirements should be addressed in a separate contract between the State and the PO. The PACE three-way program agreement can be an attachment to the State-PO contract. As we stated above, each PO must agree to meet all applicable requirements under Federal, State, and local laws and regulations.

States may implement additional or more stringent requirements if they are consistent with sections 1894 and 1934 of the Act and with Federal laws and regulations. However, if there is a conflict between the State and Federal requirements, the Federal requirements would generally take precedence.

Comment: We were asked to describe the mechanism for revising a signed program agreement.

Response: We will provide the PO and the SAA with written notification of any revisions and include updated pages of the program agreement. The PO and the SAA have 30 days to send written notification to us of any disagreement with the revisions. We have provided information on the program agreement on the PACE home page, in the PACE Fact Sheet, which is located at *http://www.cms.hhs.gov/PACE/Downloads/PACEFactSheet.pdf.*

Comment: One commenter asked that we define the procedure for expanding a service area.

Response: The procedure for expanding a service area differs depending on whether a new PACE center is also being opened. The abbreviated PACE expansion application and additional information regarding the procedures for expanding a service area on the PACE home page, in the PACE Fact Sheet, which is located at *http://www.cms.hhs.gov/PACE/Downloads/PACEFactSheet.pdf.*

Comment: Two commenters asked when we would provide the requirements on standard quality measures, the requirements for participant care data and information and asked whether the requirements are the same for all PACE programs. A number of commenters inquired when the data would be collected and what the specific measures would be.

Response: The program agreement identifies the data elements for monitoring that must be submitted quarterly by all POs. A further discussion on standard quality measures, Outcome-Based Continuous Quality Improvement (OBCQI), and COCOA–B is in section III subpart H of this final rule.

Comment: Commenters asked when CMS would provide the Medicare capitation rates.

Response: Section 1894(d) of the Act directs the Secretary to make prospective monthly payments of a capitation amount for each PACE program eligible individual enrolled under the agreement under this section in the same manner and from the same sources as payments are made to the Medicare+Choice (formerly M+C, now MA) organizations and to specify the capitation amount in the PACE program agreement. Therefore, in the 1999 interim final rule, we required that the Medicare capitation rates be included in the program agreement. The Balanced Budget Act of 1997(BBA) mandated that a risk adjustment payment methodology incorporating information on beneficiaries' health status be implemented in the M+C program. The resulting PACE payment methodology that began in 2004 includes a risk adjusted methodology that results in a unique payment for each participant. As a result, it is not possible to include the Medicare capitation rates in the program agreement. Therefore, we are amending our regulation to remove the requirement that the program agreement include the Medicare capitation amount and to require, instead, that the program agreement must include the Medicare payment methodology. This requirement is included in Appendix ''M'' of the program agreement, which can be found at *http://www.cms.hhs.gov/pace/Downloads/programagreement.pdf.* Medicare rates are annually updated, published, and posted on the CMS Web site. Current Medicare payment rates can be found at *http://www.cms.hhs.gov/healthplans/rates/default.asp.*

Final rule actions:

This final rule will amend § 460.32 to indicate that the program agreement must include the ''Medicare payment methodology'' which replaces the ''Medicare capitation rate.''

Section 460.34 Duration of PACE Program Agreement

In § 460.34, we specify that each program agreement will be effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate, in accordance with the requirements of sections 1894(e)(2)(A)(iii) and 1934(e)(2)(A)(iii) of the Act.

Comment: It was recommended that we extend the program agreement's designated 1-year contract period to a longer period of time with an automatic extender.

Response: As noted above, the statute specifies a 1-year contracting period. We provided for a flexible initial contract year that could be as long as 23 months to allow us to adjust the length of the initial or start-up contract year so that subsequent years are on a standard calendar year cycle.

PACE program agreements are considered to be ''evergreen'' meaning they will be automatically renewed without having to be re-signed. We believe the term of the program agreement is appropriate and consistent with overall Medicare policy, as well as in compliance with the requirements of the Act.

Final rule actions:

This final rule will finalize § 460.34 as published in the 1999 interim final rule.

Subpart D—Sanctions, Enforcement Actions and Termination

In subpart D of the 1999 interim final rule, we specified the violations identified in sections 1857(g)(1) and 1903(m)(5)(A) of the Act that could result in the imposition of sanctions under sections 1894(e)(6) and 1934(e)(6) of the Act. We also specified in accordance with paragraph (e)(5) of section 1894 and 1934 of the Act, that CMS or the SAA may terminate the PACE program agreement at any time for cause and that a PO may terminate an agreement after appropriate notice to CMS, the SAA, and participants. We also specified, in accordance with paragraphs (e)(5)(C) of sections 1894 and 1934(e)(5)(C) of the Act, Part IX of the Protocol, the transition procedures that must be followed by an entity

whose PACE program agreement is in the process of being terminated. Those procedures can be found in § 460.50.

Section 460.40 Violations for Which CMS May Impose Sanctions

In § 460.40 we specified, based on paragraph (e)(6)(B) of sections 1894 and 1934 of the Act, that we can impose, in addition to any other remedies authorized by law, any of three types of sanctions if we determine that a PO has committed any of nine listed violations. The following PO violations specified in this section are based on provisions of sections 1857(g)(1) and 1903(m)(5)(A) of the Act:

- Fails substantially to furnish to a participant medically necessary items and services that are covered PACE services, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the participant.
- Involuntarily disenrolls a participant in violation of § 460.164.
- Discriminates in enrollment or disenrollment among Medicare beneficiaries or Medicaid recipients, or both, who are eligible to enroll in a PACE program, on the basis of an individual's health status or need for health care services.
- Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, except as permitted by § 460.150, by Medicare beneficiaries or Medicaid recipients whose medical condition or history indicates a need for substantial future medical services.
- Imposes charges on participants enrolled under Medicare or Medicaid for premiums in excess of the premiums permitted.
- Misrepresents or falsifies information that is furnished to CMS or the State under this part; or, to an individual or any other entity under this part.
- Prohibits or otherwise restricts a covered health care professional from advising a participant who is a patient of the professional about the participant's health status, medical care, or treatment for the participant's condition or disease, regardless of whether the PACE program provides benefits for that care or treatment, if the professional is acting within his or her lawful scope of practice.
- Operates a physician incentive plan that does not meet the requirements of section 1876(i)(8) of the Act.
- Employs or contracts with any individual who is excluded from participation in Medicare or Medicaid under section 1128 or 1128A of the Act (or with any entity that employs or contracts with such an individual) for the provision of health care, utilization review, medical social work, or administrative services.

We received the following comments on § 460.40.

Comment: A commenter stated that the 1999 interim final rule did not include sanctions or enforcement actions that would apply if a program fails to comply with the data collection, record maintenance and reporting requirements in subpart L. The commenter asked what is the authority to require the POs to comply with these requirements.

Response: Under the terms of the program agreement (§ 460.32(a)(2)) the PO is committed to meet all applicable requirements under Federal, State and local laws and regulations, which would include the requirements under subpart L. The reporting requirements in subpart L impact our ability to calculate Medicare capitation payments. Lacking the necessary data to compute an appropriate payment, the PO might receive an inaccurate payment or possibly no payment at all for the corresponding month(s).

Moreover, failure to submit required reports could be interpreted as a failure by the PO to comply substantially with conditions for a PO under this part (§ 460.50(b)(1)(ii)) or to comply with the terms of its PACE program agreement. Therefore, CMS and the SAA have the option of terminating the PACE program agreement due to uncorrected deficiencies.

We believe that § 460.40 as published in the 1999 interim final rule sufficiently addresses the availability of sanctions for violations of subpart L requirements.

Comment: A commenter indicated it was not clear how CMS intended to monitor performance in an identified deficient area nor how CMS and the SAA would cooperate on investigations, agree on findings, and impose sanctions, enforcement, and termination.

Response: In a cooperative effort, CMS and the SAA jointly perform onsite monitoring reviews on a regular basis to ensure quality of participant care as well as to verify clinical and administrative compliance with the PACE regulations. Both CMS and the SAAs engage in a collaborative relationship to sustain oversight of the PO. We stress communications to ensure that each party has the information necessary to take appropriate actions.

Comment: A commenter also requested we clarify the violation incorporated into § 460.40(d), which concerns practices that would have the effect of denying or discouraging enrollment.

Response: Under § 460.40(d), CMS may impose a sanction if the PO engages in any practice that would deny or discourage a participant from enrolling in PACE whose medical condition or history indicates a need for substantial medical service. The exception to this sanction is if the applicant is otherwise ineligible under § 460.150 (that is, they are under 55 years of the age, they do not live in the PO's service area, they do not meet the level of care indicated in the State's Medicaid plan, living in the community would jeopardize their health or safety under the criteria as specified in the program agreement, or any additional eligibility requirements approved by CMS and included in the PACE provider agreement).

Final rule actions:

This final rule will finalize § 460.40 as published in the 1999 interim final rule.

Section 460.42 Suspension of Enrollment or Payment by CMS

We described the two types of sanctions that we may impose in § 460.42 and § 460.46 (civil money penalties). Each of the sanctions, or remedies, that are specified in these sections for specific violations are based on provisions of sections 1857(g)(2), 1857(g)(4), and 1903(m)(5)(B) of the Act. With respect to suspension of enrollment in PACE, we may suspend enrollment of Medicare beneficiaries after the date we notify the organization of the violation. Suspending enrollment of Medicaid recipients is an action taken by the SAA rather than CMS. With respect to suspension of payment, we may suspend Medicare payment to the PO and deny payment to the State of Federal financial participation (FFP) for medical assistance services furnished under the PACE program agreement.

Comment: One commenter recommended that a decision to suspend enrollment should be a collaborative agreement by CMS and the SAA or the SAA should have the ability to do so on its own. Therefore, the commenter recommended establishing an expectation of collaboration between CMS and the SAA, at a minimum.

The commenter also recommended that we revise § 460.42(b)(2) to prospectively notify the State that FFP will be discontinued 60 days from receipt of the notice.

Response: In the event of any violation or imposition of sanctions, we work closely with the SAA of the State in which the PO is located. The interaction between CMS and the SAA is by nature a collaborative one and any action decided upon is the result of this

collaborative effort. We do not believe that adding regulatory language will enhance the inherent collaborative working relationship between CMS and the SAAs.

Moreover, should we exercise the sanction option at § 460.42(b)(2), we will use existing procedures and timeframes for the disallowance of FFP claims. These provisions can be found at 42 CFR 430.42.

Final rule actions:

This final rule will finalize § 460.42 as published in the 1999 interim final rule.

Section 460.46 Civil Money Penalties

In addition to suspension of enrollment, CMS may impose civil money penalties as specified in § 460.46. These include penalties of $100,000 plus $15,000 for each individual not enrolled as a result of the PO's discrimination in enrollment or disenrollment or practice that would deny or discourage enrollment; $25,000 plus double the excess amount above the permitted premium charged a participant by the PO; $100,000 for each misrepresentation or falsification of information; and $25,000 for any violation specified in § 460.40.

Comment: One commenter requested clarification of CMS' authority to assess financial penalties for violations to dual eligible individuals (Medicare beneficiaries that are also Medicaid eligible individuals) as well as Medicare-only beneficiaries.

Response: Authority to assess monetary penalties is provided in sections 1894(e)(6) (Medicare provisions) and 1934(e)(6)(Medicaid provisions) of the Act. If it is determined that a provider has failed to comply with the requirements of those sections of the Act and the regulations, CMS has the authority to impose monetary penalties for violations impacting either dual eligible or Medicare-only participants.

Comment: Several commenters expressed concern that the civil monetary penalties for POs are the same or greater than those of Medicaid managed care and MA organizations. The commenters pointed out that significant size and revenue differences between MA and POs warrant lower penalties for POs. In addition POs have a smaller pool of potential participants than managed care organizations, which must enroll all individuals regardless of need.

Response: We believe the current requirement as published is appropriate in that it allows for imposition of a range of penalty amount from one dollar up to and including the amounts identified in § 460.48. It is not CMS' intent to close any PACE program. We believe the imposition of the maximum financial penalty is an option that would only be used in cases of egregious violations. We believe it is appropriate to maintain the current regulatory requirements, which provide CMS the ability to impose a broad range of penalty amounts including the maximum sanction should the situation warrant.

Comment: Six commenters indicated that the level of penalties is too severe and recommend the penalties be proportionate to the size of the PACE program. One commenter recommended penalties be left to the discretion of the State, while several others indicated that an appropriate amount would be one-quarter of the amount required for Medicaid managed care and M+C plans.

Response: As noted in the previous response, the rule permits a range of amounts to be imposed and provides CMS with the necessary flexibility to impose an appropriate amount depending upon the nature of the violation. In addition, we note that statute requires CMS to make the determination (after consultation with the SAA) to impose any sanctions.

Comment: One commenter relayed the regulation did not indicate to whom the fines should be paid. They recommended the fines be shared equally between the Federal government and the SAA.

Response: Should CMS impose a fine, the PO will be informed in writing and directed where to send the penalty. The PACE statute and regulations at § 460.46(b) specify that section 1128A of the Act governs disposition of civil money penalties. It is not the purpose of this rule to further address disposition of amounts recovered.

Final rule actions:

This final rule will finalize § 460.46 as published in the 1999 interim final rule.

Section 460.48 Additional Actions by CMS or the State

In § 460.48 we specified, based on paragraph (e)(6)(A) of sections 1894 and 1934 of the Act, that if CMS, after consultation with the SAA, determines that a PO is not in substantial compliance with requirements in these regulations, CMS or the SAA can take one or more of the following actions: Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan; withhold some or all payments under the PACE program agreement until the organization corrects the deficiency; or terminate the program agreement.

Comment: One commenter questioned whether CMS and the SAA could independently take action against a PO for violations providing there was prior consultation.

Response: The statute allows CMS to take an enforcement action but only after CMS has consulted with the SAA, and determines that the PACE provider has failed substantially to comply with the PACE requirements. While the SAA may take action based on its own regulations, we believe, that in light of the collaborative relationship between CMS and the SAA, the SAA would consult with CMS before taking any independent action.

Final rule actions:

This final rule will finalize § 460.48 as published in the 1999 interim final rule.

Section 460.50 Termination of PACE Program Agreement

In § 460.50 we specified, in accordance with paragraph (e)(5)(A) of sections 1894 and 1934 of the Act, that CMS or a SAA may terminate at any time a PACE program agreement for cause and that a PO may terminate an agreement after appropriate notice to CMS, the SAA, and its participants. In accordance with paragraph (e)(5)(B) of sections 1894 and 1934 of the Act, we specified that CMS or a SAA may terminate a PACE program agreement with a PO if CMS or the SAA determines that:

- Either there are significant deficiencies in the quality of care furnished to participants, or the PO has failed to comply substantially with conditions under these regulations or with the terms of its PACE program agreement; and
- The PO has failed to develop and successfully initiate, within 30 days of the date of the receipt of written notice, a plan to correct the deficiencies, or has failed to continue implementation of such a plan.

Based on the Protocol, Part IX, section A.1, we also provided for termination if CMS or the SAA determines that the PO cannot ensure the health and safety of its participants. This determination may result from the identification of deficiencies, which CMS or the SAA determines cannot be corrected. Based on the Protocol, Part IX, section A.2, we also required that if the organization terminates the agreement, a minimum of 90 days' notice must be given to CMS and the SAA regarding the organization's intent and that participants must be given a minimum of 60 days notice.

Comment: Termination of the PACE program and transitional care during transition were topics of several comments and recommendations we received. Recommendations included

adding regulatory language requiring CMS and the SAA to agree and coordinate their actions related to termination of a PACE program agreement. Another recommendation was to require that CMS and the State consider the likelihood of institutionalization of community participants in determining whether termination should be imposed.

Response: Neither CMS nor the State considers termination lightly, and our primary concern is protecting the health and safety of the participants. All possible ramifications of terminating a program agreement, including the likelihood of participants becoming institutionalized, will be considered before taking such a severe action. However, we disagree with the commenters and do not believe revisions to the regulations are warranted. As stated in response to previous commenters, we believe the cooperative nature of the relationships between CMS and the SAAs will lead to agreement on a decision to terminate a program agreement. We note however, the statute and regulations specify that CMS or the SAA may independently terminate a PACE program agreement.

Comment: A commenter suggested that the regulations include the appointment of a temporary manager to supervise the operation of the PACE program as an alternative to termination of the program agreement.

Response: To date our experience with the POs does not indicate the necessity of including this remedy in regulation. We will continue to assess the performance of POs and we may consider this sanction in the future. We note that § 460.48(a) states that CMS or the SAA may condition continuation of the PACE program agreement upon timely execution of a corrective action plan (CAP). The appointment of a ''temporary manager'' could be included within the provisions of a CAP. As such, it would be unnecessary to specify specific remedies (including a temporary manager) that CMS might include in the CAP for a particular PO.

Final rule actions:

This final rule will finalize § 460.50 as published in the 1999 interim final rule.

Section 460.52 Transitional Care During Termination

Based on the Protocol, Part IX, section B, we require that the PO develop a detailed written plan for phase-down in the event of termination which includes the following: The process for informing participants, the community, CMS and the SAA in writing about termination and transition procedures; and steps that will be taken to help assist participants to obtain reinstatement of conventional Medicare and Medicaid benefits, transition their care to other providers, and terminate marketing and enrollment activities. This information can be located at *http://www.cms.hhs.gov/pace/*, Chapter 1, section 3. Also, in accordance with paragraphs (a)(2)(C) and (e)(5)(C) of sections 1894 and 1934 of the Act, we specified in § 460.52 that an entity whose PACE program agreement is in the process of being terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the participant's medical records available to new providers.

Comment: We were asked what constitutes ''community'' in § 460.52(a)(1).

Response: In the context of the § 460.52(a)(1) of the 1999 interim final rule, the term ''community'' refers to the general public. Notification to the community would include publishing information regarding the termination in one or more of the generally circulated newspapers in each community or county located in the PO's service area.

Comment: A commenter asked when the transition plan is due (upon notification of termination, or at an earlier point such as at the readiness review or in the context of the program agreement).

Response: A written plan for transition in the event of termination is a component of the PACE provider application and is due at the time the POs application is submitted.

Comment: A commenter was concerned that the regulation needed to provide additional participant protection against loss of services in the event of PO termination. More specifically, the commenter recommended that except where there is an immediate threat of health and safety of the participants, the PO should be required to continue services until such time as a participant is receiving alternative services under Medicare and/or Medicaid, or both, as appropriate, in accordance with the plan of care.

Response: In the event a PACE program agreement is terminated, we believe the regulation provides for sufficient participant safeguards. These safeguards are applicable regardless of who initiates the termination; the PO, CMS, or the SAA. Section 460.52(b) provides that a PO must have a written plan for phase-down in the event of termination which describes how the organization plans to provide assistance to each participant in obtaining necessary transitional care through appropriate referrals.

If the PO initiates the termination, it must provide CMS 90 days' notice, which should provide sufficient time to transition participants to alternative care. If a participant is eligible for Medicaid, the State should provide assistance in arranging for alternative care.

For Medicare beneficiaries, disenrollment from PACE permits reinstatement into original Medicare fee-for-service or enrollment into an MA plan through a special election period.

Final rule actions:

This final rule will finalize § 460.52 as published in the 1999 interim final rule.

Section 460.54 Termination Procedures

In § 460.54, we specified termination procedures based on paragraph (e)(7) of sections 1894 and 1934 of the Act, which provide that:

- The provisions of section 1857(h) of the Act apply to termination of a PACE program agreement in the same manner as they apply to a termination of a contract with a M+C organization under Part C of title XVIII of the Act.
- The provisions of section 1857 of the Act authorize termination of an agreement with an organization based on the following:
- CMS provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the determination that cause exists for termination; and
- CMS provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the agreement.

However, termination is authorized by section 1857(h)(2) of the Act without invoking these procedures if we determine that a delay in termination, would pose an imminent and serious risk to the health of participants enrolled with the organization.

Comment: A commenter asked what is meant by ''reasonable opportunity'' in relation to the development and implementation of a CAP and ''reasonable notice'' for a hearing before terminating the program agreement.

Response: Under normal circumstances, the PO is allowed 30 days from the time they receive the written report following a monitoring review to submit a written response with the CAP to CMS and the SAA. If the PO is unable to submit a CAP within the 30 day period, they may request an extension. The determination to permit

the extension is made based on the particular circumstances at issue.

If participant health and safety is in jeopardy, the monitoring team will inform the PO before their departure that a quicker response is required.

Implementation of the CAP is dependent on the intensity and complexity of the deficiencies identified. Initiation of the CAP should be as immediate as possible. In the event the deficiency relates to the health and safety of participants, implementation of the CAP must be immediate. On the other hand, should the deficiency be related to the physical facility itself, (for example, an electrical or plumbing issue) it may take time to retain the appropriate experts to receive a quote for required construction or repair, prepare and sign a contract to perform the services, arrange for permits, materials, staff required and then to have the construction/repair performed.

Comment: A commenter asked how CMS expects to become aware of any imminent and serious risks to participants, as described in § 460.54(b).

Response: In addition to our usual monitoring procedures, there are a number of mechanisms in place that could provide CMS and the SAA with information indicating imminent and serious risk to participants. The participant's family or caregiver is actively involved in the plan of care and the PO is required to have a robust grievance and appeals process. In this manner, we could be directly notified on any concerns about quality of care. In addition, there may be an ombudsman program in the State, which could be accessed if there were concerns about quality of care. POs are also required to report quarterly data elements for monitoring and financial reports. CMS and the SAA routinely review the reports, which would provide indications that there could be issues with patient care.

For example, there is an unexpected shortfall in revenues reported and a sudden increase in the number of falls. In this case, CMS or the SAA would follow up with the PO to inquire about the changes in their patterns, and ensure that participants are receiving adequate care.

As noted above, CMS may terminate an agreement without invoking the procedures described in § 460.54(a), if CMS determines that a delay in termination, resulting from compliance with these procedures before termination, would pose an imminent and serious risk to the health of participants enrolled with the organization.

POs are also required to inform CMS and the State by e-mail within 24 hours of the occurrence of a ''sentinel event'' (or as soon as a determination is made that the occurrence may be a sentinel event).

We have defined a sentinel event as an unexpected occurrence that caused a participant death or serious physical or psychological injury that included permanent loss of function. We included in this definition any medical equipment failures that could have caused a death and all attempted suicides.

The sentinel event policy for PACE can be found at *http://www.cms.hhs.gov/PACE/Downloads/sereporting.pdf*.

The purpose of the sentinel event reporting policy is to provide guidance to the PO regarding their responsibility should a sentinel event occur. CMS views these events as opportunities to conduct analyses of the underlying root causes, which will reduce the risk of recurrence of a similar event. We also note that generally when a concern or complaint other than a sentinel event is brought to the attention of CMS or the SAA, fact finding activities are initiated, which can include but are not limited to a desk review of documentation, conference calls, or an onsite review, depending upon the case-specific circumstances.

Lastly, POs can request to have quarterly conference calls with CMS and the SAA to discuss policy or operational issues. We believe quarterly calls between the PO, the SAA and CMS are of great benefit in facilitating more open communications. Quarterly calls foster a good working relationship that is helpful when CMS or the SAA need to investigate a concern or complaint they have received.

Final rule actions:

This final rule will finalize § 460.54 as published in the 1999 interim final rule.

Subpart E—PACE Administrative Requirements

The purpose of subpart E is to establish the administrative requirements for entities applying for participation in the PACE benefit. In this subpart, we established requirements relating to organizational structure, the governing body, and program integrity of the entity, as well as relationships between entities. In addition, we specified personnel qualifications and on-going training that must be implemented by the PO for employed and contracted staff, requirements for contracting services, and oversight of employed and contracted staff requirements. This section also established requirements related to physical environment, infection control, transportation services, dietary services, fiscal soundness, and marketing.

Section 460.60 PACE Organizational Structure

We established § 460.60 to specify the structural requirements for a PO. As we explained in the preamble to the 1999 interim final rule, we believe that the requirements specified in § 460.60 are essential to the PO's ability to ensure the health and safety of the participants. The performance of certain basic organizational functions is a minimum condition for an environment in which appropriate care can occur. We based the organizational structure requirements on Part I of the Protocol.

We require that the PO have a current organizational chart showing officials in the PO. The chart for a corporate entity must indicate the PO's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities. In the 1999 interim final rule, we required a PO that is planning a change in organizational structure to notify CMS, the SAA, and its participants, in writing, at least 60 days before the change takes effect. Further, we required changes in organizational structure to be approved by CMS and the SAA, and after approval, to be forwarded to the PO's consumer advisory committee (described later in this preamble). Finally, in the event of a change of ownership, we would apply the general provisions described in 42 CFR 422.550.

The Protocol requires that a PO have a project director. In the 1999 interim final rule, we included this requirement, but changed the term to ''program director'' and further defined the role of this individual. The PO must have a program director who is responsible for the oversight and administration of the entity. The program director is responsible for the effective planning, organization, administration, and evaluation of the organization's operations. The program director would also ensure that decisions about medical, social, and supportive services are not unduly influenced by fiscal managers. The program director is responsible for ensuring that appropriate personnel perform their functions within the organization. The program director would inform employees and contract providers of all organization policies and procedures. If the PO is part of a larger health system, the program director would clearly define and inform PO staff (employees and contractors) of the policies applicable to the PO.

In the 1999 interim final rule, we also maintained the Protocol's requirement for a medical director, but we further delineated the responsibilities of this position. The PO must have a medical director who is responsible for the delivery of participant care, clinical outcomes, and the implementation and oversight of the QAPI program. Thus, the medical director is responsible for achieving the best possible clinical outcomes for all participants. Under this requirement, we would expect the medical director to use the organization's data to demonstrate internal improvements in outcomes over time.

The 1999 interim final rule established § 460.60 that required that the PACE program director and the medical director be employees of the PO. In order to allow for contracting of the PACE program director and medical director, in the 2002 interim final rule, we amended § 460.60(b) and (c) to require that the PO employ these staff members directly or have contracts for these staff that meet the contracting requirements specified in § 460.70.

Comment: We received several comments related to the possibility of PACE being operated as a for-profit entity. Commenters provided examples of organizations that are unable to participate in PACE due to the requirement that POs maintain non-profit status.

Response: We note that sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act allow private, for-profit entities to participate in PACE, subject to a demonstration waiver described in section 1894(h) of the Act. Should for-profit entities wish to participate in PACE, they should apply for a demonstration waiver under section 1894(h) of the Act. While participating in the PACE for-profit demonstration, they must meet all requirements set forth in PACE regulations. We explicitly stated that we would expect the PO to retain all key administrative functions including marketing and enrollment, quality assurance and program improvement, and contracting for institutional providers and other key staff.

Comment: We received conflicting opinions regarding whether to allow flexibility in contracting for various members of the IDT, the program director, the medical director, as well as PACE center services. The majority of commenters advocated for flexibility in order to be responsive to the needs of individual POs. However, some commenters expressed concern that by allowing the PO to contract for the medical director and program director, the PACE model would lose dedicated management. This concern was submitted in response to both the 1999 interim final rule and the amended 2002 interim final rule.

Response: We note that in the 1999 interim final rule, we retained the Protocol's requirement that the program director and medical director be employees of the PO.

However, in response to the large number of public comments received on § 460.60 of the 1999 interim final rule, we revised the regulatory requirements in the 2002 interim final rule to allow POs the flexibility to contract for all members of the IDT, the program director, and medical director as well as all PACE center services. We also expanded § 460.70 to include additional contract requirements.

In response to the comment about losing dedicated management because of contracting for the program director and medical director, we do not believe that a personal commitment to the PACE model is related to employment status. We continue to believe that anyone, contractor or employee, PCA, or director can believe in the PACE philosophy and wish to provide care through this model. Therefore, we are not amending this requirement in this final rule.

Comment: Several commenters stated that, as currently written, the regulatory requirement assigns responsibility for QAPI to both the governing body and the medical director. They requested confirmation that the governing body's responsibility is to affect a program-wide approach to quality, ensuring alignment of unit activities with overall objectives, whereas the responsibilities of the medical director would be more narrowly focused on clinical aspects of care.

Response: The commenters are correct. Although QAPI activities and objectives affect every staff member and contractor, the governing body has overall responsibility for the QAPI program and the medical director has overall clinical responsibility.

Comment: In response to our solicitation for comment regarding the extent to which changes in organizational structure are important to participants, we received a number of suggestions that we revise the requirement to notify CMS, or CMS and the SAA, of changes in organizational structure. Commenters were consistent in their recommendations that notification should only be required for a change in ownership, governing board, or delivery system, focusing on those changes that significantly impact service delivery.

All commenters recommended deleting the requirement to report changes in staffing. Several commenters requested that we clarify which changes in organizational structure require notifying CMS and the SAA because it appeared that any change of job title or the creation of a position or unit within the PO would warrant prior approval by CMS and the SAA. It was also noted that various staffing changes and shifts in reporting relationships can be implemented seamlessly with no disruption in service to the participants.

Approval of organizational changes was another topic that elicited comments. Some commenters suggested that the requirements regarding approval by CMS and the SAA of changes in organizational structure be deleted because micromanagement could impede a PO's ability to proactively adjust its structure to meet prevailing concerns as well as to respond to the needs of enrollees. Other commenters thought that advance approval by the SAA should be sufficient.

There were also a number of recommendations of timeframes for submitting advance notification. Suggestions ranged from not informing CMS at all to 60 days, which would include time for CMS and the SAA to review and approve the proposed organizational change. If CMS and the SAA did not respond within the 60-day period, the PO's organizational changes would be deemed approved. Some commenters suggested we follow the State Medicaid regulations of some States, which require notification at least 14 calendar days before the effective date of the change. Another commenter suggested that we require prior notification and approval of changes in ownership and only require notification of other changes in clinical or administrative structure.

One commenter recommended the regulatory language specify that the PO is responsible for forwarding information relating to changes in organizational structure to the consumer advisory committee.

Several commenters agreed that changes that impact the day-to-day experience of the participants or alter their normal patterns of interaction with the PACE program should be communicated to participants in sufficient time for them to adjust to the changes, and that this notification should be the responsibility of the PO.

Response: Comments on this section address three separate requirements, the requirement for CMS and the SAA to be notified in writing at least 60 days before a change in organizational

structure, the requirement that CMS and the SAA approve changes in organizational structure, and the requirement that changes in organizational structure approved by CMS and the SAA be forwarded to the consumer advisory committee.

We established this section in the 1999 interim final rule to require disclosure of organizational changes that affect the philosophy, mission, and operations of the PO and impact care delivery to participants. At that time, we believed that any change in ownership, relationships to another corporate board and to any parent, affiliate, or subsidiary corporate entities, the PACE governing body, its officials, program director, and medical director could result in a substantial impact on the participants and their care. However, it was not our intent to require the PO to notify CMS and the SAA in writing every time there was a change in personnel or a change in the line of reporting of direct participant care staff.

The 1999 interim final rule required that POs planning to change their organizational structure must notify CMS and the SAA, in writing, at least 60 days before the change takes place. This timeframe was to allow sufficient time for CMS and the SAA to approve or deny the proposed change. We agree with the commenters that notification of 60 days before implementing a change in organizational structure is unnecessary.

Therefore, in response to the numerous comments relating to the disclosure of changes in organizational structure, in this final rule we are amending this section to require any PO who is planning a change in organizational structure to notify CMS and the SAA, in writing, 14 days before the change takes place. We believe that 14 days advance notice provides an adequate timeframe for CMS and the SAA to review the changes, and is consistent with some States Medicaid notification requirements.

We are also deleting the requirement that changes in organizational structure must be approved in advance by CMS and the SAA. We agree with the commenters that POs have the ability to make such business decisions based on their individual circumstances. However, as CMS and the SAA are responsible for the health care provided to participants, requiring notification will allow CMS and the SAA to monitor whether the change is having a substantial impact on the participants or their care.

In the 1999 interim final rule, the PO was required to forward the CMS and SAA approval of their organizational changes to the consumer advisory committee. As changes will no longer need to be approved by CMS and the SAA we believe the requirement to forward the CMS and SAA approvals to the consumer advisory committee is now unnecessary and should also be removed.

We reiterate that in the event of a change of ownership, CMS would apply the general provisions described in § 422.550 (Effect of change of ownership or leasing of facilities during term of contract.)

Comment: Another commenter questioned whether two organizations wishing to develop PACE as a cooperative venture must establish a separate and distinct entity to comply with all requirements and provisions of the regulations. The commenter believed this approach would impede PACE development by restricting opportunities for entities to jointly approach PACE development. This commenter also requested clarification of the regulations to clearly permit flexibility within the provider community, including the ability for the PO to contract for the PACE center services.

Response: We view this comment as addressing two different issues. First, in response to whether a separate and distinct entity would need to be established if two organizations developed a cooperative venture, the organizations involved would need to establish a separate and distinct entity to be the PO that is responsible for complying with all requirements and provisions of the regulations. Because the PO signs a three-way program agreement and is the entity responsible for the management of the organization, we believe that this needs to be a single entity. The PO is the responsible entity for assuming full financial risk, administration activities, and comprehensive coordinated participant care. We do not believe these responsibilities can be split up and still maintained under a single entity. In our experience, this requirement has not unduly restricted organizations from developing a PO through a cooperative agreement.

The second issue is whether the cooperative venture arrangement would be precluded from using subcontractors. As long as the arrangements designated a PO, as noted above, the 2002 interim final rule provided flexibility to allow for contracting out all required PACE services as well as the PACE center services, providing that the PO retains all key administrative functions including marketing, enrollment, QAPI, and contracting for institutional providers and other key staff, as well as retaining ultimate responsibility for oversight of all direct participant care.

Final rule actions:

In this final rule, we are changing the requirements related to changes in organizational structure by:

- Requiring 14-days notice before making organizational changes;
- No longer requiring CMS and SAA approval; and
- No longer requiring the PO to forward the CMS approval to the consumer advisory committee.

Section 460.62 Governing Body

In the 1999 interim final rule, we established the requirements and responsibilities of the governing body that is legally and fiscally responsible for the administration of the PO. We left the specific approach to administration of the PO to the discretion of the governing body, reflecting our goal of promoting the effective management of the organization without limiting flexibility in determining how to achieve that goal.

The governing body must create and foster an environment that provides quality care that is consistent with participant needs and the program mission. To that end, the primary requirement is that an identifiable governing body, or designated person(s) so functioning, have full legal authority and responsibility for the governance and operation of the organization, the development of policies consistent with the mission, the management and provision of all services (including the management of contractors), fiscal operations, and the development of policies on participant health and safety. Also, the governing body will establish personnel policies and contract provisions with respect to employees or contractors with patient care responsibilities giving adequate notice before leaving the PO's network. These provisions would be intended to avoid disruptions in care and permit orderly transition of responsibilities.

We included a requirement that the governing body be responsible for the QAPI program. The purpose of this requirement is to link the development, implementation, and coordination of the ongoing QAPI program with all aspects of the PACE program. We believe this requirement will stimulate an aggressive effort by the organization to identify and use the best available practices for all participants. As discussed in the section on the QAPI program, the PO has the flexibility to design its own quality improvement program.

Consistent with the Protocol, we also included a requirement that the PO

must ensure community representation on issues related to participant care. This may be achieved by having a community representative on the governing body. In addition, the PO must establish a consumer advisory committee to provide advice to the governing body on matters of concern to participants. As we indicated in the 1999 interim final rule, consumer participation through advisory committees is a well-accepted community organization vehicle to maximize the involvement of participants in a program designed to serve them. With the use of such a committee, the governing body will have the benefit of participant input, including information on quality of care issues. Participants also are likely to feel a greater stake in the operation of the program. In order to ensure appropriate representation, participants and representatives of participants must constitute a majority of the membership of this committee. One specific duty of the participant advisory committee is to receive information from the governing body to be disseminated to participants.

Comment: We received several comments regarding community representation on the governing body. Commenters noted that a single consumer representative did not have a sufficient impact on health programs when the governing body is made up almost entirely of provider representatives. The commenters requested that the regulations be changed to require at least one-third of the governing body to be community representatives who are Medicare or Medicaid beneficiaries or are designated by organizations that advocate for these persons. In addition, they recommended that the governing body should include at least one PACE program participant and one family member of a participant. They also requested that we include a requirement that the PO provide information to CMS and the SAA to ensure compliance with community representation on the governing body.

One commenter stated that because POs are small programs, they may find it difficult to comply with the requirement of a consumer advisory committee in that it may be difficult to get enough consumers or their representatives to serve on an ongoing committee. They suggested instead that POs be allowed to request a waiver of this requirement, where they can demonstrate that sufficient opportunities exist for obtaining input from consumers and their representatives on matters of concern to participants.

Response: In response to these commenters, we are revising the regulation by changing the names and focus of the ''consumer advisory committee'' to the ''participant advisory committee'' and the ''community representative'' to the ''participant representative.'' We are also adding a definition of ''participant representative,'' which defines the responsibilities of this individual. We disagree with the commenters who indicated that the governing body needs to have a greater number of consumer representatives. By changing the names and objectives of the consumer committee and community representative, we anticipate participants and their representatives becoming more involved in topics that impact their care. We believe that the more participants feel they are stakeholders, the more involved they will be in their PO.

The interactive nature of the PACE model is such that participants are encouraged to be involved and voice their opinions. Therefore, we expect the governing body to be more receptive to participant input presented by the participant representative. This collaborative relationship is expected to achieve higher quality of care and higher participant satisfaction. Therefore, we would not be inclined to waive this requirement without significant justification on the part of the PO.

We do not specify how large the participant advisory committee must be, but we expect it to be representative of the size and population of the PO's participants.

We also understand that there may be topics or times when the governing body would believe that it is inappropriate for participants to attend the entire governing body meeting. When this occurs, we would expect the meeting agenda to be arranged such that the participant representative could attend a portion of the meeting to present participant issues.

We also disagree with the commenter that requested we require POs to submit information to ensure compliance with community representation on the governing body. Minutes and other official documents pertaining to governing body meetings must be available for review by CMS and the SAA during onsite visits and at the request of either agency.

Final rule action:

In this final rule we are:

- Changing the names and responsibilities of the consumer advisory committee, community representative to the participant advisory committee, and participant representative; and
- Rearranging the order of the requirements.

Section 460.64 Personnel Qualifications for Staff With Direct Participant Care Contact

We indicated in the 1999 interim final rule that although the Protocol does not specify personnel requirements for the various staff employed by or under contract with the PO, we believe that certain minimum standards must be met in order to ensure quality of care for the frail elderly population being served. To this end, we established § 460.64.

Our approach to personnel qualifications in the 1999 interim final rule followed principles described in a March 10, 1997 **Federal Register** publication proposing changes to the COPs for home health agencies (62 FR 11022). This is a flexible approach, which relies on State requirements as much as possible.

The personnel qualifications fall into three categories: (1) Personnel for whom there are statutory qualifications; (2) personnel for whom all States have licensure, certification, or registration requirements; and (3) personnel for whom we have specified requirements if the State does not have licensure, certification, or registration requirements.

Category 1: This category consists of personnel for whom the Act contains qualifications, which in § 460.64(b) pertains specifically to physicians. Section 1861(r) of the Act defines a physician as a doctor of medicine or osteopathy, legally authorized to practice medicine and surgery by the State in which that function or action is performed, or certain other practitioners for limited purposes. We adopted the definition as reflected in regulations at 42 CFR 410.20.

In addition, to reflect the key role of the PCP in the PACE model, we required the PCP to have a minimum of 1 year's experience in working with a frail or elderly population.

Category 2: For this category of personnel qualifications, we deferred to State law. We specified that all staff (employee or contractor) of the PO must meet applicable State requirements. That is, they must be legally authorized (currently licensed or, if applicable, certified or registered) to practice in the State in which they perform the function or action and must act within the scope of their authority to practice. For example, to practice nursing, every registered nurse in the State must be licensed and practice within their State's scope of practice authority.

Category 3: This category of personnel qualifications includes certain professions for which not all States had licensure, certification, or registration requirements. Our intention was that if a State has licensure, certification, or registration requirements for a professional listed in this section, then the State qualifications would apply. The following requirements would only apply to those personnel in Category 3 when the State they practice in does not have licensure, certification, or registration requirements.

After reviewing the personnel requirements of other Medicare and Medicaid providers that serve populations similar to PACE participants (for example, home health agencies, nursing facilities), in the 1999 interim final rule, we established personnel requirements for POs that were as consistent as possible with those applicable to other Medicare providers. If a State does not have licensure, certification, or registration requirements applicable to the following professions, then the qualifications specified below apply.

We required that the registered nurse be a graduate of a school of professional nursing and have a minimum of 1 year's experience working with a frail or elderly population.

We required that the social worker (1) have a Master's degree in social work from an accredited school of social work; and (2) have a minimum of 1 year's experience working with a frail or elderly population.

We required that the physical therapist (1) be a graduate of a physical therapy curriculum approved by the American Physical Therapy Association, the Committee on Allied Health Education and Accreditation of the American Medical Association, or the Council on Medical Education of the American Medical Association and the American Physical Therapy Association or other equivalent organizations approved by CMS; and (2) have a minimum of 1 year's experience working with a frail or elderly population.

We required that the occupational therapist (1) be a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; (2) be eligible for the National Registration Examination of the American Occupational Therapy Association; (3) have 2 years of appropriate experience as an occupational therapist and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that this determination of proficiency does not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977; and (4) have a minimum of 1 year's experience working with a frail or elderly population.

We required that the recreation therapist or activities coordinator have 2 years experience in a social or recreational program providing and coordinating services for a frail or elderly population within the last 5 years, one of which was full-time in a patient activities program in a health care setting.

We required that the dietitian (1) have a baccalaureate or advanced degree from an accredited college with major studies in food and nutrition or dietetics; and (2) have a minimum of 1 year's experience working with a frail or elderly population.

We required that all PACE center drivers (1) have a valid driver's license to operate a van or bus in the State of operation; and (2) be capable of and experienced in transporting individuals with special mobility needs.

We did not define personnel requirements for the PACE center manager or the home care coordinator. We gave POs the flexibility to determine who is best suited to fill these positions as each PACE center may have different needs. Because the home care coordinator is responsible for acting as the liaison between the IDT and the home care providers, she or he should possess good leadership and communication skills. In addition, the home care coordinator should be able to identify and understand participants' medical and social needs in order to evaluate the home care needs of participants. As a result, we indicated that a registered nurse or social worker would be a good candidate to fill this position. However, it was not our intention to deter the PO from considering another candidate with appropriate qualifications because they were neither a registered nurse nor a social worker.

We did not impose personnel requirements for personal care attendants (PCAs) as these individuals will primarily be providing non-skilled, personal care services (such as bathing, toileting, and transferring). In the 1999 interim final rule, we solicited comments on whether to include specific personnel requirements for PCAs. It is important that PCAs possess certain basic skills necessary to provide quality care to PACE participants. Thus, we required POs to implement a training program for each PCA to ensure that they exhibit competency in basic skills in personal care services. Although we did not define the parameters of the training program, we indicated the training program should include maintenance of a clean, safe, and healthy environment; appropriate and safe techniques in personal hygiene and grooming; safe transfer techniques and ambulation; reading and recording temperature, pulse, and respiration; and observation, reporting, and documentation of patient status and the care or service furnished. In addition, the training program developed for each PCA must include other elements consistent with their assigned duties for specific participants.

Finally, we acknowledged that PCAs in the home environment may furnish not only personal care services, but also home care services. Therefore, when the participant needs home care services, the PO must ensure that it has qualified staff (either employees or contractors) that meet the competency requirements established by the PO and approved by CMS for home care aides to furnish these services.

We received a large number of comments regarding personnel requirements.

Comment: Numerous commenters were concerned that the 1999 interim final rule did not appropriately emphasize that State licensure laws, certification, and registration requirements take precedence over the requirements specified in the 1999 interim final rule which may lead to creating unnecessary and unintended conflicts between the PACE regulation and State requirements.

Commenters believe establishment of provider qualifications is traditionally a State function. The commenters indicated it would be sufficient for the regulation to specify that individuals providing PACE services meet applicable State requirements. It was suggested that States be permitted to define a combination of education and experience qualifications and that CMS grant a waiver of these educational and experience requirements if there are staff development procedures in place for those waived individuals, and where the PO's decision to hire staff without the required qualifications will not adversely impact the quality of care. Commenters also recommended that services that do not require State licensure or certification not be subject to additional requirements in Federal regulations.

There was also concern that the requirements set forth in the 1999 interim final rule would be adopted as minimum Federal requirements, regardless of whether State licensure, certification, or other registration exists. If this adoption takes place, the PO's burden of locating adequate numbers of staff will be magnified. Recommendations ranged from removing personnel qualification requirements to allowing health professionals to be permitted to minimally meet State requirements for medical professional practice.

Response: In establishing personnel qualifications, we did not intend to usurp the State's authority. Throughout the regulation, we have indicated that POs must meet all Federal, State, and local regulations and laws. We believe that the present qualifications established for PACE set forth the necessary qualifications to ensure the health and safety of this frail elderly population. Should State regulations be more stringent than those of this regulation, then the PO must meet the State requirements as well.

We believe there was considerable confusion and misunderstanding of the personnel qualification requirements published in the 1999 interim final rule. In that rule, we based personnel qualifications on whether the State had licensure, certification, or registration requirements for a profession. In States where there was no State licensure, certification, or registration, we required minimum educational qualifications for each profession.

In response to the comments and to reduce the confusion over personnel qualifications, we are amending the title of § 460.64 and the personnel qualifications to clarify that the qualifications apply to all PACE staff with direct participant contact, to ensure the health and safety of the participants. We are accomplishing this by consolidating and clarifying requirements in § 460.64(a) that were previously located in other sections of the PACE regulations and by deleting paragraph § 460.64(c).

We are amending the title of § 460.64 and the personnel qualifications to clarify that the qualifications apply to all PACE staff with direct participant contact and decrease the burden in hiring and contracting for adequate numbers of staff members. We are removing the educational requirements and other qualifications at § 460.64(c) that we established where no States required licensure, certification or registration.

We believe that it is essential that all professionals be legally authorized (licensed, certified or registered) to practice in the State in which they practice if the State has established requirements. All States have licensed, certified or registered requirements for physicians, registered nurses, social workers, physical therapists, occupational therapists, and dietitians. All other direct care providers, must meet the State requirements that authorize them to practice in their State. We believe that all professions must act within the scope of their authorized practice guidelines. Each profession has established guidelines that define the services that may be performed within the scope of the minimum level of knowledge and training for each professional level. For example, the scope of practice is different for licensed practical nurses, registered nurses, clinical nurse specialist and nurse practitioners. Regardless, each nurse is expected to practice within his or her respective level.

In the 1999 interim final rule, each profession listed in § 460.64 (b) and (c) was required to have one year of experience working with the frail or elderly population (except for the Recreational Therapist/Activity Coordinator who was required to have two-years experience). The PACE population is comprised of the frail elderly who need to be cared for by staff that has the specific training and experience to understand the complexities and differences in geriatric patients. It is essential for staff to have the knowledge of geriatric practices and skill to work with these individuals. Experienced staff will be conscious that when dealing with the frail or elderly they need to be gentler, more patient and observant than with a healthy younger person. For example, a frail elderly person's skin is more likely to tear, a bone is more likely to break, a joint more likely to be stiff and painful, and medications are more likely to affect them differently with a potentially wider variety of adverse reactions. Therefore, we believe that all personnel having direct participant contact must have a minimum of one year of experience working with a frail or elderly population and are adding this requirement to the general requirements in paragraph (a)(3).

In the 2002 interim final rule, we established requirements for the oversight of direct participant care (§ 460.71), which included requiring the PO to ensure all employees and contracted staff furnishing direct care to participants demonstrated the skills necessary for performance of their position. We also required the PO to establish a competency evaluation program, which has to be evidenced as completed before an individual may perform participant care. We believe that demonstrating competency prior to performing direct participant care is essential to ensure the delivery of safe care. Therefore, we are adding competency as paragraph (a)(4) to the general personnel qualification requirements for staff performing direct participant care.

Section 460.71, Oversight of direct participant care required the PO to develop a program to ensure all staff furnishing direct participant care was free of communicable disease. We believe this is even more important with a frail elderly population considering their complex medical conditions and increased susceptibility. It is standard practice in the health care industry that an individual must be cleared as free of communicable disease prior to employment. We are therefore amending § 460.64 to require that all PACE staff with direct participant contact be medically cleared of communicable disease and have all immunizations up-to-date before engaging in direct contact with participants.

For those professions where not all States have licensure laws, State certification or registration requirements, specifically Recreation therapist/Activity coordinator and drivers, we believe that all States have minimum requirements to ensure that services are provided safely. For example, States require a special class of driver's license to transport people for money. In addition to the general personnel qualifications, we expect that any such State qualification requirements be met.

Comment: A large number of commenters opposed the Federally-defined qualifications for the physician which were not included in the Protocol.

Response: As stated above, section 1861(r) of the Act generally defines a physician and is reflected in 42 CFR 410.20, which defines physician, physician services and the limitations on services under the Medicare program. As all physicians participating in the Medicare program must meet § 410.20, we require that all physicians participating in the PACE program meet the qualifications of § 410.20, and also meet the general qualification requirements as stated in § 460.64(a).

To emphasize the key role of the PCP in the PACE model, we require the PACE PCPs to have one-year's experience working with a frail or elderly population to ensure their knowledge and skill with geriatric

patients. We require they demonstrate their competency prior to employment or contract. The PO must ascertain the competency of prospective physicians through the PO's established competency program. We also require the PCPs be cleared of communicable diseases to ensure that infectious diseases are not passed by the close physical proximity necessary to treat participants.

Comment: We received numerous comments related to specific staffing requirements. A large number of commenters opposed the detailed personnel requirements in the 1999 interim final rule, stating that they unnecessarily limited flexibility in the development and implementation of PACE programs.

The commenters recommended we require all POs establish an adequate staff development process to ensure that all staff members understand the unique needs of the PACE population. However, commenters wanted the States to have the option to waive these requirements. They also recommended we require that the PO also consider factors such as languages spoken and cultural sensitivity.

Response: To the extent the State has licensure, certification, or registration requirements, these apply and not the requirements in § 460.64(c)(1).

These qualification requirements, as noted in the 1999 interim final rule, were to be the regulatory foundation of PACE as a new Medicare benefit and State plan option. We believe that in clarifying the 1999 interim final rule in the 2002 interim final rule, permitting contracting of personnel and providing a waiver process to assist POs where they are unable to comply with regulations, we have addressed and resolved commenters concerns related to limited flexibility and personnel qualifications when no State licensure, certification, or registration laws exist.

We believe we addressed the recommendation regarding the establishment of an adequate staff development process to ensure all staff members understand the unique needs of the PACE population in the 2002 interim final rule, which required that all POs develop a competency evaluation program that identify those skills, knowledge and abilities that must be demonstrated by direct participant staff.

• In response to the recommendation that we require that the PO also consider factors such as languages spoken and cultural sensitivity, we believe that each PO understands the cultural diversity of their particular population. To be in compliance with the requirements of participant rights they must provide for language and cultural diversity, we expect that POs will take these important areas into consideration when hiring staff. As a result, we do not believe that it is necessary to repeat the requirement in this section of the regulation.

Final rule actions:

In this final rule we are making revisions to § 460.64, including:

• Amending the title to ''Personnel qualifications for staff with direct participant contact,'' to clarify that the qualifications apply to all PACE staff with direct participant contact.

• Amending paragraph (a) by adding (1) one year of experience working with a frail or elderly population, (2) meeting standardized competencies prior to providing participant care, and (3) being medically cleared of communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.

• Deleting paragraph (c).

Section 460.66 Training

In § 460.66, we require the PO to provide ongoing training to maintain and improve the skills and knowledge of each staff member with respect to their specific duties. The training should result in the staff's continued ability to demonstrate the skills necessary for the performance of their specific positions or job duties. The ability of the PO to ensure patient safety and to achieve patient-specific performance measures necessitates competent staff. We believe there is a direct relationship between the quality of an organization's staff and patient well-being. The training requirement is intended to ensure that all staff are able to adapt to new or changing job demands. The PO is responsible for ensuring that individuals are educated and trained for their specific jobs. The individuals would continue to be responsible for their own professional education and for any continuing education needed to maintain licensure or professional certification unless the organization chooses to assume this responsibility. In addition, we included a specific training requirement for PCAs as described in § 460.66(b).

Comment: Commenters' opinions regarding the training requirements varied, with recommendations that the SAA should be authorized to establish a minimum training curriculum, and criticisms that the PO should be permitted to utilize training from other sources available in the community.

We were also asked to clarify whether PCAs, who have demonstrated competency in furnishing personal care services through certification as nursing assistants or home health aides, are required to receive redundant or additional training unless it is deemed necessary by the PO.

Response: We are retaining the requirement that POs provide ongoing training to maintain and improve the skills and knowledge of each staff member with respect to their specific duties in order to ensure that PACE participants receive the highest quality care possible. We believe POs have the ultimate responsibility for all care provided to their participants and, therefore, it is in the best interest of PACE participants and the PO that they provide training specific to their participant population. Ongoing in-service training for all staff will ensure that skills remain current and any detrimental practices are caught and rectified as early as possible.

In this final rule, we wish to clarify § 460.66(b), which requires the PO to develop a training program for each PCA in order to establish the individual's baseline competency in furnishing personal care services, including specialized skills associated with the specific care needs of individual participants. We intend that the PO evaluate the skills of each newly hired PCA and develop a training program specific to the competencies or deficiencies that they demonstrate. This training must be performed by qualified professionals. Again, the intent of this training requirement is to identify and resolve any knowledge or skill deficits of each person and educate them to a level where they can demonstrate competency in all basic skills required to provide personal care services. This clarification is intended to prevent redundant training of skills already displayed by PCAs and to reduce the burden on PO resources.

Final rule actions:

In this final rule, we are clarifying the requirement in § 460.66(b) that POs develop a training program for PCAs where there are competency deficits and that personal care attendants must exhibit competency before performing personal care services independent of supervision.

Section 460.68 Program Integrity

We established § 460.68, based on Part I, section E of the Protocol to guard against potential conflicts of interest or other program integrity problems for POs. An organization must not have any staff (employees or contractors) who have been convicted of a criminal offense related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or

any social service program under Title XX of the Act. We expanded this provision from the Protocol in order to prevent an organization from employing any staff who have been excluded from participation in Medicare or Medicaid, or employing staff, in any capacity, where the employee's contact with participants would pose a potential risk because the individual had been convicted of physical, sexual, drug, or alcohol abuse. In addition, members of the PO's governing body, and their family members, are prohibited from having a direct or indirect interest in contracts with the PO. Examples of indirect interests are holdings in the name of a spouse, dependent child, or other relative who resides with the member of the governing body. These requirements are intended to protect participants by preventing fraud under Medicare and Medicaid by members of the governing body with conflicts of interest from inappropriately influencing PO decisions.

We recognize that in rural, Tribal, or urban Indian communities there may be limited availability of individuals willing to and capable of performing key functions for the PO. Therefore, the 1999 interim final rule provided for CMS and the SAA to grant a waiver of the conflict of interest requirement for POs in rural or tribal areas to allow individuals who have a direct or indirect interest in a contract or the provision of services to the PO to recuse themselves from decisions directly or indirectly affecting those interests, rather than barring them entirely from serving on the PO's governing body or serving as directors, officers, partners, employees, or consultants of the PO.

We also included a requirement that the PO must have a process to gather information on program integrity issues and respond to any request from CMS within a reasonable amount of time.

As discussed previously, in the 2002 interim final rule, we established a process for submission and approval of waiver requests and deleted § 460.68(c) that limited waivers to direct or indirect interest in contracts of rural and Tribal organizations. Although we deleted § 460.68(c), we continue to recognize the special need for flexibility in rural and Tribal areas, and remain committed to allowing waivers to promote PACE in medically underserved areas. We also remain committed to working with rural and Tribal communities to help them address the challenges of developing successful PACE programs. Organizations that seek waiver of these or any other regulatory requirements would follow the requirements specified in § 460.26.

Comment: We received several comments regarding program integrity. Commenters requested that we permit the PO the discretion to determine whether an individual's past convictions (which vary greatly in type and severity) would pose a serious threat to PACE participants and suggested modifications to § 460.68(a)(3).

Response: We believe our current policy is consistent with Medicare policy related to other provider types and do not agree that the threat posed by an individual's past convictions should be left to the discretion of the PO. PACE participants are the most frail and vulnerable members of the community, and it is their right to expect care that is free from the risk of harm by their caregivers. Therefore, it is the responsibility of Medicare, Medicaid, and the PO to ensure that every individual hired to provide care to PACE participants poses the least risk possible. We believe that facilitating contact with individuals who have a prior conviction for physical, sexual, drug or alcohol abuse increases the potential risk to the PACE participants.

Comment: One commenter recommended that conflict of interest disclosure regulations apply to the program director, medical director, and the contractor liaison. This commenter also recommended requiring disclosure of conflicts of interest to the SAA. Another commenter recommended the disclosure requirement also apply to the SAA.

Response: We discuss the SAA's role with regard to conflict of interest in this section. However, as the program director, medical director, contractor liaison, and the SAA are not on the governing body and have no voting responsibility, we do not think they are in a position to unduly influence PO decisions. Therefore, we do not believe it is necessary to amend the program integrity requirements to include them. We note that § 460.68 does not preclude a PO from developing disclosure requirements for other staff.

Comment: Two commenters requested we clarify whether the regulatory intent of § 460.68(b) is to limit contracting with related organizations or just related individuals, as many providers establish related corporations which provide services to participants and which were not prohibited in the PACE demonstration program.

Response: The intent of this requirement was to limit an unfair advantage that might be gained by any member of the governing body, or their family member, who would have a direct or indirect interest in an entity contracting with the PO for items or services.

We acknowledge that it is quite common for a PO to be part of or have a relationship with a larger entity. Consistent with § 460.60(d) and Chapter 1, Section VII of the PACE provider application, the POs' relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entity must be described in the provider application under the requirements for organizational structure. In this type arrangement it would be customary to contract for services with other entities within the system. As these are entity-to-entity arrangements and no individual would personally benefit, these kinds of common business practices do not give rise to the type of conflict of interest contemplated under § 460.68(b).

Since implementation of the 2002 interim final rule, we have also received numerous requests for waiver of this section of the rule. These waivers have been approved as general organization-wide waivers contingent upon the PO developing policies and procedures for: (1) Full disclosure to the governing body of the direct or indirect conflict or potential conflict of interest of the member or an immediate family member related to the conflict; (2) recusal of voting, discussions, negotiations or any activity that would directly or indirectly affect the interest of the PO; and (3) inclusion of the disclosure and recusal actions in official records and that are readily accessible to CMS and the SAA.

In response to commenters' requests, and based on our experience with reviewing waiver requests relating to conflicts of interest procedures, we are amending § 460.68(b) to clarify our requirements for managing conflicts of interest that may involve members of the governing body or any immediate family members. We are requiring that POs establish policies and procedures for handling such conflicts of interest, that members of the governing body must disclose any such conflicts, and that members must recuse themselves from discussing, negotiating, or voting on any matter that involves an inappropriate conflict of interest.

To illustrate, we believe the following is a conflict of interest of an immediate family member: The wife of a board member owns a supply company which is the only one in the area that provides institutional laundry services, so the PO has no option but to contract with this company. The governing body member must make full disclosure of the situation to the body, and recuse themselves when the contract

negotiations are in progress as well as when voting on the contract occurs.

In response to the comments related to the SAA, we do not believe it is appropriate for CMS to impose conflict of interest restrictions on the SAA as they are not on the PO's governing body. Our concern is that decisions made by the governing body could be made specifically for the financial benefit of certain members of the governing body or their immediate family members.

All disclosure and recusal information must be recorded in the governing body's official records, which must be available for CMS and SAA review. CMS and SAA are both authorized to review this information, which can be accomplished during on-site monitoring and survey activities, or by requesting the information from the PO. Additionally, if a conflict exists at the time a provider submits their PACE provider application, we expect the PO to disclose the conflict as part of the application.

Comment: One commenter asked if the conflict of interest requirements may be waived in rural, Tribal and urban Indian communities. The commenter also asked if those areas have been designated eligible for conflict of interest waivers, and if so, they requested that the information be shared with the States.

Response: The 1999 interim final rule provided for a waiver of conflict of interest in rural, Tribal, and urban Indian communities. As a result of expanding waiver flexibility to all POs in accordance with section 903 of BIPA, that specific waiver authority, located in § 460.68(c), was deleted in the 2002 interim final rule. We established § 460.26 to implement the expanded waiver process. As previously noted, POs will now be required to have written policies and procedures in the event of a conflict of interest, and, therefore, waiver of conflict of interest will not be necessary.

Comment: Two commenters addressed conflict of interest disclosure related to the SAA. One commenter asked whether States have the responsibility to ensure the disclosure requirement is met.

Response: The SAA is not delegated the responsibility of ensuring that conflicts of interests are disclosed. The regulation does not require full disclosure to CMS or the SAA, but the PO must be able to provide documentation should CMS or the SAA request it.

Final rule actions:

In this final rule, we are providing for disclosure and recusal in the event of a conflict of interest of a member of the PO's governing body or their immediate family member(s).

Section 460.70 Contracted Services

Under the scope of benefits described in sections 1894(b)(1) and 1934(b)(1) of the Act, a PO may enter into written contracts with each outside entity to furnish services to participants. Consequently, we require in § 460.70 that all services, except for emergency services as described in § 460.100, not furnished directly by a PO must be obtained through contracts, which meet the requirements specified in regulations. In the 1999 interim final rule, we adopted the contracting provisions in Part VII, section A of the Protocol.

We specified in § 460.70(b) that a PO may only contract with entities that meet all applicable Federal and State requirements, and provided some examples of the types of requirements that contractors would be expected to meet. For example, institutional contractors (hospital and nursing home) must meet Medicare and Medicaid participation requirements. To avoid breakdowns in communication or in the provision of care, we required that POs designate an official liaison to coordinate activities between contractors and the organization. Effective coordination of services is necessary to avoid duplicative or conflicting services. Designating an individual as liaison provides a conduit for sharing information. The liaison would inform contractors of PO policies, changes in participants' plans of care, information from team meetings, and quality improvement activities and goals. Contractor staff would inform the PO, through the liaison, of updates and changes in a participant's status, personnel changes in the contractor, and any other information necessary for the continuity of participant care. All care must be evaluated by the PO, with particular attention to care provided by contracted personnel. This requirement provides a mechanism to ensure that contracted personnel are adhering to organization policies and procedures. It also affords the organization an opportunity to identify any education or training needs of contracted personnel.

We specified in paragraph (c) that the PO is required to maintain a current list of contractors at the PACE center and provide a copy to anyone upon request and in paragraph (d) that copies of signed contracts for inpatient care must be furnished to CMS and the SAA.

Under the specific contract content requirements listed in paragraph (e), we require each contract to be in writing and contain the following information:

- Name of contractor.
- Services furnished.
- Payment rate and method.
- Terms of the contract, including the beginning and ending dates, as well as methods of extension, renegotiation, and termination.
- Contractor agreement to: Furnish only those services authorized by the PACE IDT; accept payment from the PO as payment in full and not to bill participants, CMS, the State Medicaid agency or private insurers; hold harmless CMS, the State and PACE participants if the PO cannot or will not pay for services performed by the contractor under the contract; not assign or delegate duties under the contract unless prior written approval is obtained from the PO; and submit reports as required by the PO.

We did not establish a specific notice requirement for termination of contracts. We believe that POs will contract with individuals and entities that understand and embrace the organization's mission and commitment to participants. As discussed previously, we required in § 460.62 that the governing body establish personnel policies that address adequate notice of termination by contractors and employees with direct patient care responsibilities to permit an orderly transition and avoid disruptions in care.

In the 2002 interim final rule, we amended § 460.70(e) to include additional contract requirements where the PO chooses to contract for IDT members or key administrative staff. In amended paragraph (e), we required that contractors: (1) Agree to perform all the duties of their position; (2) participate in IDT meetings; (3) agree to be accountable to the PO; and (4) cooperate with the competency evaluation program and direct participant care requirements in § 460.71.

The PACE Protocol at section IV.B.13.a. provided that the IDT may be employed by the PO or the PACE center. In developing the 1999 interim final rule, we did not address this issue because we believed that in all cases the PO and the PACE center were the same organization. After publication of the 1999 interim final rule, we learned that in 1995, changes were made to the Protocol to permit contractual arrangements for all PACE center services, which reflected an operating arrangement engaged in by one of the PACE demonstration programs, On Lok Senior Health Service. Through this contractual arrangement, On Lok, Inc. had been able to expand PACE services to a different part of their service area without disrupting the care that

traditionally had been provided by the other organization.

As described above in the 2002 interim final rule, we amended the 1999 interim final rule to allow POs to provide PACE center services through contractual arrangements. As we explained in the 2002 interim final rule, we did not view this approach as a waiver authorized by BIPA. Rather, we established specific requirements for this approach consistent with the On Lok, Inc. arrangement (67 FR 61499). We added a new paragraph (f) to § 460.70 to identify the criteria that a PO must meet to contract out PACE center services. We explained in the 2002 interim final rule that we are not inclined to approve this arrangement for a PO unless it is financially stable and has demonstrated competence with the PACE model by successful CMS and State onsite reviews and monitoring efforts.

We expect the PO to retain all key administrative functions including marketing and enrollment, QAPI, and contracting for institutional providers and other key staff. We noted that, consistent with § 460.70(e)(5)(iv), any subcontracting arrangements by the PACE center would need to be approved in writing by the PO. The PACE center may employ or contract for the team and provide PACE services in accordance with the PACE regulation. However, the PO receives all payment from CMS and the State and remains responsible for all the care provided in these centers. In addition, we emphasized that contracting out PACE center services does not change the participants' relationship to the PO. All participants, whether assigned to the PO-operated PACE center or assigned to a PACE center that contracts with the PO, are enrolled with the PO and are afforded all benefits and protections offered by the PO.

On Lok, Inc. is able to monitor the care provided in the contracted PACE center through the sharing of electronic medical records. While we did not require electronic medical records as a condition of approval, we believe it is necessary for a PO wishing to pursue this type of arrangement to describe how it will monitor the care provided and perform all the administrative duties required by the PACE regulation.

In the 2002 interim final rule, we also discussed the obligation of the PO to monitor the care provided by contracted entities providing PACE center services now allowed by the amended requirements in that final rule. Given the vulnerable frail population served by the PACE program and the increased opportunity for a PO to contract out participant care services, it is important to reiterate the PO's obligation to monitor the care furnished by direct participant care staff. This obligation applies not only to employees of the PO, but extends to the care provided by contracted staff, including employees of organizations with which the organization contracts (for example, a home health agency, rehabilitation agency, nursing facility, transportation service, or staffing agency). It is especially important for the PO to monitor the care provided in all settings, including the PACE center and the participant's home, as well as in offsite locations such as physician offices and institutional providers to ensure quality care. To effectively monitor care provided outside the PACE center, the PO must be vigilant in following up on all unusual occurrences and complaints. In addition, the PO must foster an atmosphere that promotes the voicing of participant complaints about quality of care to assist the PO in monitoring the care provided by contracted staff and organizations.

In the 1999 interim final rule, § 460.66 required the PO to provide training to maintain and improve the skills and knowledge of each staff member that results in his or her continued ability to demonstrate the skills necessary for the performance of the position. In conjunction with the decision to allow POs to contract for key staff, in the 2002 interim final rule, we created a new § 460.71 to identify PO oversight requirements for PACE employees and contractors with direct patient care responsibilities. We address these requirements later in greater detail and respond to specific comments on this issue. We revised § 460.70(e) to require contractors who furnish direct participant care to cooperate with the requirements of § 460.71 as well.

We received the following questions and requests for clarification regarding contracted services.

Comment: One commenter requested we explain why a contractor must be prohibited from accepting private insurance payments directly.

Response: PACE is a capitated program at full financial risk for all services required by their participants. PACE participants sign an enrollment agreement, which states they must get all services (directly or indirectly) from the PO. To ensure coordination of care directed by the IDT, the PO needs to be aware of all services provided.

If a contractor receives payment directly from a private insurer, the contractor would have been paid twice, once by the PO and once by the private insurer. Therefore, we included § 460.70(e)(5)(ii) to require contractors to accept payment from the PO as payment in full and agree not to charge CMS, the State, the participant, or private insurers for services to PACE participants.

Comment: One commenter asked which entities are considered ''organizational contractors'' that must meet the COPs.

Response: The term ''organizational contractors'' was replaced with ''institutional contractors'' in the 2002 interim final rule. Institutional providers include but are not limited to acute care hospitals, rehabilitation hospitals and distinct part rehabilitation units of acute care hospitals, psychiatric hospitals and distinct part psychiatric units of acute care hospitals, and critical access hospitals, nursing facilities and skilled nursing facilities. The PO must contract only with institutional entities that meet all applicable Federal and State requirements. There are provider-specific COPs for institutions that participate in the Medicare program. Therefore, all institutional contractors must be in compliance with their respective COPs.

Comment: One commenter requested the rationale for singling out inpatient services contracts for submission while contracts with other entities need only be on file.

Response: We agree with the commenter and do not believe the requirement is necessary. For this reason, we are revising § 460.70 to delete paragraph (d). Our experience has indicated that having inpatient service contracts on file, provides sufficient accessibility. CMS and the SAA will review these contracts during routine monitoring surveys.

Comment: One commenter requested clarification of the role CMS expects the SAA to play in ensuring contracts are appropriate.

Response: We expect the SAA to ensure that the PO's contracts meet applicable State and local laws and requirements.

Comment: Commenters asked whether it is acceptable for an entity to submit a prepared but unsigned contract with the initial application and, following a readiness review, submit the signed contract with language specifying that the contract is not effective until the PO's program agreement is signed.

Response: We have determined that it is inappropriate for entities that are not operational to submit signed and dated contracts when they submit their PACE application. Rather, it is acceptable for entities to submit contract templates

with their initial applications. As part of the State readiness review, the SAA determines that all contracts are signed and dated. However, the contracts may not become effective until a program agreement with the entity is signed.

Comment: One commenter indicated that it is unnecessary to designate one official liaison to coordinate contracted services and urged us to leave the coordination of contracted services to the discretion of each PO. The commenter requested that we require the POs to establish a mechanism for the coordination of contracted services, but not specify the means by which to effect this objective.

Response: We do not agree with the commenter that the means of coordinating contracting services should be left up to the discretion of each PO. To ensure the health and safety of the participants, we require a contract liaison to ensure that there is a designated individual with the responsibility and authority to facilitate communication and coordinate activities, to track delivery and follow-up of services related to contractor provided care, and to act as a conduit for contractor issues whether raised by the contractor, the PO, or a participant.

Comment: In the 1999 interim final rule, we requested comments on whether to include a notification timeframe for termination of contractor or employee contracts. Three commenters supported a requirement for prior notification to terminate a subcontract, but each with a different timeframe. One commenter suggested a minimum of 60 days notice, one suggested 90 days, and the last suggested a timeframe that is consistent with M+C (now MA) and Medicaid managed care requirements.

Two commenters did not support a prior notification requirement. One commenter indicated a termination notice can be difficult and may even be contrary to the needs of the participants while the other commenter believed this was a subject best left to the POs and individual contractors. Finally, one commenter indicated that the regulations are sufficiently flexible to allow the POs to structure their employee/contractor agreements in a way that maximizes benefits to the organization and participant.

Response: We agree with the commenter who pointed out that the current regulations are flexible enough to allow the POs to take into account the needs of the organization and the participants. The 1999 interim final rule established the requirement in § 460.70 that the terms of a contract include a specified method of termination. The intent of advanced notice of termination is to provide the participants sufficient time to adjust to a change in providers. We believe the current regulation makes adequate provision for establishing any notification timeframe for termination and are retaining the language in the 1999 interim final rule.

Comment: One commenter indicated that the wording of the 2002 interim final rule may lead to unintended legal implications for contractors and POs. Specifically, the commenter believes that terms ''agree'' and ''accountable'' may be construed as evidence of an employment relationship between the PO and the contractor. The commenter recommended deletion of the accountability provision. In place of the provision, they suggested a written agreement with the contractor which sets forth the contractor's duties and responsibilities.

One commenter responded to our request for comments related to the criteria for contracting out PACE center services by recommending that we should exempt applicants in rural areas from the requirement to have demonstrated competence with the PACE model before they contract out for PACE center services. This commenter also expressed concern regarding contracting for IDT members. The commenter was concerned that contracted IDT members might be unavailable in person, participating in IDT meetings via telephone which would distance them from care planning.

Response: We require POs to have formal written contracts with all service providers, and that these contracts specifically identify the services to be provided and the responsibilities of both parties. The use of the terms questioned by the commenter does not imply an employment relationship. The PO has the ultimate responsibility for all care and services provided to participants including those provided under contract. The PO is also responsible for oversight of participant care. We are, therefore, retaining the requirement for PACE contractors to be accountable to the PO for their performance.

As we indicated in the 2002 interim final rule, we are more likely to allow POs to contract out PACE center services when they have attained experience in delivering services and managing the risk associated with the frail elderly. We continue to believe that an experienced organization will be better equipped to adequately monitor this arrangement and ensure that participants assigned to contracted PACE centers are afforded all benefits and protections offered by the PO.

We are not inclined to exempt all POs in rural areas, as we believe a PO needs experience in operating a PACE center and providing the range of services to understand exactly what they will be ultimately responsible for when they contract for services. The waiver process established in the 2002 interim final rule provides new POs the opportunity to indicate in detail the specific barriers to meeting requirements that would be resolved by contracting for services.

In response to the concern regarding the contracted IDT members being unavailable for care planning, we believe that as the PO has oversight responsibility of all care provided to participants, they will ensure that care planning is performed appropriately by all IDT members.

Comment: We received one comment suggesting that when services are contracted, funds should be allocated to permit contractual staff to participate in all clinical and administrative activities with the PACE program.

Response: Although we agree with the commenter that this could be a beneficial arrangement, we believe CMS should not dictate how POs allocate or spend their resources; thus, making this a regulatory requirement would be inappropriate. However, staff refers to both employed and contracted staff, with no distinction in job duties or responsibilities. Contracted staff are required to perform all the duties of a PACE employee related to their position including, but not limited to, being oriented to the PACE model's philosophy, mission, policies on participant right, emergency plan, ethics, and the PACE benefit, and policies related to job duties; participate in IDT meetings; meet competency requirements; and be accountable to the PO. Therefore, we expect contractual staff to participate in all clinical and administrative activities with the PACE program.

Final rule actions:

In this final rule, we are:

- Deleting § 460.70(d),
- Redesignating paragraph (e) as paragraph (d), and
- Redesignating paragraph (f) as paragraph (e).

Section 460.71 Oversight of Direct Participant Care

We intend that personnel requirements apply to both staff and contractors. In this section, we intend to clarify the requirements for the oversight of direct participant care.

As noted previously, in the 2002 interim final rule, we created a new

§ 460.71 to identify PO oversight requirements for PACE employees and contractors with direct patient care responsibilities. These requirements fall into two categories, that is, (1) competency evaluation and (2) staff and contractor requirements.

- The PO must ensure that employees and contracted staff providing care directly to participants demonstrate the skills necessary for performance of their positions.
- The PO must provide each employee and all contracted staff with an orientation. The orientation must include at a minimum the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and policies and procedures relevant to each individual's job duties.

The PO must develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff (employees and contractors). The program must be evidenced as completed before performing participant care and on an ongoing basis by qualified professionals. The PO must designate a staff person to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff.

We note that the PO may satisfy this requirement for contract staff through receipt of competency evaluation documentation from certain independent contractors where licensure requirements include a competency evaluation component, or from organizations or agencies that employ these individuals and contract with the PO.

The PO must develop a program to ensure that all staff providing direct participant care services meet the requirements listed below. The PO will verify that direct participant care staff or contractors meet the following requirements:

- Comply with any State or Federal requirements for direct patient care staff in their respective settings;
- Comply with the requirements of § 460.68(a) regarding persons with criminal convictions;
- Have verified current certifications or licenses for their respective positions;
- Are free of communicable diseases;
- Have been oriented to the PACE program; and
- Agree to abide by the philosophy, practices, and protocols of the PO.

Comment: One commenter indicated that the requirements pertaining to contracted staff are administratively burdensome and may compromise the PO's ability to contract with high quality providers.

Response: We believe the requirements pertaining to contractual staff are essential for appropriate participation in the PACE benefit. All staff (employees and contractors) need to understand what the PACE service delivery model is and how it differs from other models. With regard to the competency evaluation requirements, we believe they are consistent with PACE, Medicare, and health care industry standards.

Comment: One commenter asked that we clarify the relationship between § 460.71(a) and (b) because they seem to cover similar points (staff and orientation).

Response: We believe § 460.71(a) is a requirement directed towards the education of staff of the PACE model; specifically, § 460.71(a) requires that all staff and contractors receive an orientation to the PACE model, what it is and how it works, and demonstrate clinical competency before performing direct participant care. Section 460.71(b) pertains more to the quality of the staff, as well as ensuring that the PO verify that staff and contractors have certification or licensure, pass a criminal background check, have been determined free from communicable diseases, and are up-to-date with immunizations. As discussed previously in § 460.64, staff furnishing direct participant care must be free of communicable diseases and are up-to-date with immunizations. Thus, we are applying this provision to both contractors and staff, amending § 460.71(b)(4) to clarify that direct participant care staff or contractors must be determined to be free from communicable diseases and are up-to-date with immunizations before performing patient care.

Comment: A commenter requested clarification regarding who is considered a contractor.

Response: A contractor is an entity with a legally binding written agreement to deliver items or services for the PO in return for payment and is not considered an employee of the PO. All contractors must meet PACE competency requirements except for staff in inpatient and nursing facilities that must meet provider-specific COPs.

Comment: One commenter asked that we clarify if references to staff include contracted staff.

Response: In § 460.71(a), we state that the PO must ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position. In most other provisions of § 460.71, we similarly specify that oversight requirements related to direct participant care apply to all employees and contracted staff. For purposes of this regulation, references to staff are intended to include contracted staff. Their orientation to the PACE model, specifying their direct care responsibilities, the days and hours they provide services for the PO to PACE participants, and their demonstration of clinical competency must be accomplished in the same manner as employed staff. We also assume that the PO is aware of the work schedule availability of the staff, both employed and contracted.

Comment: One commenter asked if individual provider competency is required and if mechanisms such as contracting requirements established by the PO for contract providers, credentialing of staff and contractors, State licensing requirements, and Medicare certification requirements would be sufficient for ensuring compliance with § 460.71(b).

The commenter also indicated that requiring orientation of the employees of contracted provider entities (for example, hospitals, nursing homes, home care agencies, transportation providers) will not have any impact on the quality of care provided. The commenter stated that the PO's scarce resources would be better spent in focusing on the quality of communication between the PO and its contractors to ensure participant services are provided appropriately. Communication is viewed as more important than provider knowledge about the PACE program. They requested that POs be granted the discretion to orient contract providers to the program as they deem appropriate.

This commenter also views the requirement that competency evaluation must be completed before performing participant care as problematic. The commenter pointed out that emergency situations may exist where fulfilling this requirement may not be possible (for example, when temporary staff must be called upon to fill in during unanticipated absences).

Response: In response to this comment, we want to clarify that individual provider competencies are required and that contractual agreements, credentialing for physician staff and contractors, State licensure, and Medicare certification are not in themselves proof of competency. The PO must follow-up to validate individuals' competency.

We continue to believe that all direct care providers need to understand the philosophy of the PACE service delivery

model and recognize its unique features that have been proven effective in managing the health care needs of the frail elderly. We expect that during the orientation, the importance of communication will be emphasized as a pivotal aspect of the PACE model. Therefore, we are retaining the current requirement for orienting contractual providers.

Competent staff is of paramount importance when dealing with this frail population. Although we understand that emergency staffing needs may arise, we expect the PO to contract with providers that have provided information and competency evaluation documentation before assigning temporary staff.

Final rule actions:

In this final rule, we are amending § 460.71(b)(4) to clarify direct participant care staff or contractors must be determined to be free from communicable diseases and are up-to-date with immunizations before performing patient care in order to be consistent with the general requirements of § 460.64(a).

Section 460.72 Physical Environment

As we explained in the 1999 interim final rule, we established § 460.72 to ensure that the PACE center and home are free of hazards that may cause harm to the participants, staff, or visitors. Because issues of adequate space, infection control, fire prevention, dietary services, and the safety of transportation services are important to ensure quality care, we added requirements for each in the regulation.

We maintained the following requirements from the PACE Protocol, with the modifications noted below:

- The PACE center must be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors;
- The PACE center must ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services, that protects the dignity and privacy of the participant; and
- The PACE center must include sufficient suitable space and equipment to provide primary medical care and suitable space for team meetings, treatment, therapeutic recreation, restorative therapies, socialization, personal care, and dining. (We believe that a PO should furnish primary care services in the PACE center, but this provision allows flexibility to avoid duplicating an entire primary care clinic if that is not necessary.)

The PO must establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations to keep all equipment (mechanical, electrical, and patient care) free of defect. Based on the manufacturer's experience with the equipment, we believe it has the most knowledge about routine maintenance and recommended repair schedules necessary to keep the equipment in good operating condition.

With respect to protecting participants from fire and fire-related events, we incorporated by reference in our regulation at § 460.72, the Life Safety Code (LSC). The LSC was developed by the National Fire Protection Association and adopted by the Department of Health and Human Services as the standard which ensures reasonably fire-safe facilities. The LSC specifies requirements for building construction features such as walls and doors, exits and exit access, and fire protection devices such as sprinklers, smoke detectors, and fire extinguishers.

In the 1999 interim final rule, we adopted the 1997 edition of the LSC, which was divided into occupancy chapters, including Business, Education, and Health Care Occupancies. Business occupancies include clinics and offices, and educational occupancies cover schools and day care centers. Health care occupancies include facilities where the patients are rendered incapable of self-preservation and where they remain overnight. Unfortunately, the LSC does not designate a specific category for comprehensive outpatient services provided to nursing home eligible individuals, so we chose to stipulate that the PACE center must meet the occupancy provisions of the 1997 edition of the LSC for the type of setting in which it is located (for example, hospital, office building, etc.).

Each type of LSC occupancy requires a fire alarm system. A fire alarm system must provide three functions: (1) Initiation—a method of initiating the alarm, such as a pullbox; (2) Notification—a method of notifying the occupants, such as a loud bell, horn, chimes, or flashing lights for those patients who are deaf; and (3) Control—a method of controlling other fire protection functions and features, such as air conditioning shutdown, automatic release (closing) of fire doors, etc.

We require a PACE center to meet the requirements for a fire alarm system in accordance with the occupancy section of the LSC that applies to the building in which it is located. Each occupancy section also requires evacuation plans, fire exit drills, and fire procedures. The purpose of the drills is to test the efficiency, knowledge, and response of the staff and to ensure that safe care will be provided to participants during an emergency.

The statute and implementing regulations governing some Medicare providers (nursing facilities, hospitals, and hospices) authorize us to accept a State code in lieu of the LSC if it adequately protects patients. Likewise, under these regulations the LSC will not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects PACE participants and staff.

We recognize that it could be burdensome to require strict adherence to all of the requirements of the LSC. PACE centers may be established in a variety of building types (for example, hospitals or office buildings), which must be considered in requiring adherence to the LSC. We also recognize that some PACE centers may have alternative features that provide an equivalent level of protection to that required by the specific requirements of the LSC. In some buildings it may be impractical or impossible to provide a specific feature due to the construction of the building. Therefore, we specified that CMS may waive specific provisions of the LSC which, if rigidly applied, would result in unreasonable hardship on the organization. Specific provisions may be waived only if the waiver does not adversely affect the health and safety of the participants and staff.

We established four requirements that we believe are fundamental for a PO to effectively prepare for emergency situations. The PO must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies or disasters that are likely to threaten the health or safety of participants, staff, or the public including, but not limited to, fire, equipment, water or power failures, care-related emergencies, and natural disasters likely to affect their geographic location. We also stated that we do not expect organizations to develop emergency plans for natural disasters that typically do not affect their geographic area. For example, organizations in the Southeast would not typically need to develop emergency procedures for earthquakes.

POs must train each staff member (employee and contractor) on the actions necessary to address different medical and nonmedical emergencies. This requirement is designed to ensure the safety and security of both the participants and the staff. In addition, the participants must be appropriately trained on the organization's emergency procedures since they may need to take

steps to protect themselves during an emergency. PACE participants need to be informed of what to do, where to go, and whom to contact if a PACE center emergency occurs.

Appropriate medical practice dictates that the organization must have trained personnel, drugs, and emergency equipment immediately available at every PACE center at all times to adequately support participants until an Emergency Medical System (EMS) responds to the PACE center. We defined the minimum emergency equipment that must be on the premises and immediately available as easily portable oxygen, airways, suction, and emergency drugs. In addition, the PACE center must have a documented plan to obtain EMS services from sources outside the PACE center when needed.

At least annually, a PO must test, evaluate, and document the effectiveness of its emergency and disaster plans to ensure and maintain appropriate responses to the situations and needs that may arise from both medical and nonmedical emergencies. Drills and emergency episodes often reveal a weakness or flaw in the design of the emergency plan. An annual review will allow flaws or potential problems to be identified and corrected.

In the January 10, 2003 **Federal Register**, we published a final rule, ''Fire Safety Requirements for Certain Health Care Facilities'' (68 FR 1374), which among other changes, amended § 460.72(b) to adopt the 2000 edition of the LSC for Medicare and Medicaid health care facilities. It is important to note that the 2000 LSC prohibits the use of roll latches on corridor doors in buildings not fully protected by an approved sprinkler system and requires replacement with positive latching devices in both existing sprinklered and unsprinklered buildings. It also requires that, effective March 13, 2006, emergency lighting must provide illumination for at least a 90-minute duration.

Section 460.72(b) was further amended by the March 25, 2005 (70 FR 15229) publication of the interim final rule, ''Fire Safety Requirements for Certain Heath Care Facilities; Amendment,'' which allows certain health care facilities, including PACE facilities, to place alcohol-based hand rub dispensers in egress corridors under specified conditions.

Comment: One commenter stated they believe that identification and enforcement of physical plant standards for PACE centers are responsibilities of the State. The commenter indicated that the provisions allowing CMS to waive the LSC effectively permits an organization to disregard State requirements.

Response: Current regulations require that PACE centers meet the LSC with the following limited exceptions: (1) The LSC provisions do not apply in a State in which CMS determines that a life and safety code imposed by State law adequately protects participants; and (2) CMS may waive specific provisions of the LSC that, if rigidly applied, would result in unreasonable hardship on the PACE center, but only if the waiver does not adversely affect the health and safety of participants and staff.

Although there is specific waiver authority under § 460.26 and § 460.28, it does not apply to the approval of LSC waivers. CMS staff responsible for LSC compliance would approve LSC waivers. However, we note that PACE centers are often licensed as adult day health centers or clinics, which are not among the types of Medicare providers that we typically survey for compliance with the LSC. As a result, in these cases, we will accept State licensure requirements for fire and safety as meeting the LSC.

Comment: Three commenters indicated that a PO's responsibility related to safety in the home should be limited.

One commenter indicated the regulation only mentions POs being responsible for safety of the physical environment of the PACE center and the primary care clinic, while the background description states that this section's purpose is ''to ensure that the PACE center and home are free of hazards.'' The commenter continued by stating the regulation does not address the PO's responsibility for ensuring that an enrollee's home is free of hazards. The enrollee is living at home and not in a licensed health care facility subject to Federal and State oversight. However, the local fire marshal, health department, Adult Protective Service, and building inspectors have specific responsibilities to ensure a safe living environment. Therefore, the commenter recommended that we limit PO responsibilities by requiring that the initial comprehensive assessment includes an assessment of the home environment and that the participants must be determined as able to live in a community setting without jeopardizing their health or safety.

Response: We disagree with the commenters. POs are at risk for all health care services the participant receives, and, therefore, we expect that POs will be involved in assuring the health and safety of participants at all times, including when they are at home.

However, PACE staff will not have the ultimate authority regarding potential hazards. PACE staff performing the initial assessment should identify all potential hazards and make all reasonable attempts to explain them to the participant and caregiver. Should staff be unable to rectify the potential hazard before enrollment, they should document the hazard, their attempts to have the hazard rectified, and all other pertinent information. Should the participant and caregiver agree to a resolution of the hazard, that information should be included in the participant's care plan. If the participant and caregiver do not agree to rectify the hazard potential, the PO staff are expected to document the hazard, their suggestions to resolve the hazardous issue, and all other pertinent information.

Comment: One commenter recommended that the regulations require that accessibility requirements be met in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

Response: Both the 1999 and 2002 interim final rules state repeatedly that POs must meet all applicable Federal, State, and local laws and regulations, which include the Americans with Disabilities Act and section 504 of the Rehabilitation Act. We note the Americans with Disabilities Act is specifically addressed in § 460.32.

Comment: Another commenter recommended that this section of the regulation include suggestions for addressing the common visual deficits of the PACE population and provided the following as examples of potential safety concerns: High gloss floors and surfaces which provide high contrast in floors, steps, and walls and installing low glare but sufficient lighting.

Response: We expect each PO to assess their participants and to implement all appropriate safety precautions. We do not believe it is necessary to establish regulatory requirements specific to individual health issues. We believe the addition of specific common deficits to the regulation would be unreasonably burdensome. Therefore, we are not including specific requirements regarding visual deficits or other individual health deficits. We will continue to assess LSC and State licensure developments to ensure participants receive services in a safe manner.

Comment: Two commenters requested clarification of the emergency equipment requirement, which states that staff be on the premises of the PACE center at all times. The

commenter indicated that it would be helpful to clarify what emergency drugs are required to be available at the PACE center.

One of the commenters requested that we clarify that the requirement that the POs are required to establish, implement, and maintain a written plan to ensure maintenance in accordance with manufacturer's recommendations refers only to equipment deemed to be life-sustaining and biomedical equipment.

Response: The intent of the staffing requirement is that we believe POs should have staff qualified to operate emergency equipment on the premises whenever the PACE center is open.

For purposes of this regulation, emergency drugs are those pharmaceuticals that would be used in an emergency that follow current emergency practice guidelines/protocol.

We agree with the commenter asking for clarification on the equipment maintenance requirement, and we are clarifying that in addition to written policies, the PO is responsible for implementing the manufacturer's recommendations for emergency and biomedical equipment maintenance.

Final rule actions:

In this final rule, we are clarifying that POs must perform the manufacturer's recommended maintenance on all equipment as indicated in their written plan.

Section 460.74 Infection Control

Infection control is vital to the health and safety of participants, so we require in § 460.74 that the PO adhere to accepted policies and standard procedures, including the standard precautions developed by and available from the Centers for Disease Control and Prevention (CDC). These guidelines have been developed by the CDC in collaboration with industry representatives and have proven effective as a means of diminishing the spread of blood-borne pathogens and other infectious agents. The PO must establish, implement, and maintain a documented infection control plan that will ensure a safe and sanitary environment and prevent and control the transmission of disease and infection. At a minimum, the infection control plan must include the following:

(1) Procedures to identify, investigate, control, and prevent infections in every PACE center and in a participant's place of residence;

(2) Procedures to record any incidents of infection; and

(3) Procedures to analyze the incidents of infection, to identify trends, and develop corrective actions related to the reduction of future incidents.

Comment: We received several comments regarding infection control. One commenter did not find the requirements overly onerous, while another commenter was concerned this provision preempts State's regulatory authority regarding infection control practices.

Another commenter requested we clarify that the intent of this section is to hold POs responsible for universal precautions. Five commenters requested we distinguish between what can be required in a PACE center and what can be expected in a participant's home.

Response: It is not our intent to usurp the State's authority in this area. Should State requirements be more stringent than those of CMS, we would expect States to enforce their more strict requirements. We believe these regulations to be the minimum acceptable requirements for infection control.

In response to the question on universal precautions, the intent of these regulations is to require the POs to practice universal precautions. Universal precautions are CDC guidelines accepted as routine practice by the health care industries at large.

Moreover, POs are expected to observe infection control practices in all settings including the participant's residence and teach and reinforce infection control practices to participants and their caregivers. This would include reinforcing the simple practices such as handwashing after using the restroom or blowing one's nose, and refrigerating foods appropriately. It is in the PO's interest to work with participants and caregivers to minimize the risk of infections.

Final rule actions:

This final rule will finalize § 460.74 as published in the 1999 interim final rule.

Section 460.76 Transportation Services

Transportation services are a critical component of PACE service delivery, so it is crucial that the PO take appropriate steps to ensure that participants can be safely transported from their homes to the PACE center and to appointments. We established § 460.76 to require that the PO's transportation services must be safe, accessible, and equipped to meet the needs of each participant. In addition, we require that the organization's transportation program include procedures on at least the following: (1) Maintaining of transportation vehicles according to the manufacturer's recommendations; (2) equipping transportation vehicles to communicate with the PACE center; (3) training transportation personnel on the special needs of participants and appropriate emergency response; and (4) as part of the IDT process, communicating relevant information about the participants' to transportation personnel or other PACE staff in accordance with the PO's policies and procedures.

Comment: We received two comments that addressed concerns regarding transportation. The first commenter emphasized that transportation must meet the special needs of persons with disabilities while the second commenter indicated that there are situations in which routine transportation services can not be safely provided to participants. The commenter believes this point needs to be a consideration when determining if a participant can be cared for appropriately in PACE.

Response: We agree with the commenter, that transportation services that meet the special needs of disabled participants are crucial especially for frail elderly PACE participants. The requirements established in the 1999 interim final rule were intended to ensure that safe and appropriate transportation practices are used with this frail participant population.

We also agree that when the PACE staff performs their initial assessment, it is the PO's responsibility to determine if they can adequately address the transportation needs of the individual, and that this should be a consideration in determining whether or not a prospective enrollee can be cared for safely in their community. However, we believe that transportation considerations alone would rarely, if ever, be the reason to deny enrollment.

Final rule actions:

This final rule will finalize § 460.76 as published in the 1999 interim final rule.

Section 460.78 Dietary Services

In the 1999 interim final rule, we established that it is important that each PACE center provide participants with nourishing, palatable, well-balanced meals that meet the daily nutritional and special dietary needs of each participant. We required that each meal must meet specific requirements, including preparation by methods that conserve nutritive value, flavor, and appearance; preparation in a form designed to meet individual needs; and preparation and service at the proper temperature. The PACE center must provide substitute foods or nutritional supplements that meet the daily nutritional and special dietary needs of any participant who refuses the food served, cannot tolerate the food served,

or who does not eat adequate amounts. In addition, the PO must provide nutritional support (that is, tube feedings, total parenteral nutrition, or peripheral parenteral nutrition) to meet the daily nutritional needs of a participant if indicated by his or her medical condition or diagnosis.

It is vital to the health and safety of participants that the food provided meets acceptable safety standards. Therefore, we require the PO to:

(1) Procure foods (including nutritional supplements and items to meet special nutrition needs) from sources approved or considered satisfactory by Federal, State, Tribal, or local authorities that have jurisdiction over the service area of the organization;

(2) Store, prepare, distribute, and serve foods (including nutritional supplements and items to meet special nutrition needs) under sanitary conditions; and

(3) Dispose of garbage and refuse properly.

Comment: We received several comments regarding dietary services, with several proposed language changes. One commenter reiterated these are areas under State responsibility. Dietary and food service sanitation practices in a variety of establishments, including those under which PACE would operate, are regulated by the State. This commenter recommended that the regulation simply state that the PACE center will provide the enrollee a meal when necessary.

Response: In response to the comment regarding State requirements, we want to clarify that we believe the requirements in our regulation to be the minimum acceptable requirements for dietary services. If State requirements are more stringent than those under this regulation, we expect the State to enforce its more stringent requirements.

In response to the suggestion that we amend the requirement as recommended, we believe that as a participant protection, the PACE dietary services requirement must be more specific. Again, due to the frailty of the targeted population, a greater effort must be made to ensure that the appropriate nutrition is received by the most appropriate method in a safe and sanitary manner.

Comment: One commenter provided two technical suggestions. First, to ensure that dietary needs are provided in accordance with the participant's treatment plan, the commenter recommended inserting the phrase ''In accordance with each participant's plan of care'' at the beginning of § 460.78(a)(1), § 460.78(a)(2), and § 460.78(a)(3).

The second suggestion was to replace the phrase ''provide each participant'' with ''offer each participant'' ensuring participant choice with respect to meals.

Another commenter disagreed with the requested language change of ''offer each participant'' stating there is a high proportion of PACE participants with some form of dementia who may require supervision or assistance with eating. The commenter requested the language be modified to read ''Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PO shall ensure, through the assessment and care planning process, that each participant receives nourishing, well-balanced meals that meet the participant's daily nutritional and special dietary needs.''

Another commenter requested that we clarify that the requirement is meant to apply when PACE participants are institutionalized or to limit the requirement to individuals when the provision of meals is specified in the plan of care. Alternatively, they recommended that the regulations could specify that the PO must ''assure that each participant has access to meals to meet the daily nutritional requirement,'' which would enable the PACE provider to document the provision of meals by family or others, as appropriate.

Response: In response to comments on provision of meals, we want to clarify that meals are a required service in the PACE program. Dietary services are to be provided when a participant is attending the PACE center, when he or she is institutionalized, and when he or she is in the home as indicated in the participant's plan of care. The PO must assess each participant's individual situation when determining the most appropriate method of assuring that each participant's daily nutritional needs are met in the most appropriate manner. The POs must ensure that each participant is receiving adequate nutrition by the required modality, as prescribed in the participant's plan of care. We agree with this commenter and recognize that in the geriatric population, for a number of medical and psychosocial reasons, eating is not a high priority for many individuals. Thus, we do not believe that language such as ''offering'' or ''has access to'' is sufficient to ensure participants receive adequate and appropriate nutrition. Therefore, in this final rule we are revising the first sentence of § 460.78(a)(1) by adding the requirement that the ''PO must ensure, through the assessment and care planning process,'' that each participant receives nourishing, palatable, well-balanced meals that meet the participant's daily nutritional and special dietary needs.

Comment: One commenter indicated that the regulation fails to mention the special needs of those with swallowing problems.

Response: In response to this comment, we believe that although choking is a serious issue, particularly in this population, and has been known to lead to death, this problem should be assessed by the appropriate professional, as part of the participant assessment. This comment provides a good example of where it would be appropriate for an additional discipline (for example, a speech therapist) to be included in the initial comprehensive assessment and periodic reassessments.

Final rule actions:

In this final rule, we are amending the regulatory language of § 460.78(a) by revising the first sentence to read as follows: ''Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PO must ensure, through the assessment and care planning process, that each participant receives nourishing, palatable, well-balanced meals that meet the participant's daily nutritional and special dietary needs.''

Section 460.80 Fiscal Soundness

Part I, section F of the Protocol addresses fiscal soundness and paragraph (e)(4)(A)(ii) of section 1894 and section 1934 of the Act requires that, during the trial period, we conduct a comprehensive assessment of a PO's fiscal soundness. We established § 460.80 to address requirements for fiscal soundness.

As we indicated in the 1999 interim final rule, each PO must have a fiscally sound operation as demonstrated by total assets being greater than total unsubordinated liabilities, sufficient cash flow and adequate liquidity to meet obligations as they become due, and a net operating surplus or a plan for maintaining solvency.

Each organization must have a documented insolvency plan approved by CMS and the SAA which, in the event of insolvency, provides for the continuation of benefits for the duration of the period for which capitation payment has been made; the continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge; and protection of participants from liability for payment of any fees which are the legal obligation of the PO.

Each organization must have adequate arrangements to cover expenses if it becomes insolvent. To this end, we specified requirements in this section that are consistent with the Protocol.

We received comments from five commenters regarding fiscal soundness.

Comment: Two commenters indicated that this section of the regulation made no reference to meeting applicable State requirements, which in some situations may be inconsistent with these requirements.

Response: As with any type of regulatory requirement, States may establish or impose more restrictive requirements applicable to the PO regarding fiscal soundness as long as they do not conflict with the Federal PACE regulations. We recognize that some States have specific fiscal requirements applicable to the POs, particularly based on State licensure programs for POs. We also acknowledge the State's role in relation to fiscal soundness; however, we do not believe the regulations would need to reflect the States' role in this case.

Comment: Two commenters recommended that CMS specify that POs must have requirements to cover expenses of $250,000.

Response: We appreciate that a minimum amount of capital is critical to ensure that the organization can adequately cover the costs of meeting the needs of a frail elderly population. However, we are not inclined to impose specific dollar amounts because we assess each organization's financial situation individually. In addition, an amount set at a particular point in time may not be adequate over an extended period due to inflationary and economic factors.

Comment: Two commenters agreed with the fiscal soundness requirements, but pointed out that the measure of fiscal soundness is different for a new PACE program than for an established program. One commenter questioned whether fiscal soundness should apply during the trial period because it could inhibit the start-up of new programs. The commenters recommended that POs be permitted to utilize a variety of arrangements to cover expenses in case of insolvency.

The other commenter indicated that the requirements are based on a shared-risk model of an established PACE program that enrolls the certain number of participants and spreads its risk among all its enrollees. The commenter believes that the measures are too stringent for a program just starting operations. The commenter recommended that CMS consider the measure for fiscal soundness and differentiate the measure for new PACE programs and established programs. The commenter suggested that for an established program, the minimum of 1 month of cash available be liquid financial assets and not merely line-of-credit. However, for new POs, cash in the form of line-of-credit would be appropriate.

Response: We assess each PO's fiscal soundness individually taking into account whether it is an established or newly operational organization. However, we believe that it is critical for the organization to meet the established requirements upon start-up to ensure that the organization can adequately cover the costs to meet the needs of a frail elderly population. As each situation is different, we do not dictate the means for providing arrangements to cover expenses. Organizations have flexibility to meet the requirements, and the regulation offers potential options such as letters of credit or other guarantees.

Final rule actions:

This final rule will finalize § 460.80 as published in the 1999 interim final rule.

Section 460.82 Marketing

Based on Part III, section B of the Protocol, we established § 460.82 to address marketing activities of PACE programs. POs must conduct marketing activities that inform the general public about their programs.

As we indicated in the 1999 interim final rule, all marketing material must be approved by CMS and the SAA. Initial marketing material is reviewed as part of the application process. After an organization is under a PACE program agreement, any new or revised marketing materials must be submitted for review by CMS and the SAA. We will complete our review within 45 days after we receive the information from the organization or the material will be deemed approved. We included the requirement for review and approval of revised marketing materials as revisions could potentially introduce false or misleading information. Although the Protocol includes a 30-day review and approval timeframe, we adopted a 45-day period to be consistent with the process used by CMS for review of changes to M+C organization (now MA) marketing materials.

Printed marketing materials must meet participants' special language requirements. Marketing materials must also provide complete and clear information regarding the requirement that all services (other than emergency services), including primary care and specialist physician services, be furnished by or authorized by the PO and that participants may be fully and personally liable for the costs of unauthorized or out-of-PACE program agreement services.

POs must ensure that their employees or agents do not conduct prohibited marketing activities such as discrimination of any kind among individuals who meet PACE eligibility standards; activities that could mislead or confuse potential participants or misrepresent the PO, CMS, or the SAA; activities that involve gifts or payments to induce enrollment; contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment; or unsolicited door-to-door marketing.

Each PO must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness.

We received numerous comments regarding the marketing section.

Comment: Three commenters believed that to ensure that all PACE participants are fully informed of the services they will receive, the PO's marketing materials should specify not only the covered benefits and services, but also the benefits and services excluded from the program both before and at enrollment, with one commenter providing proposed regulatory language.

Response: We disagree with the commenter because of the dynamic nature of PACE, its reliance on the IDT's determination of a specific participant's need to determine the covered and excluded services and its interaction with the participant. We do not believe identifying excluded services appropriately expresses the flexibility of services provided by the PACE model.

Comment: Several commenters requested clarification of the process for review of marketing materials, with some commenters addressing the State's role in the review of marketing materials. One commenter questioned the intent regarding SAA approval of marketing materials noting that as the initial program application must be submitted with SAA approval, marketing materials would have been approved by the SAA before CMS review.

Another commenter suggested that CMS delegate the approval of any revised or updated educational and marketing materials to the SAAs in order to prevent unnecessary delay in approvals and to avoid discouraging POs from revising their materials.

Response: We believe the process for review is fairly noted in the regulations but remind the public that as a partner in the three-way program agreement, the SAA has the right to review and approve all educational and marketing materials the PO intends to distribute.

Accordingly, all materials must go through the SAA for approval before the SAA forwarding the materials to CMS. This review of marketing and educational materials by CMS is to ensure that marketing materials meet CMS requirements.

Although a PO's initial educational and marketing materials are approved by CMS and the SAA during the application process, revised and updated materials must be approved to ensure that no erroneous information is disseminated. The requirement to have educational and marketing materials reviewed is consistent with MA requirements.

Comment: This commenter suggested the regulations differentiate between educational and marketing components of the PACE program, as the desired outcomes of marketing activities are fundamentally different from those of educational activities and materials.

Response: We view marketing materials as those materials used to promote the PACE program before an individual enrolls in PACE. Educational materials, on the other hand, are those materials provided to PACE participants and family or their authorized representatives, that provide information about the PACE program. The regulation addresses review of the marketing materials as it is essential that accurate and complete information be disseminated to potential PACE participants. We believe that the educational component of PACE is covered by annual notices, newsletters, and other materials presented to participants, and their families or authorized representatives, after they have enrolled in PACE. We believe the differentiation between marketing and educational materials is an operational issue and not appropriate for regulation.

Comment: A commenter indicated that marketing plans should be a submission requirement in support of program oversight and monitoring.

Response: We agree with the commenter, and the regulation reflects this requirement. The PO is required to establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking effectiveness. Marketing plans are submitted by the PO and reviewed by the SAA and CMS as part of the provider application and when there is a significant revision to the marketing plan. These materials are also reviewed during onsite monitoring visits.

Comment: A commenter indicated that PACE marketing requirements should be the same as the Medicare and Medicaid managed care requirements, particularly the prohibited practices. The regulation prohibits door-to-door solicitation but does not mention other forms of unsolicited marketing such as telephone calls, e-mails, or targeted mailings.

Response: The commenter is correct. The only prohibited marketing practice included in the 1999 interim final rule was unsolicited door-to-door marketing. We are not aware of marketing abuses by POs. We believe that any change in marketing policy should be presented in a proposed rule and allow for public comment. We will continue to monitor marketing practices by POs and will propose additional safeguards as appropriate.

Comment: A commenter recommended that the information supplied to prospective participants should include a review of the responsibility to share in the cost of services by way of post-eligibility treatment of income, which is not expressly included in the rule.

Response: We agree that participants should be made aware that the share of cost requirements continues to apply after PACE enrollment; however, this requirement is not a PACE eligibility requirement. We would expect that the participant be informed at the time of his or her enrollment that their Medicaid eligibility requirements continue to apply as required in § 460.152(a)(1).

Comment: Since the regulations state that approval of an entity's provider application includes approval of marketing materials, one commenter asked whether the application process would permit use of the marketing materials in attracting enrollees.

Response: A prospective PO is not permitted to market PACE services until they have an approved application. Prospective applicants are informed in writing when their application has been approved. In this way, marketing activities may begin before the effective date of the program agreement.

Comment: One commenter indicated that the marketing materials must state that enrollees may be fully liable for unauthorized or out-of-plan services, and asked what would be the financial responsibility of a Medicaid recipient in this situation.

Response: The 1999 interim final rule established in § 460.82(d)(2) that all marketing materials must clearly state that PACE participants may be fully and personally liable for unauthorized or out-of-network services. Thus, a Medicaid recipient would be financially responsible for any unauthorized out-of-network services.

Comment: One commenter asked what constitutes a principal language of the community, whether there is a percentage threshold, and whether we intended that the reference to principal languages of the community applies to the community as a whole or the target population PACE intends to enroll.

Another commenter urged CMS to consider providing programs serving multilingual populations with some financial assistance to cover translation expenses.

Response: The determination of the principal languages of a PO's service area is a State determination. Therefore, we recommend that interested parties contact their State for specific information.

In response to the request that we consider providing financial assistance for translation services, we have no mechanism to provide financial assistance for entities serving multilingual populations.

Comment: One commenter asked whether, like M+C organizations, the prohibition against gifts and payments to induce enrollment does not include items of nominal value.

Response: We have adopted the MA policy regarding nominal gifts. In response to inquiries regarding nominal gifts, we consulted § 422.80(e) of the MA rule. For further guidance related to promotional activities, we reviewed § 50.1 of the Medicare Managed Care Manual, which was originally developed for M+C plans and is currently being revised for MA plans.

Offering gifts to potential enrollees that attend a marketing presentation is permitted as long as these gifts are of a nominal amount and are provided whether or not the individual enrolls in the PACE program. The gift cannot be a cash gift or be readily converted into cash regardless of the amount.

Final rule actions:

The final rule will finalize § 460.82 as published in the 1999 interim final rule.

Subpart F—PACE Services

The purpose of subpart F is to establish the service requirements for POs. In this subpart we specify the limitations and conditions relating to Medicare and Medicaid benefits. We stipulate that participants must receive all services from the PO, the required services that must be provided by the PO and those that may be excluded, emergency services, and the requirements for delivery of required services at the PACE center and other settings. In addition, we establish the requirements for composition of the IDT and its responsibilities, and

requirements for participant assessments and the plan of care.

The scope of this subpart led to a large number of comments related to the IDT, required services and their delivery. Included among the comments were requests for clarification, re-evaluation of various service related policies, and proposed changes to regulatory language.

Section 460.90 PACE Benefits Under Medicare and Medicaid

Under sections 1894(a)(2)(B) and (b)(1) and 1934(a)(2)(B) and (b)(1) of the Act, we established § 460.90 to specify that Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost sharing that are generally applicable under the Medicare and Medicaid programs do not apply to PACE benefits. In addition, we specified that, in accordance with sections 1894(a)(1)(B)(i) and 1934(a)(1)(A) of the Act, the PACE participant shall receive Medicare and Medicaid benefits solely through the PO.

Comment: We received one comment requesting clarification that the amount, duration, and scope of services are not subject to the limits of traditional Medicare and Medicaid services but also are not required to exceed those amounts unless the IDT determines it to be necessary and appropriate.

Response: The limits on amount, duration, and scope of services that apply to either the traditional Medicare or Medicaid benefit packages do not apply to PACE. The amount, duration or scope of services provided to PACE participants are participant-specific; therefore the amount, duration, or scope of services for each participant are indicated in his or her plan of care based on the IDT assessment. If an assessment indicates need for a particular service, the PO must provide the service without regard to whether the service would otherwise be covered for a Medicare beneficiary or a Medicaid recipient not enrolled in a PO.

Final rule actions:

This final rule will finalize § 460.90 as published in the 1999 interim final rule.

Section 460.92 Required Services

Based on the provisions of sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act, we require in § 460.92 that each PACE benefit package include for all participants, regardless of payment source, all Medicare services and all Medicaid covered services as specified in the State plan, a variety of services specified in the Protocol, and other services determined necessary by the IDT to meet the participant's needs (for example, respite care). Based on the Protocol, we included the following required services in § 460.92 of the 1999 interim final rule:

(a) All Medicaid-covered services, as specified in the State's approved Medicaid plan.

(b) Multidisciplinary assessment and treatment planning.

(c) Primary care, including physician and nursing services.

(d) Social work services.

(e) Restorative therapies, including physical therapy, occupational therapy, and speech-language pathology services.

(f) Personal care and supportive services.

(g) Nutritional counseling.

(h) Recreational therapy.

(i) Transportation.

(j) Meals.

(k) Medical specialty services including, but not limited to the following:

(1) Anesthesiology.
(2) Audiology.
(3) Cardiology.
(4) Dentistry.
(5) Dermatology.
(6) Gastroenterology.
(7) Gynecology.
(8) Internal medicine.
(9) Nephrology.
(10) Neurosurgery.
(11) Oncology.
(12) Ophthalmology.
(13) Oral surgery.
(14) Orthopedic surgery.
(15) Otorhinolaryngology.
(16) Plastic surgery.
(17) Pharmacy consulting services.
(18) Podiatry.
(19) Psychiatry.
(20) Pulmonary disease.
(21) Radiology.
(22) Rheumatology.
(23) General surgery.
(24) Thoracic and vascular surgery.
(25) Urology.

(l) Laboratory tests, x-rays and other diagnostic procedures

(m) Drugs and biologicals.

(n) Prosthetics, orthotics, durable medical equipment, corrective vision devices, such as eyeglasses and lenses, hearing aids, dentures, and repair and maintenance of these items.

(o) Acute inpatient care, including the following:

(1) Ambulance.
(2) Emergency room care and treatment room services.
(3) Semi-private room and board.
(4) General medical and nursing services.
(5) Medical surgical/intensive care/coronary care unit.
(6) Laboratory tests, x-rays, and other diagnostic procedures.
(7) Drugs and biologicals.
(8) Blood and blood derivatives.
(9) Surgical care, including the use of anesthesia.
(10) Use of oxygen.
(11) Physical, occupational, respiratory therapies, and speech-language pathology services.
(12) Social services.

(p) Nursing facility care.

(1) Semi-private room and board.
(2) Physician and skilled nursing services.
(3) Custodial care.
(4) Personal care and assistance.
(5) Drugs and biologicals.
(6) Physical, occupational, recreational therapies, and speech-language pathology, if necessary.
(7) Social services.
(8) Medical supplies and appliances.

(q) Other services determined necessary by the IDT to improve and maintain the participant's overall health status.

Comment: We received several comments related to the list of required services. One commenter stated that the list of services is extensive and considerably longer than the list for nursing facilities, presenting a dilemma to States to establish the cost effectiveness of PACE compared to nursing facility cost.

Another commenter requested we re-evaluate the required services and ensure they are in fact the minimum requirements necessary to protect the health, safety, welfare, and rights of consumers in the PACE program.

Response: In accordance with sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act, the scope of benefits for PACE is all items and services covered under title XVIII and all items and services covered under title XIX without regard to an individual participant's source of payment and without any limitation or condition as to amount, duration, or scope and without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply. In addition, the PACE scope of benefits includes all additional items and services specified in regulations, based upon those required under the Protocol. Based on this authority, we established § 460.92 in an attempt to list the items and services covered under titles XVIII and XIX of the Act and the Protocol, to clarify that the scope of benefits under title XIX is the services specified in the State's approved Medicaid plan, and to clarify that the scope of benefits under PACE includes any other item or service determined necessary by the IDT to improve and maintain the participant's overall health status.

We have examined our approach to setting forth required PACE services and have determined that it is not possible to provide a complete list of all inpatient, outpatient, physician specialty, care planning, and social support services that must be furnished to participants if ordered by the IDT. As the scope of benefits under PACE is so broad, we are revising this section to summarize Medicare and Medicaid covered items and services and to highlight the services that are unique to the PACE model, instead of the current listing of services required. Under this final rule, the required services under PACE are all Medicare-covered items and services (including outpatient prescription drug coverage), all Medicaid-covered items and services identified in the State Medicaid plan, and other services determined necessary by the IDT to improve and maintain the participants' overall health status.

In response to the commenter's concern that the PACE benefit package is broader than the services furnished in nursing facilities, which complicates cost comparison, we note that currently most States establish capitation rates based on a blend of the cost of nursing home and community-based care for the frail elderly.

Comment: We received several comments related to the respiratory therapy and the respiratory therapist (RT). Several commenters recommended that the IDT be expanded to include RTs and that respiratory therapy be added to the list of required services provided not just in an acute care setting but also in nursing facilities and in community settings. We were also asked to clarify our expectations for coverage of respiratory therapy in these additional settings.

Response: The IDT is responsible for determining whether additional disciplines are required to assess specific health concerns. If a participant requires the services of specialists, whether or not the specialist is on the IDT, then the services become required for that participant. Unlike traditional Medicare and Medicaid, the site of service is not an issue in PACE. The participant may receive services wherever the IDT determines appropriate. Therefore, respiratory therapy services may or may not be furnished in an inpatient setting, based on the particular participant's needs. We believe the regulation as revised will provide the flexibility needed for providing Recreational Therapy (RT) in a PO if needed. Upon review, we believe the RT is a valuable adjunct position but not an essential position for every IDT. Therefore, we are not requiring the addition of this discipline to the IDT at this time.

Comment: One commenter asked that we clarify the description of the benefit package as ''all State plan services'' because this characterization includes services not applicable to and not expected to be accessed by the PACE population, as well as being mutually exclusive services.

Response: In accordance with section 1934(b) of the Act, PACE is required to provide all items and services covered under title XIX. The services that are actually provided are those determined by the IDT to be required for a particular PACE participant. For example, neonatal intensive care unit services will probably not be needed by a PACE participant; however, these services are required services under Medicaid and must be furnished by the PO if the IDT were to determine they are necessary for a particular PACE participant.

Comment: We were also asked to clarify our expectations regarding mental health services, other than psychiatric services, for alcohol and substance abuse.

Response: We expect participants to be assessed, diagnosed, and treated for all types of health issues or conditions, including mental health issues or substance abuse.

Comment: Two commenters objected to POs being responsible for providing three meals per day, recommending we either omit meals from the benefit package or, alternatively, clarify that POs are required to provide meals on a limited basis.

Response: The intent of this rule is to ensure all PACE participants' nutritional needs are met. PACE is responsible for a participant's health and safety including his or her nutritional needs 24 hours a day/7 days a week. That responsibility includes providing nourishing, palatable, well-balanced meals that meet the daily nutritional requirements and the special dietary needs of each participant. The IDT must assess the participant's needs as well as his or her access to adequate nutrition. The participant's nutritional requirements and dietary needs should be included in the participant's plan of care, whether it is providing tube feedings, arranging for Meals on Wheels, sending meals home with the participant after his or her visit to the PACE center or documenting that appropriate meals are provided by the family/caregiver.

Comment: One commenter recommended that durable medical equipment (DME) requirements should not be unnecessarily restrictive as technology is continually changing and as more options become available, these options should not be excluded for PACE participants. Therefore, we should relax the regulatory requirement by adding ''other assistive devices'' and ''magnification devices'' to § 460.92(n).

Response: We do not believe there needs to be a change in the regulatory language as the PO is required to provide anything the IDT determines necessary to assist the participant to remain living safely in the community. When determined necessary by the IDT, POs must provide participants with assistive devices that may not be provided under traditional Medicare.

In order to clarify the services provided by the PACE program and to emphasize what makes a program uniquely PACE, in this final rule we are revising § 460.92 by removing the enumerated list of required services and replacing the list with a requirement that the PACE program must provide all Medicare services, all Medicaid-covered services specified in the State's approved Medicaid plan, and other services determined necessary by the IDT to improve and maintain the participant's overall health status.

Final rule actions:

In this final rule, we are revising § 460.92 by replacing the current list of required services with the following:

(a) All Medicare-covered items and services;

(b) All Medicaid-covered items and services, specified in the State's approved Medicaid plan;

(c) Other services determined necessary by the IDT to improve and maintain the participant's overall health status.

Section 460.94 Required Services for Medicare Participants

In accordance with paragraph (b)(1)(A)(i) of sections 1894 and 1934 of the Act, we specified in the 1999 interim final rule that the PACE benefit package for Medicare participants must include, in addition to the services required by § 460.92, the scope of hospital insurance benefits described in 42 CFR part 409 and the scope of supplemental medical insurance benefits described in 42 CFR part 410.

We also specified the following requirements of title XVIII of the Act (and regulations relating to such requirements) that are waived and do not apply to services under the PACE program:

- The provisions of subpart F of part 409 of 42 CFR that limit coverage of institutional services;
- The provisions of subparts G and H of 42 CFR part 409 and parts 412

through 414 that relate to rules for payment for benefits;

• The provisions of subparts D and E of 42 CFR part 409 that limit coverage of extended care services or home health services;

• The provisions of subpart D of 42 CFR part 409 that impose a 3-day prior hospitalization requirement for coverage of extended care services; and

• The provisions of 42 CFR 411.15(g) and (k) that may prevent payment for PACE program services to individuals enrolled in the PACE program.

Comment: We were asked to clarify whether the reference in § 460.94(b)(5) to ''payment for PACE program services to PACE participants'' means payment ''on behalf of'' participants. If not, commenters asked whether the regulatory language was meant to permit PACE centers to implement direct payment/cash benefits to enable consumers to hire personal care attendants directly. The commenters stated that this would be a positive innovation in the PACE model.

Response: Section 411.15 specifies items and services excluded from traditional Medicare. Section 411.15(g) pertains to requirements related to custodial care, and § 411.15(k) pertains to requirements related to services that are not reasonable and necessary. Section 460.94 waives Medicare exclusion of these services for POs. Therefore, it allows payment for PACE services that are provided to PACE participants, including custodial services and services that would be considered not reasonable and necessary under traditional Medicare when furnished by a PO to a participant. This section in no way implies that the PO can implement direct payment or cash benefits to be paid to PACE participants. We are amending § 460.94(b)(5) to waive those specified sections that may prevent payments for PACE program services ''that are provided to'' PACE participants to clarify this issue.

Final rule actions:

In this final rule, we are amending § 460.94(b)(5) to clarify that payment is for PACE program services ''that are provided to'' PACE participants.

Section 460.96 Excluded Services

In this section, we provide a list of excluded services based on Part IV, section A.6 of the Protocol. The services that are excluded from coverage under the PACE program are as follows:

• Any service that is not authorized by the IDT, even if it is listed as a required service, unless it is an emergency service.

• For services in inpatient facilities, private room and private duty nursing services, unless medically necessary and non-medical items for personal convenience such as telephone, radio or television rental, unless specifically authorized by the IDT as part of a participant's plan of care.

• Cosmetic surgery does not include surgery required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy.

• Experimental medical, surgical, or other health procedures.

• Services furnished outside the United States, except as may be permitted in accordance with 42 CFR 424.122 and 424.124 or as may be permitted under the State's approved Medicaid Plan. While the Protocol did not recognize any exceptions, the required inclusion of Medicare and Medicaid covered services results in certain limited exceptions being possible. For example, a State that borders another country might include some Medicaid coverage across the border, and Medicare covers some emergency hospital, ambulance, and physician services outside the United States. (As defined in 42 CFR 400.200, the United States includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.)

In the 1999 interim final rule, there was a technical inconsistency between the § 460.96(e) preamble language and regulatory language regarding services furnished outside the United States. In the preamble, we referenced § 424.122 and § 424.124; in the regulatory language, we referenced § 424.122 through § 424.124. To rectify this technical inconsistency, we are revising the regulatory language in § 460.96(e)(1) to conform the regulatory language to the preamble language. The regulatory language in § 460.96 will now read: (e) Services furnished outside of the United States, except as follows: (1) In accordance with § 424.122 and § 424.124 of this chapter.

Comment: Two commenters requested clarification regarding excluded services. One commenter questioned whether the PACE center is prohibited from covering services such as a private room, experimental medical, surgical, or other health procedures. The commenter questioned why under a capitated payment, a PO would be prohibited from covering procedures they deemed beneficial if they have the resources to do so.

The second commenter stated that he believed that some Medicaid programs cover a procedure deemed experimental and CMS may choose to cover such a procedure under Medicare. Thus, the regulation should clarify that such a procedure is not prohibited but at the discretion of the PACE program.

Response: In response to the comments relating to services that are generally excluded services under the PACE program, the list of services excluded from coverage under PACE is based on the Protocol. Therefore, the Medicare and Medicaid capitation rates are not based on these excluded services. As with all items and services provided by PACE, it is the IDT and each participant's plan of care that establish whether or not a service is covered as a required PACE service.

To further clarify, should the IDT determine that an experimental surgery or procedures would be appropriate for a participant and complications arise, the PO would remain at full risk and would not be able to disenroll the participant for changes in health status resulting from the experimental surgery or procedure.

Final rule actions:

In this final rule, we are making a technical correction by revising § 460.96(e)(1) by replacing the word ''through'' with the word ''and'' so that paragraph (e) reads ''Services furnished outside of the United States, except as follows: (1) In accordance with § 424.122 and § 424.124 of this chapter.''

Section 460.98 Service Delivery

We require in § 460.98 that the PO must establish and implement a written plan for providing care to each individual participant that meets that individual's needs across all care settings on a 24-hour basis, each day of the year. The PO must furnish comprehensive medical, health, and social services that integrate acute and long-term care. At a minimum, these services must be furnished in the PACE center, the participant's home, and inpatient facilities. The PO must not discriminate against any participant based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.

The requirements in this section implement provisions in Part IV, section B of the Protocol and ensure the availability of and access to services as a PO grows. The following requirements are based on the Protocol:

• At least the following services must be furnished at every PACE center: primary care (including physician and nursing services); social services; restorative therapies (including physical and occupational therapy); personal care and supportive services; nutritional

counseling; recreational therapy; and meals.

- The PO must operate at least one PACE center either in or contiguous to its designated service area, with sufficient capacity for routine attendance by its participants.
- The PO must ensure accessible and adequate services to meet the needs of all its participants. When necessary, the organization must increase the number of PACE centers, staff, and other PACE services.
- The frequency of a participant's attendance at the PACE center is determined by the IDT based on the needs and desires of each participant.

Finally, if the PO operates more than one PACE center, each PACE center must offer the full range of services and have sufficient staff to meet the needs of participants.

Comment: We received numerous comments relating to the minimum range of services required to be furnished at the PACE center. One commenter recommended we delete the requirement that each PACE center offer the full range of services, if the organization operates more than one PACE center in a defined service area, as long as all required services are readily available to all participants.

Two commenters believe the focal point of PACE service delivery is the IDT rather than the PACE center and requested that we explicitly recognize the provision of services at alternative sites. One commenter indicated that this approach would avoid potentially adverse situations in which all alternative delivery sites are subject to PACE center regulatory requirements and survey criteria, in addition to any State certification or licensure requirements applicable to such facilities. One of the commenters proposed that services be allowed in alternative locations provided they meet applicable State licensure and certification requirements.

One commenter emphasized that there is a critical distinction that should be made between a participant being assigned to a team ''operating from'' a PACE center and PACE center attendance. As published in the rule, § 460.98(e) states that ''the frequency of a participant's attendance at a PACE center is determined by the IDT, based on the needs and preferences of each participant.''

Commenters indicated the regulation should afford flexibility to enable programs to offer services either on or off site in order to best meet the needs and preferences of participants and maximize efficient use of organizational resources.

Another commenter suggested that satellite PACE centers that furnish a core set of services (but not full range of services) and are within a reasonable distance of a full-service PACE center should be allowed.

Response: We disagree with these commenters. We believe that omitting the requirement that each PACE center provide the full range of services would fragment the care the PACE program was established to coordinate.

In addition, we believe that the PO has the flexibility to provide services in settings other than the PACE center. However, every participant must have a PACE center home that is capable of furnishing all PACE required services. For POs that are sufficiently large to require multiple PACE centers, each center would need to have a sufficient number of IDTs to provide the full range of services to meet the needs of all participants assigned to that PACE center.

We believe the success of the PACE delivery model is due to the combination of the IDT assessment and care planning and the PACE center. Independent of each other, neither would produce the remarkable participant care successes they do together. The PACE center provides a point of service where the primary care clinic is located, where services are provided, and socialization occurs with staff that is consistent and familiar. The IDT not only works from the PACE center, they provide the majority of services to participants at the PACE center, where most participants come on a regular basis to receive the majority of their care. We also believe the attendance at the center is an important aspect of the PACE model, which helps to differentiate it from home health care or institutional care. Therefore, we will continue to require that the full range of PACE services be offered at the PACE center and will encourage development of PACE centers in rural and Tribal areas, wherever possible.

We allow alternative care settings (ACS) where a limited number of services may be provided. Should participants choose to attend an ACS to receive certain services, they would attend the PACE center for the services not offered at the ACS. We do not believe that an ACS should replace the PACE center. We believe that every participant must be assigned to and have the option to receive PACE services at a PACE center.

Comment: Another commenter endorsed flexibility in staffing for POs that operate more than one PACE center.

Response: Each PACE center must have at least one complete IDT and enough support staff to ensure all participants receive the services and attention they require. We believe the flexibility the commenter requested was provided in the 2002 interim final rule, which permits POs to contract for IDT staff and as well as for PACE center services.

Comment: Another commenter added that flexibility would increase access to PACE services in rural areas and in the development of specialized POs, that is, programs designed and staffed for treatment of the mentally ill or Alzheimer's patients.

Response: We believe that every PACE center must provide for every participant that meets the eligibility requirements and wishes to enroll in PACE. We are aware that some POs have specialized staff and accommodations specifically for Alzheimer's/Dementia patients. As the regulation reads currently, a PO choosing to limit enrollment to a targeted population would be viewed as discriminatory. We are not inclined to permit POs to limit enrollment to certain target populations at this time. Should we consider such a change, we would include it in future rulemaking and permit the public to comment.

Comment: Two commenters requested we broaden the list of categories under which the PO cannot discriminate to include sexual orientation.

Response: In response to this request, we are amending the language of § 460.98(b)(3) to include sexual orientation.

Comment: We also received a request for an explanation of the procedures a PO needs to follow in order to establish additional PACE centers.

Response: We have provided a number of scenarios to explain our policy regarding expansions on our CMS PACE home page at *http://www.cms.hhs.gov/pace/*. A separate application for the sole purpose of expansion is also provided on the CMS PACE homepage. This expansion application is abbreviated to take into account only processes or practices that would be different due to the expansion.

Final rule actions:

In this final rule, we are amending § 460.98, paragraph (b)(3), to add sexual orientation.

Section 460.100 Emergency Care

We note that as sections 1894 and 1934 of the Act do not contain specific requirements regarding emergency care, in the 1999 interim final rule we relied on the Protocol and regulations governing emergency care under Medicare and Medicaid managed care to develop the requirements for emergency

care under PACE. We expanded on and clarified the provisions in Part IV, section A of the Protocol to ensure access to necessary services and to adopt a beneficiary-centered approach.

Section 460.100 requires a PO to establish and maintain a written plan for handling emergency health care needs. The organization must ensure that the participants and their caregiver know when and how to access emergency services and ensure that CMS, the State, and PACE participants are held harmless for emergency services.

As we explained in the 1999 interim final rule, emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PO or a network provider would cause the risk of permanent damage to the participant's health. Thus, emergency care services include inpatient and outpatient services, furnished by a qualified emergency services provider (other than the PO or one of its contract providers) either in or out of the PO's service area, that are needed to evaluate or stabilize an emergency medical condition.

An emergency medical condition means a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in: Serious jeopardy to the health of the participant; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part.

Emergency services that fall within this description do not require prior authorization by the PO. We believe that relying on the prudent layperson standard in establishing a participant's need for emergency services is more clear than the definition of emergency care in the Protocol. We adopted the prudent layperson standard from the Consumer's Bill of Rights and Responsibilities (CBRR) (discussed in the section on participant rights). The same standard is used in the M+C (now MA) definition of emergency medical condition. This standard encompasses a slightly broader range of circumstances than does the Protocol language, by including some situations that could fit under the Protocol description of urgent care or urgently needed services. We think this clarification is helpful because the Protocol wording does not clearly distinguish between emergency and urgent care.

Services a participant may need while temporarily absent from the PO's service area that are not emergency services but cannot be delayed until the participant returns would need prior authorization. The fact that these services may be urgently needed means that the PO would be expected to authorize a participant to obtain them from a non-contract provider outside of the service area, but it does not exempt them from the requirement for prior authorization. This approach differs from that applied to MA organizations, where prior authorization for urgently needed services is not required. We believe that the differences in the population served by POs warrant the different treatment of urgent, though not emergency, care needs. Due to the relative frailty, more limited mobility, and more complex health status of PACE participants, we believe the need to maintain the coordination of care by the IDT justifies contact with and authorization by the PO before receipt of non-emergency care outside the PACE network.

The emergency services plan must also provide for the availability of appropriate on-call providers. We expanded this requirement from the Protocol to provide a safety net for unanticipated health incidents, so participants do not encounter difficulty in obtaining care when they are away from the PACE center, when they are away from the PO's service area and require services that cannot be delayed until they return, or when they require post-stabilization care services following emergency services. An on-call provider must be available 24 hours per day to address any participant questions about accessing emergency services and respond to requests for authorization of urgently needed out-of-network services or post-stabilization care services following emergency services.

We believe that POs must be responsive to all participant care needs, including the need for urgently needed or post-stabilization services. In order to ensure that unforeseen circumstances do not result in delays in needed care, we clarified that the PO must cover urgently needed out-of-network or post-stabilization care services if it does not respond to a request for approval within 1 hour after being contacted or cannot be contacted for approval.

Comment: We received several comments regarding emergency care. One commenter requested clarification about when the PO would not be responsible for the cost of emergency services, and asked whether the PO would always be obliged to provide for emergency care if the prudent layperson test is met.

Response: The PO is obligated to pay for all emergency care if the prudent layperson standard as specified in § 460.100(c) is met and the participant believes he or she is in a critical health emergency or, in other words, if the participant fears for his or her life or well-being.

Comment: One commenter recommended that the requirement that POs explain policies regarding emergency care be modified to include a clarification that no prior approval is required for emergency services.

Response: We agree with this commenter and are modifying paragraph (d) in this final rule to require the PO to explain that no prior authorization is required for emergency care.

Comment: One commenter requested a definition of the term ''caregiver'' in our requirement at § 460.100(d) that the PO must explain policies regarding emergency care.

Response: We believe that the nature of PACE and the living arrangements experienced by PACE participants covers a wide range of diverse circumstances making a definition of ''caregiver'' inappropriate. A PACE participant could be living alone, with family members, in a residential facility or be in another type of living arrangement. They could have a caregiver or many different caregivers. The caregiver could be a family member, attendant, friend, neighbor, member of a church or other organization, or anyone who attending to participant's needs and which constitutes a caregiving relationship. Therefore, for purposes of PACE, we consider a caregiver anyone who attends to the participant's needs and we use the terms ''family member'' and ''caregiver'' interchangeably.

Comment: One commenter asked that we clarify if on-call providers can be accessed via an answering service, beeper, or other device and if the on-call provider must be a member of the IDT.

Response: There is no prohibition on providers using an answering service, beeper or other device, but we expect that on-call providers respond to all participant calls as soon as possible and at a minimum within the 1 hour allotted for response to calls for prior authorization. There is no requirement that the on-call provider must be an IDT member.

Comment: Three commenters requested we define urgently needed care, and distinguish between emergency, urgently needed care, and post-stabilization services.

Response: In response to these requests, we are establishing the following definitions in this final rule:

As defined in the 1999 interim final rule, an *Emergency Medical Condition* is a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possess an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in placing the health of the individual in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

As also defined in the 1999 interim final rule, *Emergency care* is appropriate when services are needed immediately because of injury or sudden illness and the time required to reach the PO or one of its contact providers, would cause risk of permanent damage to the participants health. Emergency services include inpatient and outpatient services that are furnished by a qualified emergency services provider, other than the PO or one of its contract providers, either in or out of the PO's service area and are needed to evaluate or stabilize an emergency medical condition. In addition, in accordance with § 460.112(d), we are clarifying in this final rule that we are amending paragraph (d) of this section to require POs to explain to PACE participants that emergency care services that are provided for medical conditions that fall within this description must be covered by the PO and do not require prior approval.

Urgent care means the care provided to a PACE participant who is out of the PACE services area, and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or functioning is not in severe jeopardy.

We note that participants are expected to seek prior approval from the PO in order to be covered for urgent care.

Post-stabilization care means services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized. They are not emergency services, which POs are obligated to cover. Rather, they are non-emergency services that the PO should approve before they are provided outside of the service area.

Prior approval of these services is intended to ensure efficient and timely coordination of appropriate post emergency care by the IDT.

To further clarify, an example of urgent care might be a severe cough without other symptoms. The participant does not believe his or her life is in jeopardy, so he or she must call the PO. The PO physician advises the participant not to go to the ER, take a certain over-the-counter medication, and see the physician when the participant returns tomorrow.

While post-stabilization care services are the follow-up care required after an emergency condition that has stabilized, also while the participant is outside the PO service area. For example, the participant is hospitalized due to bacterial pneumonia. It was treated and resolved enough for discharge but some residual symptoms remain. The treating physician knows the participant will not be returning home for 2 weeks, which he believes is too long a period of time before having a follow-up x-ray ordered by her physician. Therefore, the treating physician must contact the PO for approval to order a follow-up x-ray. The x-ray is not emergency care but is necessary and customary to ensure the improving condition of the lungs.

Comment: One commenter requested that we lengthen the time the PO may take to respond to a request for approval of non-emergent care services from 1 hour to 24 hours.

Response: We believe that the PO's responses to urgent and post-stabilization care services requests need to be completed as expeditiously as possible in order to prevent any misunderstanding between the PO, the participant, and the non-network physician. We seek to avoid a situation that might result in failure to provide essential care or result in providing non-covered services because of the length of the PO's response time. Therefore, we are retaining the 1-hour response time for urgent care and post-stabilization care requests.

Final rule actions:

In this final rule, we are:

- Adding language to paragraph (d) to require the PO to explain to the participant that no prior authorization is required for emergency care; and
- Revising § 460.100 to include definitions for urgent and post-stabilization care.

Section 460.102 Interdisciplinary Team

This section is based on provisions in Part IV, section B of the Protocol. In the 1999 interim final rule, we included a requirement that the PO must establish an IDT at each PACE center to comprehensively assess and meet the individual needs of each participant. In § 460.102(a)(1), we require that the PO assign each participant to an IDT based at the PACE center the participant attends.

As we explained in the 1999 interim final rule, we believe that a well-functioning IDT is critical to the success of the PACE program, as the team is instrumental in controlling the delivery, quality, and continuity of care. Members of the IDT should be knowledgeable about the overall needs of the participants, not just the needs that relate to their individual disciplines. In order to meet all of the health, psychosocial, and functional needs of the participant, team members must view the participant in a holistic manner and focus on a comprehensive care approach.

Based on the Protocol, in paragraph (b) we require that the IDT be composed of at least the following members:

a. Primary care physician (PCP)—We considered expanding this to include nurse practitioners but decided to retain the requirement in the Protocol. While it would be acceptable for a PO to include a nurse practitioner on the IDT, we believe that this should be in addition to rather than instead of the PCP, at this time. This approach is consistent with other Medicare regulations. We believe such a change should be included in a proposed rule in order to allow for public comment on this issue. In the meantime, we are continuing to assess the appropriateness of allowing nurse practitioners to assume the role of the PCP consistent with State licensure for nurse practitioners.

b. Registered nurse (RN)—The Protocol requires the inclusion of a ''nurse.'' In paragraph (b)(2), we specified that this team member be an RN. The nurse represented on the IDT must exhibit leadership and management skills that are more consistent with the training received by RNs, as opposed to licensed practical nurses. In addition, we believe that an RN would be better able to determine and respond to the health care needs of the frail population, particularly for home care services.

c. Social worker;

d. Physical therapist (PT);

e. Occupational therapist (OT);

f. Recreational therapist or Activity Coordinator;

g. Dietitian;

h. PACE center manager—We changed the Protocol terminology from ''PACE Center Supervisor'' to ''PACE Center Manager.'' The PACE center manager is responsible for overall operation of the PACE center and ensuring service delivery. The individual who holds this position should be a good facilitator and should possess good communication skills. In many POs, the PACE center manager

leads IDT meetings. We are permitting the PO and the IDT the flexibility to decide who should lead the team and facilitate the discussions.

i. Home care coordinator—Since PACE services may be furnished in the home, the coordination of in-home services with PACE center and primary care services is critical to effective service delivery. This coordination is especially important if the PO has contractors providing the home care services. The PO must designate a home care coordinator to supervise and coordinate home care services, whether these services are furnished by a PACE employee or through a contractor. We changed the Protocol's term ''home care liaison'' to ''home care coordinator,'' because ''home care liaison'' has another meaning in Medicare, and we wanted to avoid confusion.

j. Personal care attendants (PCAs) or their representatives—We changed the Protocol term ''health care worker/aide'' to ''personal care attendant,'' as we believe this term more accurately describes this position. We believe that ''health care worker'' is too general and could apply to other members of the team.

k. Drivers or their representatives—This requirement remains unchanged from the Protocol.

Due to the age of most PACE participants, a geriatrician could be a valuable member of the IDT. As one option, the PCP could be a geriatrician. However, physicians who specialize in geriatrics are relatively rare, and availability might be a serious problem. We have not required the involvement of a geriatrician but in the 1999 interim final rule, we invited comments about whether such a requirement would be desirable and, if so, whether the geriatrician should be employed by the PO and should primarily serve PACE participants.

Consistent with the Protocol, we require in paragraph (c) that primary medical care for all participants be furnished by the PCP(s). The PCP must serve as the gatekeeper to the participant's use of medical specialists and inpatient care, and he or she must be an integral member of the IDT. Ultimate responsibility for management of medical situations must rest with the PCP.

The IDT is responsible for the initial assessment, periodic reassessments, the plan of care, and coordinating 24-hour care delivery. A critical element of the success of the IDT is the degree to which team members share information and communicate with one another. The Protocol requires the physician to keep the IDT informed of the medical condition of each participant and to remain alert to pertinent input from other team members. We believe this should be the responsibility of each member of the team rather than just the physician, as it is critical to timely intervention to address potential problems. To reflect this position, we require in paragraph (d) that each member of the team must regularly inform the IDT of the medical, functional, and psychosocial condition of each participant and remain alert to pertinent input from other team members, participants, and caregivers. This communication can take place through formal measures such as team meetings and written documentation in participants' medical records, but should not be limited to formal mechanisms. Informal communication between team members (for example, CARDEX systems, informal updates during shift changes) should be encouraged as well. It is critical that personal care attendants be involved in the communication process. As they often have the first contact with the participant, it is important that they regularly share information, for example, on the participant's mood, activities, and daily habits. In the 1999 interim final rule, we required that each team member must document all changes in the participant's condition in the participant's medical record.

In paragraph (d)(3), we require that members of the IDT must serve primarily PACE participants, unless a waiver is granted. After considering this issue, we concluded that in order to effectively serve a frail elderly population, such as is served by the PACE program, it is important to support and retain measures that promote quality and continuity of care. If team members serve primarily PACE participants, they are able to develop a rapport with participants and are better able to plan for and provide their care. We recognize that team members may have other clients, but this must not interfere with the provision of services for PACE participants.

In paragraph (g), we included conditions for waiver of the employment requirement for IDT members. CMS and the SAA were authorized to grant a waiver of this requirement if they determined that—

- There are not enough individuals available in the PO's service area who meet the PACE requirement or State licensing laws make it inappropriate for organizations to employ physicians; and
- The proposed alternative does not adversely affect the availability of care or the quality of care that is provided to participants.

In response to public comment on the 1999 interim final rule, and to implement section 903 of BIPA, we made the following changes in § 460.102 in the 2002 interim final rule.

We amended paragraph (d)(2)(iii) to clarify that IDT members must document changes in a participant's condition in the participant's medical record consistent with the documentation policies established by the medical director of the PO. This ensures that only designated team members have access to patient records.

Also, in consideration of the expanded contracting opportunities in the 2002 interim final rule, we removed paragraph (f) that required members of the PACE IDT to be employed by the PO. Finally, we removed paragraph (g) that allowed CMS and the SAA to waive the employment requirement for the PCP and the requirement that the IDT serve primarily PACE participants. Since the PO may contract for PCPs in accordance with the requirements specified in § 460.70 (described in the section I.B.3.b. of this preamble) and other waivers are governed by § 460.26 (described in section I.B.f. of this preamble), these specific waiver provisions are no longer necessary. We amended paragraph (d)(3) by removing the cross reference to paragraph (g).

Comment: There were numerous recommendations on variations of IDT composition, the roles of the IDT members, services the IDT members provide and the locations where the IDT members may provide services. One commenter recommended we grant greater flexibility by specifying in the regulation the teams ''operate from'' the PACE center, regardless of where the services are furnished. This commenter also recommended we omit the requirement relating to physical location of the IDT. Commenters also recommended that we provide greater flexibility in composition of the IDT including when POs operate multiple PACE centers.

One commenter recommended we omit the positions of dietitian, PACE center manager, home care coordinator, PCA, and driver from mandatory membership on the IDT and add a requirement that the core team coordinate and supervise services provided by other staff.

Response: There are other delivery models with an interdisciplinary team approach but none revolve around a PACE center. We believe the cohesive interaction between the IDT and the PACE center is one of the elements that makes PACE not only different but also successful.

The 2002 interim final rule expanded the flexibility available to POs by permitting contracting of individual IDT members or contracting for the entire PACE center and services. One of the essential elements of the IDT is the consistency with which services are provided to participants. Each PACE center is required to have at least one IDT or more if necessary to ensure that each participant is assigned to an IDT at the PACE center the participant attends. As a result, we are not inclined to delink the physical location of the IDT service to the PACE center.

After reviewing the recommendations made by commenters for members of the IDT, we continue to believe that the required membership of the IDT specified in paragraph (b) has been an essential element in the PACE program's proven success in managing the complex health conditions of the frail elderly. Nutritional status has an immense impact on health especially on the frail and the elderly; thus, we believe a dietitian is an essential member of the IDT. The home care coordinator is another position that has a vital impact on the health and safety of participants while they are living at home in the community. The PCAs often have the first and closest interaction of the day with the participants and the driver has contact with the participants both in the early morning and in their home environment. Input from these IDT members or their representatives can be instrumental in the detection of the first signs of impending illness or environmental issues. Therefore, we are retaining the required membership composition of the IDT as published in the 1999 interim final rule in § 460.102(b).

Comment: We received one comment regarding the 2002 interim final rule modifications to the IDT. This commenter requested we retain paragraph (f), which was deleted from the 2002 interim final rule. The commenter also suggested that paragraph (g) be replaced with language the commenter proposed related to contracted PCPs.

Response: The changes to the 2002 interim final rule were made in response to numerous comments requesting flexibility to contract for all members of the IDT. As we stated in the preamble to the 2002 interim final rule, we removed paragraph (f)(requiring members of the IDT to be employed by the PO) and paragraph (g)(allowing waiver of specified requirements) in consideration of the expanded contracting opportunities that were added in the 2002 interim final rule. As the PO may contract for PCPs in accordance with the requirements specified in § 460.70 and other waivers are governed by § 460.26, we determined that this provision was no longer needed.

The commenter's proposed language would have permitted contracting of services for most IDT positions, but dictated when and where services could be provided. We continue to believe that the amendments made in the 2002 rule provide the flexibility requested in comments we received on the 1999 interim final rule. Therefore, we are retaining the changes implemented in the 2002 interim final rule.

Comment: One commenter recommended the IDT include the participant's personal representative.

Response: The intent of § 460.102 was to establish the staff responsibilities for the disciplines that constitute the IDT team of care providers. Although the participant (or his or her representative) is not specifically identified as a member of the IDT under § 460.102, § 460.106(e) requires the team to develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both to ensure there is agreement with the plan of care and the participant's concerns are addressed. Although the participant or his or her representative contributes to the decision-making process, we do not believe that it is appropriate to include the participant or their representative as an IDT member.

The following are comments and recommendations related to specific IDT members.

Comment: In response to our request for comments related to requiring that the PO employ a geriatrician on the IDT, a number of commenters indicated that it is desirable but not feasible to require POs to employ a geriatrician at each PACE center.

Response: We agree with these commenters and are not requiring a geriatrician on each IDT.

Comment: One commenter requested we delete the requirement that PCPs must serve primarily PACE participants.

Response: We are retaining the ''primarily serve'' requirement for all IDT members because this requirement was established to ensure the participants receive the unique benefits offered by the PACE program model.

Comment: A very large number of comments were related to physician adjunct positions, specifically nurse practitioners (NPs) and physician assistants (PAs). One commenter recommended that we include NPs and PAs in IDT requirements because the role of the NP to include primary care and team leadership under a collaborative agreement with an actively involved and fully accessible physician.

Another commenter requested we permit more flexibility in the delivery of primary care through the acknowledgement of the role of NPs and PAs and modify both regulatory sections by adding the phrase ''or a nurse practitioner/physician assistant working in collaboration with a PCP, as reasonable, appropriate, and allowable under State law and regulation.''

Response: In accordance with the PACE Protocol, the regulation requires participation of a physician. Physician is defined in the Medicare program to mean a doctor of medicine or osteopathy as recognized in section 1101(a)(7) of the Act. As a result, there must a PCP on the IDT. The regulation does not prevent the participation on the IDT of NPs or PAs acting in collaboration with the physician and within their scope of practice. However, NPs and PAs may participate on the IDT in addition to the PCP, but may not replace the PCP.

We acknowledge the dedicated service and quality care provided by NPs and PAs to PACE participants, but we do not believe that addition of a specific role description for NPs or PAs in the regulatory language in § 460.102 would provide any additional flexibility to the POs in establishing their IDTs.

Comment: We received three comments related to the requirement for an RN on the IDT. One commenter supported the regulation requiring an RN as opposed to a nurse on the IDT. Another commenter supported flexibility depending on the composition of the team. Another commenter requested the roles of the NP and the clinical nurse specialist (CNS) be consistent with established CMS rules and regulations.

Response: We believe the term ''registered nurse'' is a more clear and definitive title than ''nurse'' and have therefore specified that the IDT must include a registered nurse. We believe that the IDT membership should include an RN, but that does not imply that the PO cannot utilize licensed practical nurses, NPs, or CNSs in other direct care positions acting in collaboration with the physician and within their scope of practice. This approach is consistent with established CMS rules and regulations.

Comment: Several commenters requested that the requirements for the social worker be consistent with those contained in the nursing home regulations with the additional requirement that each PO employ or

contract with at least one Master's level social worker (MSW).

One commenter recommended an alternative to a Master's degree in social work. They recommended that social workers hold a Baccalaureate degree in social work or in a human services field and 1 year of supervised social work experience in a health setting working directly with individuals.

Response: We agree with the commenter and note that a Baccalaureate degree in social work does not include the training in social counseling that is required for a Master's in social worker. Therefore, to clarify the position and responsibilities of the social worker on the IDT, we are amending § 460.102(b)(3) to require a MSW be part of the IDT, rather than a ''social worker.'' In the 1999 interim final rule, § 460.64(c)(2) listed the personnel qualification for a social worker, which included having a Master's degree in social work from an accredited school of social work. In this final rule, we have removed § 460.64(c)(2). We are requiring a MSW on each IDT to establish the social work plan of care and to provide counseling services. The MSW may participate on several teams, perform assessments, reassessments, care planning, and counseling consistent with their education and training. For consistency we are also reviewing § 460.104(a)(2)(iii) and § 460.104(c)(1)(iii), to refer to a Master's-level social worker to perform assessments and reassessments.

Therefore, in § 460.64, we are deleting the specific educational and experience qualifications for social workers as all States require licensure, certification, or registration of social workers as well as qualifications for MSWs. The PO may contract with other MSWs to augment their staffing levels to ensure all participants receive the counseling services provided by MSWs. The PO may employ or contract with Baccalaureate social workers to provide services within their scope of practice.

Comment: A commenter requested that we clarify the terms ''Personal care attendant or his or her representative'' and ''Driver or his or her representative'' in relation to composition of the IDT.

Response: We expect the driver and PCA to be members of the team but understand that a representative may attend morning meetings. Most POs conduct morning IDT meetings during the time when PCAs are actively engaged in morning caring at the PACE center or participants' residences and drivers are engaged in the transporting participants to the PACE center. Therefore, neither the PCA nor the driver are available to attend these IDT meetings. However, we believe these staff are often in a position to provide important details about the participants' physical and emotional condition and changes in their home environment. Information from these IDT members can be relayed through a representative, such as the PACE center manager, home care coordinator, transportation coordinator, RN, social worker, a supervisor, designated colleague, or other IDT member. Therefore, we included representatives of PCAs and drivers in § 460.102(b).

Comment: We received several requests to modify the rule to include the following positions on the IDT: qualified occupational therapy assistants (OTAs), Licensed Practical Nurses (LPNs), certified occupational therapy assistants (COTAs), and Baccalaureate-level social workers (BSWs).

Response: We believe LPNs, OTAs COTAs, and BSWs, provide dedicated quality care to PACE participants and are essential to the operation of POs. However, as we noted above, our current regulations provide ample opportunity for the POs to involve personnel with these educational qualifications in providing the best possible PACE services, without necessarily including them as part of the IDT. We do not think revising our regulation is necessary.

Comment: One commenter recommended that we include an RT on the IDT, stating the statute provides flexibility for the PO to include additional services.

Response: Composition of the IDT was based on the Protocol, which did not include respiratory therapy. However, our regulations do not prevent the inclusion of these professionals. The extent to which POs routinely include respiratory therapists on their IDT will be based on their participants' medical conditions. The IDT is required to involve any discipline necessary to treat the participant's individual needs, which includes assessment, collaboration during the development of the plan of care, and providing treatment.

Final rule actions:

In this final rule we are changing the term ''social worker'' to ''Master's-level social worker'' consistent with our changes to § 460.64.

Section 460.104 Participant Assessment

The information obtained through the participant assessment is the basis for the plan of care developed by the IDT. As such, it is important that the assessment be as comprehensive as possible in order to capture all of the information necessary for the IDT to develop a plan of care that will adequately address all of the participant's functional, psychosocial, and health care needs.

The assessment process begins before enrollment, as set forth in § 460.152, when the PO evaluates whether a potential participant can be cared for appropriately in the program. Often, POs present a proposed plan of care to the potential participant as part of the enrollment process. The initial comprehensive assessment must be completed promptly following enrollment, but individual team members' in-person assessment of the participant should be scheduled at appropriate intervals based on the participant's level of health. Because the initial assessments are thorough, this will ensure that the participant is not overwhelmed with several team members conducting assessments at one time. However, the initial comprehensive assessment must be completed quickly so that the plan of care can be completed and implemented without delay. This often is accomplished by the effective date of enrollment and should never be delayed more than a few days beyond that date. With the team concept, the goal is to obtain input from each discipline, as well as from the participant, through comprehensive assessment that identifies the services necessary to address the participant's needs and care preferences.

Section 460.104(a) requires that as part of the initial comprehensive assessment, each of the following members of the IDT must individually evaluate the participant in person and develop a discipline-specific assessment of the participant's health and social status:

- Primary care physician;
- Registered nurse;
- Social worker;
- Physical therapist or occupational therapist, or both;
- Recreational therapist or activity coordinator;
- Dietitian; and
- Home care coordinator.

We believe the specified IDT members represent the core disciplines needed to determine the specific treatment and psychosocial development needs of the participants. At the recommendation of individual team members, other professional disciplines (for example, speech-language pathologists, dentists, or audiologists) may participate in the initial comprehensive assessment if the participant's needs warrant their inclusion.

In the 1999 interim final rule, we stated that we were in the preliminary stages of developing a standardized core assessment instrument, the COCOA–B, to be used by POs for outcome-based continuous quality improvement. Until such time as this instrument was completed, we specified in § 460.104(a)(4) that the participant's assessment must include, at a minimum, the following information:

- Physical and cognitive function and ability;
- Medication use;
- Participant and caregiver preferences for treatment;
- Socialization and availability of family support;
- Current health status and treatment needs;
- Nutritional status;
- Home environment, including home access and egress;
- Participant behavior;
- Psychosocial status;
- Medical and dental status; and
- Participant language.

We believed that this information would provide a basic framework from which a comprehensive plan of care could be developed, would be appropriate for every participant, and would ensure that the plan of care focused on the participant's medical, psychosocial, and functional needs. However, this list represented the minimum information to be included in the comprehensive assessment, and the PO was encouraged to include other assessment items as necessary.

Although a core assessment instrument has been developed, since the publication of the 1999 interim final rule, our experience with the PACE program has led us to having some misgivings about its long term application. Given the need for flexibility for POs, we are concerned that specifically mandated measures may compromise the discretion of POs to use other assessment tools that may be more appropriate for their settings.

Therefore, we are not inclined to replace the information requirements contained in § 460.104(a)(4) with a specific standardized core assessment instrument. In time, we expect that POs will become more familiar with using the quality assessment and performance indicators that are contained in § 460.134 (physiological well being, functional status, cognitive ability, social/behavioral functioning, and quality of life) as a framework for participant assessments. At this time, we are finalizing the information listed in § 460.104(a)(4) as the required information POs must obtain as part of a comprehensive assessment.

The Protocol requires that the discipline-specific plans be consolidated into a single plan of care for the participant. The development of the plan of care must occur through discussion and consensus of the entire IDT. We established this requirement in § 460.104(b) by stating that the discussion must take place during team meetings, in order to facilitate group discussion of the plan of care and ensure that all members of the team are actively involved in the decision-making process, and that the plan of care must be completed promptly.

In developing the plan of care, the PACE IDT is also required by § 460.104(b) to inform female participants that they are entitled to choose a women's health specialist from the network of PACE providers. We have included this requirement to ensure compliance with the Consumer's Bill of Rights and Responsibilities (CBRR), as explained in detail in the preamble of the 1999 interim final rule.

Reassessments are necessary to provide information to adjust participants' plans of care. Periodic reassessments ensure the continued accuracy and effectiveness of the participant's plan of care. Consistent with the Protocol, we require in paragraph (c) that the following members of the IDT conduct an in-person reassessment on at least a semi-annual basis:

- Primary care physician;
- Registered nurse;
- Social worker;
- Recreational therapist or activity coordinator; and
- Other team members actively involved in the development or implementation of the participant's plan of care, for example, home care coordinator, physical therapist, occupational therapist, or dietitian.

The primary care physician, registered nurse, social worker, and recreational therapist/activity coordinator are required to perform assessments at least semiannually as they are the most critical in terms of defining outcomes of care. Other team members actively involved in the participant's plan of care must also reassess semiannually, as they have an impact on the care the participant is receiving. However, if the participant is not receiving certain services (such as home care, physical therapy, occupational therapy, dietitian services), these members of the team would not be required to conduct a semi-annual assessment for that participant.

Consistent with the Protocol, we require the following members of the IDT to conduct an in-person reassessment on at least an annual basis:

- Physical therapist and/or occupational therapist;
- Dietitian; and
- Home care coordinator.

It is important for the IDT to monitor and respond to any changes in a participant's condition or family situation or any concerns raised by the participant or his or her designated representative. The Protocol requires that the participant be reassessed by the team or by selected members of the team to develop a new plan of care when the health status or psychosocial situation of a participant changes. We believe that all members of the IDT that are required to perform the initial comprehensive assessment should reassess the participant because if fewer members participate in this reassessment, a critical component of a participant's care might be overlooked.

In addition, paragraph (c)(3) requires that if a participant's health or psychosocial status has changed or if a participant (or his or her designated representative) believes that a particular service needs to be initiated, continued, or eliminated, the appropriate IDT members must reassess the participant. The purpose of this reassessment is to evaluate whether it is necessary to increase, continue, reduce, or terminate particular services and whether a different course of treatment is needed. A complete reassessment should ensure that the participant is receiving a continuing program of care that meets his or her current needs. Requiring a reassessment based on the concerns of the participant emphasizes the active role the participant plays in the assessment process and development of his or her plan of care. The participant's adherence to the plan is critical to the successful delivery of services. Therefore, permitting the participant (or designated representative) to trigger a reassessment gives participants the opportunity to express any dissatisfaction with the manner in which care or services are furnished.

We believe the requirements in § 460.104(c)(3) are appropriate, but in this final rule, we wish to clarify that not all changes in health or psychosocial status require reassessment by the entire IDT. We are allowing the PO the flexibility to determine the appropriate staff to reassess changes that are not significant. We continue to believe that significant changes in health or psychosocial status require the in-person reassessment by the IDT members identified in § 460.104(a)(2).

Section 460.104(c)(3) also requires the PO to have explicit procedures for timely resolution of requests from participants (or their authorized representatives) to initiate, continue, or terminate a particular service. Unless an extension is granted, the IDT must notify the participant (or designated representative) of its decision to approve or deny the request as expeditiously as the participant's condition requires, but no later than 72 hours after the IDT receives the request. We considered establishing both a standard process and an expedited process for responding to participant requests; however, because of the frailty of this population, we concluded that every request is urgent and requires a quick response. We want to ensure that a participant's health is not adversely affected due to a delay in reassessing the participant's condition. The goal of the program is to maximize the participant's functioning, and a quick response is meant to ensure that all factors are evaluated, all necessary services are being furnished, and participant health is not compromised. A timely notification also allows participants adequate time to consider appeal rights, if necessary, without compromising their health.

The IDT may extend the 72-hour timeframe by no more than 5 additional days if the participant or designated representative requests the extension, or if the team documents its need for additional information and how the delay is in the interest of the participant. An extension may be warranted because not all of the appropriate members of the IDT may always be able to meet with the participant, conduct a discipline-specific reassessment, discuss the results of the reassessment with the entire IDT, and develop a response to the request within 72 hours. The PO retains the flexibility to determine the most appropriate manner in which to provide notification to the participant (or designated representative).

If, based on the reassessment, the IDT decides to deny the participant's request, the denial must be explained to the participant (or designated representative) orally and in writing. The PO must provide the specific reasons for the denial in understandable language.

If the participant (or designated representative) is dissatisfied with the outcome of the reassessment, the participant may appeal the decision in accordance with. § 460.122. Specifically, the PO must: (1) Inform the participant or designated representative of his or her right to appeal the decision; (2) describe both the standard and expedited appeals processes, including the right to and conditions for obtaining an expedited appeal of a denial of services; and (3) describe the right to and conditions for continuation of contested services through the period of the appeal.

If the IDT fails to provide the participant with timely notice of the resolution of the request for reassessment or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed as an appeal by the PO in accordance with § 460.122.

Team members who reassess a participant must reevaluate the plan of care. Any changes in the plan of care must be discussed and approved by the IDT and the participant (or designated representative). The plan of care reflects the team's and participant's goals for the participant's care. Obtaining the participant's approval of the proposed plan of care is important to the successful delivery of services and the participant's adherence to the plan.

In addition, we also require that any services included in the revised plan of care as a result of a reassessment must be furnished to the participant as expeditiously as the participant's health condition requires. It is critical that care not be delayed and that the participant receive comprehensive care that maintains his or her functional status. Because we recognize that some changes in the participant's plan of care (for example, installing a wheelchair ramp at the participant's home) may require more time to accomplish, we chose not to specify a timeframe for delivering services. However, we solicited comments on the necessity of requiring a specific timeframe. Whenever a participant assessment or reassessment occurs, the information must be documented in the participant's medical record.

Comment: Two commenters requested confirmation that the requirements for the initial comprehensive assessment in § 460.104(a) were not intended to govern the practice of assessment before enrollment or to prescribe which IDT members must conduct assessments before enrollment for purposes of determining whether the individual's needs can safely be met through the PACE program. One commenter requested clarification that the regulation requires that a complete assessment by the full team take place after enrollment. This commenter also asked which members of the team must have conducted assessments before enrollment.

Response: The assessment process begins before enrollment when the PO evaluates a potential participant to determine if they can be cared for appropriately in the community by the PACE program. We do not dictate the disciplines that must perform this assessment; we leave that to the discretion of the PO. The remainder of the initial comprehensive assessment can be performed before the enrollment agreement is signed or the PO can decide to wait until after the enrollment agreement is signed. The only requirement is that the assessment be completed as soon as possible after enrollment so the plan of care can be implemented after the effective date of enrollment with as little delay as possible.

As specified in § 460.104(a)(2), the initial comprehensive assessment must be performed by the following disciplines:

- Primary care physician.
- Registered nurse.
- Social worker.
- Physical therapist.
- Occupational therapist.
- Recreational therapist or activity coordinator.
- Dietitian.
- Home care coordinator, and any other professional discipline the IDT recommends be included in the comprehensive assessment process.

We believe these requirements reflect the current intake, assessment, and enrollment practices of POs. In the discussion regarding 460.102, we clarified that a MSW is a required discipline on the IDT. In order to be consistent with 460.102, we are amending 460.104(a)(2)(iii) and 460.104(c)(1)(iii) to clarify that a MSW performs assessments and reassessments.

Comment: One commenter supported the assessment and reassessment requirements but proposed a modification to § 460.104(a)(2)(i) and § 460.104(c)(1)(i) by adding ''or a nurse practitioner/physician assistant working in collaboration with a PACE PCP, as reasonable, appropriate, and allowable under State law and regulation.''

Response: We believe that the physician should perform the initial comprehensive assessment and semiannual reassessments, because these assessments are the foundation of the participant's plan of care. The NP role is an adjunct position, supportive of the physician when conducted within the NP's scope of practice and as allowable under State law. Therefore,

we are not modifying the regulatory language.

Comment: One commenter requested the requirements in § 460.104(a)(2)(iv) and § 460.104(c)(2)(i) which state, ''Physical therapist or occupational therapist or both,'' be changed to designate these disciplines into separate sections. The commenter pointed out that these disciplines are not interchangeable and both OTs and PTs should be required to participate in the initial comprehensive assessment and annual re-assessment.

Response: After reviewing the comments, we agree that PTs and OTs both needed to participate in the initial assessment and annual reassessments. Therefore, we are revising § 460.104(a)(2)(iv) and § 460.104(c)(2)(i) to require a PT and an OT to perform initial comprehensive assessments and the annual reassessments.

Comment: Two commenters requested clarification on the delivery of gynecological (GYN) services. One commenter asked whether the PO could limit GYN services to providers in their network and, if so, whether there was an assumption that the PO must have more than one GYN specialist under contract.

The other commenter requested clarification of which health professionals would meet our definition of ''qualified specialist for women's health services.'' They questioned whether PCPs would be acceptable due to the time commitment required by the geriatric and cognitive deficits of many participants. The commenter questioned whether adequate GYN services would be available to PACE participants with contracted specialists and recommended the elimination of the regulatory requirement.

Response: We first want to clarify that the PO must provide access to all specialties within its network and participants are required to receive all services through the PO. The CBRR guarantees participants the choice of providers as well as the right of female participants to choose a qualified specialist in woman's health. Therefore, we expect that when possible the PO will contract with more than one provider of gynecological services.

In response to whether the PCP is a qualified specialist for women's health services, a PCP is qualified to perform primary care including basic GYN services, but the PCP is not a ''qualified specialist for women's health services.'' Although female participants may choose their PCP for basic GYN services, if a participant requests a GYN specialist or the participant requires more complex GYN services, the participant must be provided a GYN specialist and, when possible, be provided a choice of GYN specialists.

Accordingly, we are retaining the requirement to provide participants a choice to use a woman's health specialist, consistent with the CBRR protections we adopted in the 1999 interim final rule.

Comment: The majority of commenters on this section disagreed with the regulatory language related to how to accomplish, when to perform, and who must conduct the periodic reassessments required by § 460.104(c). Recommendations ranged from deleting various requirements to requests to provide POs the flexibility over the timing and scope of reassessments. Commenters also provided proposed language changes, including some that are consistent with the Protocol.

Several commenters requested clarification of whether all team members must perform reassessments or whether only relevant team members may perform reassessments.

Response: In response to the numerous comments related to the reassessment requirements, we want to confirm that we believe that the disciplines designated in the 1999 interim final rule at § 460.104(c) are the minimum disciplines required to perform reassessments. We also expect that, should the results of the reassessments raise further issues related to other disciplines, reassessments by additional disciplines must be conducted and included in the development of the comprehensive plan of care.

In contrast, the initial comprehensive assessment must be conducted by those disciplines listed in § 460.104(a)(2), and any other professional disciplines recommended by the IDT. The results of the discipline specific assessments must be consolidated into a single comprehensive plan of care.

Again as specified in our regulation, periodic reassessments must be conducted as follows;

- At least semi-annually, and more frequently if the participant's condition dictates, by the PCP, RN, MSW, recreational therapist or activity coordinator, and other appropriate members of the IDT that are actively engaged in the development or implementation of the participant's plan of care.
- At least annually the PT, OT, dietitian, and home care coordinator must conduct in-person reassessments.

Comment: Numerous commenters remarked on the provision requiring reassessment based on change in participant status or at the request of the participant or his or her designated representative. Several commenters suggested the reassessments initiated by the PO based on changes in health status be differentiated from those requested by the participant.

Many commenters suggested that the requirement that a formal reassessment be conducted based on a change in participant health status be limited to a ''significant change.'' These commenters also suggested including a definition more consistent with the definition contained in nursing home regulations where ''a ''significant change'' means ''a major decline or improvement in the participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease related clinical interventions, that has an impact on more than one area of the participant's health status, and requires an IDT review or revision of the care plan or both.'' Another commenter recommended that we provide POs the same discretion as the nursing home regulations afford nursing homes, to determine whether and to what extent a reassessment or a change in the plan of care, or both, are necessary. Other commenters recommended that if a non-significant change occurs, the reassessment may be conducted by the discipline impacted.

One commenter recommended that this requirement be eliminated, particularly when there is agreement between the IDT and the participant or his or her designated representative.

One commenter suggested that we require the PO to have a defined process for responding to participant requests, which includes assigning appropriate team members to the reassessment.

Response: Due to the fragility of the PACE population, we do not believe it would be prudent to restrict the requirement at § 460.104(c)(3) by limiting reassessments to significant changes in participant health status. The philosophy of PACE requires the staff to be cognizant of any and all changes in participant health status so that they can take a proactive approach to the care of this frail and vulnerable population and prevent development of a major problem. We believe the suggested changes would compromise the integrity of the PACE philosophy.

Moreover, individuals that do not participate in the PACE program and reside in a NF will generally be less independent and mobile. In addition, as they reside in a more restricted environment under constant observation by staff, residents of NFs need less formally defined IDT reassessment requirements. These individuals do not require evaluation of home health or

transportation issues and generally receive more limited PT and OT services than community dwelling PACE participants. For these reasons, we believe that the requests for consistency with NF requirements is inappropriate.

PACE is based on the collaborative relationship between the participant and the PO. We believe it is in the best interest of both the participant and the PO to conduct a reassessment when there is a request for a specific service regardless of whether or not the participant and the PO agree. The reassessment might uncover other issues not previously detected.

In response to comments, we are revising § 460.104(c)(3) by renaming paragraph (c)(3) as paragraph (d) Unscheduled reassessments. We are separating the requirements for reassessments based on a change in participant status in paragraph (d)(1) from those performed at the request of the participant or designated representative in paragraph (d)(2). We are amending the requirements to require the IDT members listed in paragraph (a)(2) to perform in-person reassessments for change in participant status while permitting the IDT the flexibility to determine the appropriate IDT members when the assessment is performed at the request of a participant or his or her representative.

Comment: There was strong disagreement by one commenter regarding the PO's responsibility to inform participants about the appeal process if they are dissatisfied with a determination. The commenter stated the PO should provide appeal information with all written denials, reductions, and terminations of services or changes in the plan of care.

Response: The requirement for written notification of the PO's appeal process is discussed in § 460.122 under Subpart G, Participant rights. This section states, among other things, that participants are provided with written materials on the appeal process upon enrollment and annually thereafter and whenever there is a denial of a request for services. Denial of services includes denial, continuation, or termination of a requested service. The provisions for reassessment at the request of a participant was intended to serve as the first stage of the appeals process.

Comment: In the 1999 interim final rule, we solicited comments on whether to impose a timeframe under which POs must initiate changes in services after a revision to a participant's plan of care. Comments varied and included the following, while some commenters agreed with the existing requirement that services be furnished to the participant as expeditiously as the participant's health condition requires; others indicated that the timeframe should be left to the discretion of the PO. Those commenters stated that specifying a timeframe for service delivery merely adds a layer of regulation and oversight that in all likelihood will not be necessary. Of the comments supporting a specific timeframe, some commenters urged us to set a maximum timeframe of no more than 5 days for initiating service delivery following an approved change in the plan of care plan and permit the timeframe to be waived in specific situations. Other commenters recommended that any individualized timeframes be specified in the participant's plan of care.

Response: In response to the varied and different comments received in response to our solicitation for comment on timeframes for delivering services, we believe further consideration of this issue is needed before adopting a specific timeframe. Accordingly, we are retaining the requirement as published in the 1999 interim final rule which requires the PO to implement changes in a participant's plan of care expeditiously as the participant's health condition requires.

Final rule actions:

In this final rule, we are:

- Amending § 460.104(a)(2)(iv) and § 460.104(c)(2)(i) to require that both the PT and OT perform the initial comprehensive assessment and annual reassessments.
- Amending § 460.104(a)(2)(iii) and 460.104(c)(1)(iii) changing social worker to Master's-level social worker.
- Redesignating paragraph (c)(3) as paragraph (d) titled ''Unscheduled reassessments'' to permit the IDT the discretion to determine the disciplines necessary to perform reassessments that are requested by a participant or his or her representative.

Section 460.106 Plan of Care

Based on Part IV, section B of the Protocol, we developed requirements for the participant's plan of care. In § 460.106(a), we require that the IDT promptly develop a comprehensive plan of care that specifies all care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment. As required by paragraph (b), the plan of care must identify measurable outcomes to be achieved and must be developed in collaboration with the participant and his or her caregiver. The specified outcomes need not be discipline-specific. Instead, these are team goals for the participant's care. Involving the participant in the plan of care is important to the successful delivery of services and the participant's adherence to the plan.

In paragraph (c), we require the team to implement, coordinate, and monitor the plan of care by providing services directly and by supervising the delivery of services furnished by contract providers. The participant's health and psychosocial status, as well as the effectiveness of the plan of care, must be monitored continuously throughout the provision of services, informal observation, input from participants and caregivers, and communications among members of the IDT and other providers.

In paragraph (d), we require that, on at least a semiannual basis, the IDT must reevaluate the participant's plan of care, including the defined outcomes, and make changes as necessary.

Semiannual review of the participant's plan of care ensures that the needs of the participant are being met. It allows the team to determine whether the participant's level of health has changed enough to warrant a change in the level of services or even the setting in which care is provided.

In paragraph (e), we require that participant plans of care be developed, reviewed, and reevaluated in collaboration with the participants or caregivers. The purpose of participant/caregiver involvement is to assure that they approve of the care plan and that participant concerns are addressed. We give POs the flexibility to determine how often care plans should be reviewed with the participant.

In paragraph (f), we require that the participant's plan of care and any changes in the plan must be documented in the participant's medical record.

Comment: We received several comments related to participant involvement in their plan of care. One commenter stated that the participant should always be included in the development of the plan of care to the extent possible and desired, but that use of the term ''or'' in ''participant or caregiver'' suggests that the team may elect not to involve the participant in the development of his or her plan of care.

Another commenter suggested we include a provision to provide for a more negotiated plan of care process incorporating discussion with the participant as part of the process.

Two respondents suggested that the participant and/or his or her representative be given the opportunity to review the plan of care at the time of the official review (semiannually), when

the plan requires significant revision and upon a request of the participant.

Response: It is our expectation that the IDT will include the participant in the plan of care development when possible and include the participant's representative when it is not appropriate to include the participant or at the instruction of the participant.

We believe that the current requirements in § 460.106 provide sufficiently for the inclusion of the participant, or the participant's representative, in the plan of care development.

Comment: One commenter requested we provide some samples of what CMS considers measurable outcomes that could be included in the plan of care.

Response: Some examples of measurable outcome measures that would be specific to an individual plan of care include the following:

- Participant will receive yearly flu shot.
- Participant will gain and maintain 1 pound each 2 week period until weight achieves 100 pounds.
- Participant will be instructed in blood sugar testing. Within 1 week, the participant will able to explain and demonstrate the use of the glucometer and recording of the results.

Final rule actions:

This final rule will finalize § 460.106 as published in the 1999 interim final rule.

Subpart G—Participant Rights

The purpose of subpart G is to establish requirements for patient rights and protections that POs must include in their program agreements and provide to PACE participants.

In accordance with sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act, the PACE program agreement requires the PO to have in effect, ''written safeguards of the rights of enrolled participants (including a patient bill of rights and procedures for grievances and appeals) in accordance with regulations and with other requirements of this title and Federal and State law that are designed for the protection of patients.'' In addition, sections 1894(f)(3) and 1934(f)(3) of the Act allow CMS the discretion to apply the requirements of Part C of title XVIII and sections 1903(m) of the Act and 1932 of the Act relating to the protection of beneficiaries and program integrity as would apply to M+C (now MA) organizations under Part C and to Medicaid managed care organizations under prepaid capitation agreements under section 1903(m) of the Act. Moreover, sections 1894(f)(2) and 1934(f)(2) of the Act require us to incorporate the requirements in the Protocol which includes a patient bill of rights.

In addition, we made every effort to assure that the rights and protections established in the PACE program agreement are in substantial compliance with the Presidential Advisory Commission's (The Commission) Consumer Bill of Rights and Responsibilities (CBRR), which appeared as an addendum to The Commission's Final Report to the President, entitled ''Quality First: Better Health Care for All Americans'' (March 1998). The President issued an Executive Memorandum to the Secretary of the Department of Health and Human Services dated February 20, 1998, which required that, by December 31, 1999, Medicare and Medicaid health care programs be brought into substantial compliance with the CBRR. The PACE program is included within that framework.

As we explained in the 1999 interim final rule, in considering how to apply these patient protections, the statute requires that we take into account the differences between the populations served and benefits provided under PACE, MA, and Medicaid managed care. We believe that the PACE program is unique in its approach to meeting the needs of the frail elderly. Unlike most managed care organizations which are responsible for meeting health care needs alone, the PACE program is an integrated partnership between the individual, the community, and the PO, which is dedicated to providing all-inclusive care to meet all medical and social needs to enable the participant to remain in the community.

We believe it is important to establish participant rights that reflect the differences in the PACE delivery approach from that of other managed care systems. For example, since PACE participants receive services most days of the week, either at the PACE center or through home visits, POs are able to monitor changes in a participant's medical condition and social service needs on a daily basis. When PACE participants are referred to contracted specialists, in most cases, the PO makes the appointment, provides transportation, and often provides an aide or other staff member to accompany the participant. While managed care organizations may provide this level of care management to some enrollees, POs do so routinely for their entire participant census. Also, while managed care organizations furnish a selected array of medical services, they do not furnish all-inclusive care, including social and recreational services intended to enhance participants' quality of life.

To reiterate the philosophy set forth in the Protocol, the PO furnishes comprehensive services designed to: (1) Enhance the quality of life and autonomy for frail, older adults; (2) maximize dignity and respect of older adults; (3) enable frail, older adults to live in their homes and in the community as long as medically and socially feasible; and (4) preserve and support the older adult's family unit. The bill of rights for PACE participants must complement and maintain this philosophy. In the 1999 interim final rule, we relied on the Protocol and incorporated the basic rights that it identifies. However, we were also guided by the M+C regulations in effect at that time and by the CBRR.

The statute also directs us to consider State law. We interpreted this to mean that a PO's participant bill of rights may include additional rights and protections as required by State or local laws and regulations or ethical considerations of particular concern, but only if these additions or modifications provide stronger rights and protections than those established in the 1999 interim final rule. Consistent with the Protocol and the CBRR, we included a provision allowing participants to choose to be represented by family members, caregivers, or other representatives. We intend that a participant may designate a representative to exercise any or all of the rights to which the participant is entitled.

In addition, we require, as did the Protocol, the PO to provide encouragement and assistance to participants in understanding and exercising their rights and in recommending changes in PACE policies and services.

In the discussion on consultations with the State Administration on Aging in section I.B.2.c. of this final rule, we referred to the State Long Term Care Ombudsman Programs. These State programs promote and monitor the quality of care in nursing homes, including identifying and resolving complaints, making regular visits to nursing homes, and generally, improving the quality of care and quality of life of nursing home residents. The role of the ombudsman is to engage in a variety of activities designed to encompass both active advocacy and representation of residents' interests. In the 1999 interim final rule, we specifically requested public comment on whether the ombudsman program could play a role in consumer assistance to potential PACE participants, as well

as to those who have disenrolled and need assistance in organizing their care. With regard to PACE participants, we were also interested in receiving public input as to whether an ombudsman could provide one-on-one consumer assistance to PACE participants and their caregivers to exercise their rights and work effectively with the IDT.

We received a very large number of comments related to participant rights.

Comment: We received 10 comments responding to our request for input regarding whether to require the use of the State Ombudsman Programs as advocates for PACE participants, prospective participants, and disenrolled PACE participants, and to monitor the quality of care provided to PACE participants. The comments related to this request varied. Some commenters recommended that the State Ombudsman Program be extended to cover PACE participants as a natural and appropriate expansion of the ombudsman program. However, the majority of commenters recommended leaving the option to State discretion rather than mandating it in regulation. The primary concern was the limited resources available to State's ombudsman programs. Commenters recommended that should the ombudsman role be expanded to include PACE, CMS should provide the appropriate funding. Other commenters indicated concerns related to funding for training and funding for pilot programs to test the efficacy of the ombudsman program in relation to PACE.

Response: We agree with the majority of commenters who recommended that CMS not mandate the use of the State Ombudsman Program for PACE. We acknowledge the limited resources available to the ombudsman program and agree that utilization of these resources is best left to the States' discretion. Additionally, our experience with the program to date indicates that the PACE grievance and appeal processes are working effectively to resolve participant concerns. We, therefore, are not revising our regulations at subpart G to mandate the use of the State Ombudsman Program for PACE.

Section 460.110 Bill of Rights

In § 460.110, we require a PO to have a written participant bill of rights that is designed to protect and promote the rights of each participant. The organization is required to inform participants upon enrollment, in writing, of their rights and responsibilities, and all rules and regulations governing participation in PACE. In addition, the organization must protect participants' rights and provide for the exercise of those rights.

Comment: Numerous commenters supported the requirement for a written participant bill of rights, and rights published in the 1999 interim final rule.

Response: We appreciate the commenters' support of the participant bill of rights, as we believe in the importance of participant rights and the protection they provide participants.

Final rule actions:

This final rule will finalize § 460.110 as published in the 1999 interim final rule.

Section 460.112 Specific Rights to Which a Participant Is Entitled

Section 460.112(a) Respect and Nondiscrimination

Right #1—

Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.

The individual's right to respect and nondiscrimination is embedded in the basic philosophy of the PACE program. In keeping with the PACE model, we recognize the participant's right to receive comprehensive care in a safe and clean environment and in an accessible manner. The Protocol states that a PACE participant must receive treatment and rehabilitative services. We expanded this requirement to state that the participant has a right to receive comprehensive health care.

The Protocol stipulates that the participant has the right to have dignity, privacy, and humane care. We require the PO to treat the participant with dignity and respect, to afford the participant privacy and confidentiality in all aspects of care, and to provide humane care. The PO must assure that a participant's dignity and privacy are respected not only in its own facilities but also in affiliated or contract providers. Staff should be instructed that any discussions with participants regarding treatment, the participant care plan, and medical conditions should be held in private and kept confidential. While recognizing the participant's right to privacy and confidentiality, we do not advocate physical barriers because participants should be in the view of the staff at all times to ensure safety. However, in situations where there is participant body exposure during treatment, the staff should be instructed to provide temporary screens or curtains.

We adopted from the Protocol the right to be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms. The use of restraints must be based on the assessed needs of the patient, be monitored and reassessed appropriately, and be ordered for a defined and limited period of time. The least restrictive and most effective method available must be utilized and it must conform to the patient's plan of care. Restraints may only be used as a last resort and must be removed or ended at the earliest possible time. We do not believe that restraints of any kind should ever be used as a preferred approach to care and we expect PACE organizations to ensure that their programs are ''restraint free'' to the greatest extent possible. Specific requirements regarding the use of restraint are established in § 460.114.

We adopted the rights established in the Protocol to encourage and assist the participant to exercise his or her rights, including the Medicare and Medicaid appeals processes as well as civil and legal rights. Participants are encouraged and assisted in recommending changes to PO policies and services. We also maintained the right to have reasonable access to a telephone. However, we altered the right established in the Protocol not to be required to perform services for the organization unless the services are included for therapeutic purposes in the plan of care. As we explained in the 1999 interim final rule, we do not believe that a therapeutic program should be tied to performing services for the PO.

The CBRR specifies that organizations should not discriminate on the basis of race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment. POs are required to comply with all Federal, State, and local laws, including discrimination statutes with regard to marketing, enrollment, and provision of services. However, we recognize that, with regard to health status considerations, POs are required as part of the intake process to assess whether a potential participant is appropriate for PACE, that is, meets the State's nursing facility eligibility standard and can be safely cared for in the community. Meeting required certification standards within the PACE context is not deemed a violation of antidiscrimination laws. However, in

order to ensure that the qualification decision is free from other, illegal forms of discrimination, we require POs to retain information on individuals who are assessed but, for whatever reason, are not enrolled.

Comment: One commenter requested that we broaden the list of demographic categories under which the PO cannot discriminate against a PACE participant to specifically include sexual orientation.

Response: We agree with the commenter that the list of demographic categories under which the PO cannot discriminate against a PACE participant should be broadened to specifically include sexual orientation. As discussed in § 460.98(b)(3), we do not believe anyone should be denied enrollment in PACE because of discrimination of any kind. Therefore, in this final rule we are amending the antidiscrimination requirement in § 460.112(a) to include sexual orientation.

Comment: Several commenters asked to what extent the PO is responsible for meeting the following assurances for an enrollee at home:

- Receiving health care in a safe and clean environment and in an accessible manner; and
- To be afforded privacy; to be free from harm, including physical or mental abuse, neglect, punishment, involuntary seclusion, excessive medication, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

Response: In accordance with section 1894(f)(2)(B)(v) of the Act, we may not grant a waiver of the requirement that the PO is at full financial risk and is responsible for the health and safety of the enrolled participants. In accordance with § 460.180(b), the monthly capitation amount is payment in full regardless of a change in health status, and a PO must not seek additional payment except for the limited exceptions specified in § 460.180(b)(7). We expect that locations which furnish medical care to maintain a standard of cleanliness and safety (for example, no bodily fluids on the floors, no broken plumbing, no exposed wires or broken windows). This requirement was specifically aimed at the facilities providing PACE services. However, should the IDT determine and include in the participant's plan of care that assistance is required in the home, then home care would become a required service, subject to the safety and cleanliness requirements of § 460.112. With regard to privacy, consistent with standards of practice, we expect that PO staff and contractors to furnish services in the home in a manner that respects the participant's privacy.

The requirement to be free from harm relates primarily to the behavior of and treatment by the PACE staff and contractors to the participant. However, if PACE staff or contractors identify that the participant is being abused or harmed by a family member or other caregiver, they are obligated to report this abuse to the appropriate authorities, and if acceptable to the participant, may assist the participant in acquiring new living accommodations, or otherwise resolving the abusive situation.

Comment: Another commenter asked if the right to reasonable access to a telephone means the PO is financially responsible for a participant's personal telephone bills.

Response: This requirement was not intended to make the PO financially responsible for the participant's personal telephone bill. Should the IDT determine a telephone is necessary for the health and safety of a participant and includes it in the participant's plan of care, then a telephone would become a required service and the PO would be financially responsible. In this situation, we recommend the PO investigate special telephone plans available in its area that provide only emergency service for those individuals with medical conditions that require the person to have telephone access. In addition, participants should have reasonable access to a telephone at the PACE center that can be used for local calls.

Section 460.112(b) Information Disclosure

Right #2—

Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions.

As we explained in the 1999 interim final rule, in order for consumers to make rational decisions, they need accurate, reliable information that will allow them to comprehensively assess differences in their health care options, including information critical to their initial decision to enroll in PACE and whether to remain in PACE. The CBRR provides for comprehensive information to be provided to consumers in three basic categories: health plan information; health professional information; and health care facilities. Topics addressed include benefits, cost-sharing, dispute resolution, consumer satisfaction and plan performance information, network characteristics, care management information, corporate organization, etc. The CBRR indicates that certain information should be provided routinely with the remaining information available upon request.

Information that is provided to potential enrollees is addressed in more detail in the sections on marketing (§ 460.82) and enrollment (§ 460.154). With regard to participant rights, we linked the right to information disclosure to the information that is included in the enrollment agreement. The PO must explain the enrollment agreement in a manner that the participant is capable of understanding in order to ensure that all participants fully comprehend their rights and responsibilities from the beginning of their relationship with the PO.

Among the items in the enrollment agreement are an acknowledgment that the participant understands that the PO is the participant's sole service provider; a description of PACE services available and how services are obtained from the PO; the procedures for obtaining emergency and urgently needed out-of-network services; information on the grievance and appeals processes; conditions for disenrollment; description of participant premiums, if any, and procedures for payment of premiums.

The enrollment agreement also indicates that the PACE organization has a program agreement with CMS and the SAA that is subject to renewal on a periodic basis. In order to provide participants with information on the status of their organization's program agreement, in paragraph (b)(3), PACE participants have the right to examine the results of the most recent review of the PO conducted by CMS and the SAA and any corrective action plan in effect.

Comment: Several commenters requested that we eliminate the requirement for disclosure of all PACE services available, including all services delivered by providers under contract.

Response: The 2002 interim final rule provides flexibility by allowing POs to contract for all IDT members and all required PACE services. Therefore, we believe it is even more important for POs to disclose to participants which services are furnished by PACE staff and which are provided under contract with another individual or entity. Knowing who will be furnishing services is an essential component of the participant's right to make informed choices. Therefore, we are not adopting the commenter's suggestion to eliminate this requirement.

We have learned that there is confusion over the meaning of § 460.112(b)(1)(iii). That provision requires POs to notify participants when there is a change in services. Our

intention was that participants be provided information regarding a PO's contracted providers at the time a participant's needs change and a referral to a contracted provider may be necessary. This allows the participant to make an informed choice and to be able to choose from the list of the organization's contracted providers, if multiple contractors are available, and be provided the information to make an informed choice. To clarify this point, we are revising § 460.112(b)(1)(iii) to require disclosure of all PO services and services delivered by contracted providers at the time a participant's needs necessitate the disclosure and delivery of such information in order to allow the participant to make an informed choice.

Section 460.112(c) Choice of Providers

Right #3—

Each participant has the right to a choice of health care providers within the PO's network which must be sufficient to ensure access to appropriate high-quality health care. Specifically, each participant has the right:

(1) To choose his or her primary care physician (PCP) and specialists within the PACE network.

(2) To request that a qualified specialist for women's health services provide routine or preventive women's health services.

(3) To disenroll from the program at any time.

The right to access specialists must be seen in the context of the PACE model. Active involvement by participants in their care planning in conjunction with an IDT approach to care management and service delivery are fundamental aspects of the PACE model of care. In fact, although sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act provide for waiver of certain provisions of the Protocol, the use of an IDT approach may not be waived.

As we explained in the 1999 interim final rule, development of a participant's plan of care begins with a comprehensive assessment. Participant preferences for care are identified components of the assessment. Moreover, the team is required to develop, review, and reevaluate the plan of care in collaboration with the participant in order to ensure there is agreement with the plan of care and that participant's concerns are addressed. These provisions complement the participant's rights to participate in treatment decisions, to be fully informed of his or her functional status by the IDT, to participate in the development and implementation of the plan of care, and to make health care decisions, including the right to refuse treatment and to be informed of the consequences of such decisions.

It is in this context that the determination with regard to the need for specialty care is made by the IDT and the participant. If there is disagreement, then the participant has the right to engage the dispute resolution process. The IDT is expected to give ample consideration to a participant's request to see a specialist and to objectively determine whether such visits are necessary to meet the needs described in the plan of care.

We believe that access to qualified specialists for women's health services is extremely important. Therefore, we identified such a request as one of the participant preferences that must be considered in developing the plan of care.

In addition, the CBRR asserts that consumers with complex or serious medical conditions who require frequent specialty care should have direct access to a qualified specialist of their choice within a plan's network of providers. Authorizations, when required, should be for an adequate number of direct access visits under an approved treatment plan. We believe that central to the PACE model is the organization's interest in ensuring that participants obtain the care they need, including specialty care, in the easiest and most efficient manner possible. A participant who needs a course of therapy with a specialist will have that need reflected in his or her plan of care and would receive that care for the duration and number of visits specified in the plan. In light of the requirements elsewhere in this rule concerning the development and management of the plan of care, we believe it would be redundant to include an explicit requirement that would mirror this CBRR provision, and have, therefore, not included such a requirement.

In addition, CBRR provides the right to transitional care for patients who are undergoing an extensive course of treatment for a chronic or disabling condition.

With regard to having a participant's choice of PCP and specialists, the PO is required to maintain sufficient staff and contractors to meet participant needs. Given the initial participant census of POs, it is likely that choice will be limited. POs may start out with one of each type of specialist and perhaps only one PCP. Although the CBRR includes the right to choose among physicians in the provider's network, it was aimed at managed care organizations with thousands of enrollees and numerous providers. This is not always the case with the PACE model. Potential participants must weigh the limited network of POs with the benefits of a comprehensive, all-inclusive delivery system when choosing to enroll. As we discuss in more detail in the enrollment section, potential participants must be advised that the PO is the participant's sole source provider and that although the organization guarantees access to services, it does not guarantee access to a specific provider.

Comment: We received numerous and varied comments on this provision. One commenter pointed out that there is no requirement in the regulation that POs must have more than one PCP or specialist. Two commenters stated the bill of rights should clearly require disclosure when a PO has only one PCP.

One commenter requests that CMS qualify § 460.112(c)(1) as follows: ''[T]o choose his or her primary care physician and specialists from within the PACE network, as accessible and feasible * * *''

Other commenters recommended that POs be required to contract with several of the more frequently required specialists to provide choice to participants.

Response: We expect POs to have contractual arrangements with PCPs and specialists to meet the needs of their participants. CMS and the SAA determine compliance with the requirement as part of the application process and through ongoing monitoring to ensure that all participants have access to specialist services to meet their needs.

We note that there are many geographic areas that have a limited number of specialists available and providing a choice of specialists may not be possible. In addition, many PACE programs begin operations with a few participants and gradually gain participant census over time. In these cases, it would be unnecessary for the PO to employ or contract with more than one PCP or specialist in order to ensure appropriate access to specialist services. For this reason, we are not adopting the change in this final rule.

We believe that POs will have an adequate number of primary care providers and commonly-needed specialists to care for their participant population. The POs are financially responsible for all their participants' health care needs. Delays in the provision of primary care services or referrals for specialist services may have significant impact on the PO's overall financial viability. Likewise, early identification of emerging health care

problems has helped POs manage the risk associated with programs for the frail elderly. Failure to furnish timely primary care services may lead to more expensive care including the need for institutionalization.

In order to ensure that participants and potential enrollees are aware of the PO's network, § 460.112(b) requires that POs disclose all PO services and services furnished by contractors before enrollment, at enrollment, and when a change in a participant's needs necessitates the disclosure in order to allow the participant to make an informed choice. The lists will provide information about the number of PCPs and providers within each specialty and allow participants or prospective enrollees to make an informed decision about enrollment or continued enrollment in the PO.

Finally, we believe changing the regulatory language as the commenter suggested could be read as allowing a participant to choose from outside the PO's network if a PCP or specialist within the PO's network was not considered ''accessible and feasible.'' We are unsure what the commenter meant, but we do not agree that participants should have access to non-network providers. Before enrollment, when participants sign the enrollment agreement, they are informed that the PACE program is their sole health care provider. In addition, each PACE program has a network that is sufficient to ensure access to appropriate high quality care. As a result, we do not believe it would be necessary to allow access to non-network providers. This requirement is intended to ensure all-inclusive and coordinated care. Therefore, we are not amending the regulatory language.

Comment: Commenters also requested clarification as to a participant's right to request services from a qualified specialist whether or not the IDT has determined that specialist care is medically necessary.

Response: It is a participant's right to request a service they believe is necessary, which includes a request to see a specialist. If the IDT disagrees that specialist services are necessary, the participants may request a reassessment under § 460.104(d) and access the appeals process to ensure appropriate consideration is given to their request for coverage of specialist services.

Comment: One commenter recommended that we eliminate the requirement concerning women's health services and instead, allow an appropriately trained PACE PCP to serve as a qualified specialist for women's health services.

Response: As discussed in § 460.104, in developing the plan of care, female participants must be informed that they are entitled to choose a specialist in women's health services from the PO's network of providers.

Although we believe that a PCP trained in women's health care is capable of providing adequate care, we included this right to be consistent with the CBRR and Medicare managed care regulations. To further clarify the importance of access to a woman's health care specialist, we included these requests as one of the participant preferences that must be considered in developing the plan of care under § 460.104(b). We recommend that POs contract with a sufficient number of woman's health care specialists to respond to participant requests.

Section 460.112(d) Access to Emergency Services

Right #4—

Each participant has the right to access emergency health care services when and where the need arises without prior authorization by the PACE IDT.

We establish a participant's right to emergency services without prior authorization, and define emergency care, emergency medical condition, urgently needed services and post-stabilization care services in § 460.100 as these terms relate to obtaining emergency care.

Comment: One commenter requested that we define prior authorization to mean any requirement or request imposed on the participant to call or notify the PO before or during the emergency.

Response: We do not believe the term ''prior authorization'' needs to be defined as it is a well understood concept as used in the health care arena. In addition, while we generally agree with the commenter's definition, we do not believe it is needed in this context. In emergency situations, as described in § 460.100, prior authorization under any possible interpretation could delay a participant from receiving life saving critical care. Therefore, we are not revising the regulation as requested.

We note, however, that prior authorization is appropriate for urgent care outside of the service area and for post stabilization care services. The PO needs to educate its participants in the difference between emergency care (where prior authorization is not required), and urgent care (where prior authorization is appropriate). Participants need to understand when to request prior authorization and when to request urgent care. In addition, in accordance with § 460.100(e), participants must be informed that they are required to wait 1 hour after requesting prior authorization for urgent care before pursuing this care. POs need to understand their responsibility to respond to these requests within one hour or the PO relinquishes its opportunity for prior authorization for the services and will be responsible for payment of the services obtained by the participant. Section 460.100, as discussed above, further describes the concepts of urgent, emergency, and post stabilization care.

Section 460.112(e) Participation in Treatment Decisions

Right #5—

Each participant has the right to fully participate in all decisions related to his or her care. A participant who is unable to fully participate in treatment decisions has the right to designate a representative. Specifically, each participant has the right:

(1) To have all treatment options explained in a culturally competent manner, and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions.

(2) To have the PO explain advance directives and to establish them, if the participant so desires, in accordance with § 489.100 and § 489.102 of this chapter.

(3) To be fully informed of his or her health and functional status by the IDT.

(4) To participate in the development and implementation of the plan of care.

(5) To request a reassessment by the IDT.

(6) To be given reasonable advance notice, in writing, of any transfer to another treatment setting and the justification for the transfer (due to medical reasons or for the participant's welfare or that of other participants). The PO must document the justification in the participant's medical record.

Active involvement by participants and their designated representatives in care planning is fundamental to the PACE model of care. As a result, we included the rights from the Protocol related to participant involvement in the development and implementation of the plan of care. We included the participant's right to be fully informed by the IDT of his or her health and functional status. In support of this right, the participant must have, upon written request, access to all records pertaining to herself or himself. Moreover, the team must provide care information in a manner that is responsive to the culturally diverse

populations whom they serve. The PO may need to develop strategies for enhancing cultural competence in its staff such as increased use of interpreters, incorporating in-house training programs, recruiting culturally diverse staff or contractors, or establishing relationships with organizations that provide technical assistance regarding cultural aspects of health care.

The Protocol states that a participant has the right to refuse treatment and be informed of the consequences of such refusal and that PACE participants may establish advance directives and make health care decisions. We restructured these two requirements in order to place greater emphasis on the participant's right to make health care decisions and to clarify that to refuse treatment is a type of health care decision. We maintained the participant's right to make advance directives, we clarified that within this right, the PO is required to fully explain advance directives to participants (in accordance with § 489.100 and § 489.102 of this chapter).

We maintained the requirement that POs provide reasonable advance notice, in writing, of any transfer to another treatment setting. In the 1999 interim final rule, we solicited comment on the necessity of specifying a timeframe for participant notification. Given the frailty of the PACE population, while some participants may require additional time to prepare for a transition to another setting, others may be able to transfer without delay.

In addition to these specific rights, there are other processes embodied in the PACE model that promote participant involvement in care planning and implementation. For example, the comprehensive assessment that serves as the basis for the plan of care includes participant and caregiver preferences for care. This input from participant and caregivers is used by the IDT to monitor the effectiveness of the plan of care. Finally, the team is specifically required to develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, to ensure that there is agreement with the plan of care and that participant concerns are addressed.

In support of effective involvement in care planning and communication between participants and providers, we note that the statute provides a specific sanction if we determine that the PO imposes a physician incentive plan that does not meet statutory requirements (see § 460.40(h)) or prohibits or otherwise restricts a health care practitioner from discussing treatment options with the participant or caregiver (see § 460.40(g)).

Comment: In response to our request for comment relating to specifying a timeframe for notification to participants of transfers to other treatment settings, we received several comments which provided general consensus that the regulation should not impose a timeframe on notification for transfers. Most commenters supported permitting the PO the flexibility to distinguish between the different types of situations and to determine whether a written notification and/or verbal advanced notice would be most appropriate based on emergency and non-emergency situations.

One commenter suggested that the term ''reasonable'' is sufficient, with the understanding that the timeframe must be justified by the documentation in the medical record.

Another commenter stated the PACE program is designed around its collaborative nature, but the ''right to be given reasonable advanced notice in writing of transfer to another treatment setting with justification'' sounded like a unilateral decision by the PO. The commenter believes that transfer decisions should also be collaborative and agreed upon by the participant.

Several other commenters supported advanced written notice for a planned transfer, while some identified situations when immediate transfers would preclude the appropriateness of an advanced written notice (for example, a heart attack).

Another commenter recommended that CMS incorporate the requirement of timely notice, by both written notice and verbal explanation, of at least 30 days. This notification timeframe would permit participants to file a grievance or appeal, as appropriate.

Response: We agree with the majority of the commenters who pointed out the difference between planned and emergent transfers, and the need for PO flexibility in determining an appropriate timeframe to notify the participant based on the individual situation. We also note that while generally a transfer may be collaborative depending on the participant's need for the transfer, the PO may need to make the decision and should be afforded the flexibility to do so without undue time restrictions. We also expect full documentation for the transfer to be reflected in the participant's medical record. Therefore, we are maintaining the current language, requiring ''reasonable advanced notice'' for transfers to any treatment setting. We urge POs to provide as much advance notice as possible for non-emergent transfers.

Section 460.112(f) Confidentiality of Health Information

Right #6—

Each participant has the right to communicate with health care providers in confidence and to have the confidentiality of his or her individually identifiable health care and other information protected, including information contained in an automated data bank (see § 460.200). Each participant also has the right to review and copy his or her own medical records and request amendments to those records.

Consistent with the CBRR and MA and Medicaid managed care organization requirements, participants have the right to communicate with any member of the IDT and contract providers in confidence and to have the confidentiality of their individually identifiable health care information protected.

In addition, the section on maintenance of records and reporting of data specifically addresses confidentiality and the safeguarding of health, financial, and other information (see § 460.200). It requires POs to establish written policies and implement procedures to safeguard the privacy of participant information and ensure appropriate use and release of participant information. POs are also required to comply with the HHS privacy standards as required by the Health Insurance Portability & Accountability Act (HIPAA) of 1996, Pub. L. 104–191, and its implementing regulations codified at 45 CFR parts 16 and 164.

Comment: We were asked to clarify that a participant's right to communicate with health care providers in confidence and to have the confidentiality of his or her individually identifiable health care information protected does not preclude IDT members and other care providers from sharing such information with each other.

Response: Members of the IDT and other care providers are permitted to discuss a participant's confidential individually identifiable health care information for treatment, payment, and health care operations, provided that such use or disclosure is consistent with other applicable requirements of the HIPAA Privacy Rule (45 CFR parts 160 and 164). Confidentiality requirements are intended to protect the participant's health information from being disclosed to individuals who are not involved with the participant's health care needs. This requirement does not prevent members of the IDT, contracted

providers, and caregivers from discussing a participant's health information, which may be essential in ensuring appropriate care.

Section 460.112(g) Complaints and Appeals

Right #7—

Each participant has the right to a fair and efficient process for resolving differences with the PO, including a rigorous system for internal review by the organization and an independent system of external review. Specifically, each participant has the right:

(1) To be encouraged and assisted to voice complaints to PACE staff and outside representatives of his or her choice, free of any restraint, interference, coercion, discrimination, or reprisal by the PACE staff.

(2) To appeal any treatment decision of the PO, its employees, or contractors through the process described in § 460.122.

We received no comment on this section. We note that comments regarding grievance and appeals procedures are addressed in § 460.120 through § 460.124.

Final rule actions:

In this final rule, we are revising § 460.112 by:

- Expanding paragraph (a) to include sexual orientation; and
- Revising paragraph (b)(1)(iii) to require the disclosure of all PO services and services delivered by contracted providers at the time a participant's needs necessitate the disclosure and delivery of such information in order to allow the participant to make an informed choice.

Section 460.114 Restraints

We revised the wording used in the Protocol regarding the use of restraints in order to emphasize that the use of restraints must be limited to those situations with adequate, appropriate clinical justification. The PO must limit use of restraints to the least restrictive and most effective method available. If the use of a restraint is needed to ensure the participant's physical safety or the safety of others, the use must be in accordance with certain conditions. First, restraints may only be used for a defined and limited period of time based on the assessed needs of the patient; second, such use must be imposed using safe and appropriate restraining techniques; third, such use may only be imposed when other less restrictive measures have been found to be ineffective to protect the participant or others from harm; and finally, such restraints must be removed or ended at the earliest possible time. As noted above, the use of restraints must be based on the assessed needs of the patient, and be continually assessed, monitored, and reevaluated.

We do not believe that restraints of any kind should ever be used as a preferred approach to care, and we expect POs to ensure that their programs are ''restraint free'' to the greatest extent possible. Specific requirements regarding the use of restraints are established in § 460.114.

We have re-examined our seclusion and restraint policy for all CMS-covered providers and have begun amending our restraint and seclusion policies. We call your attention to the discussion of the use of seclusion and restraints in the CMS interim final rule concerning the conditions of participation for hospitals (CMS–3018–IFC, published July 2, 1999, 64 FR 36070). In that regulation, we established explicit standards for the use of seclusion and restraints both in medical/surgical care and for behavior management (see § 482.13(e) and (f)). While the standards are not identical to those we included in § 460.114, they share the common principle that patients have the right to be free from restraints of any form that are not medically or psychiatrically necessary or are used as means of coercion, discipline, convenience, or retaliation by staff. In the preamble to the interim final rule for the hospital conditions of participation, we indicated our intent to examine the applicability of the hospital restraint and seclusion standards to other providers. In our 1999 PACE interim final rule, we asked for comments about how best to extend the protections established for hospital patients to participants in the PACE program.

We received no public comments on § 460.114.

Final rule actions:

This final rule will finalize § 460.114 as published in the 1999 interim final rule.

Section 460.116 Explanation of Rights

Section 460.116 requires the PO to have written policies and implement procedures to ensure that the staff, the participant, and his or her representative understand the participant's rights. The regulations also require that, at the time of enrollment, staff review participant rights with the participant and his or her representative, if any, in a manner which he or she understands. The PO is expected to assure that information is provided to the physically and mentally disabled, that translator services are available as needed for non-English speaking participants, and that interpreter services and other accommodations (such as TTY connections) are made available to the hearing-impaired.

We also incorporated the requirement that participant rights be posted in a prominent place in the PACE center in English and any other principal language of the community. This allows participants, PACE center staff, and other concerned persons to review the participant rights at any time. For those participants who speak or read in only a ''non-predominant'' language, the participants should have their rights explained to them in a manner they understand.

Comment: We received three comments related to multilingual issues. One commenter recommended that we specify that written information should be in a language easy to understand by the participant and should be given out at enrollment. Commenters also recommended that the participant bill of rights be displayed in English and other principal languages in the PO's service area. One commenter recommended that we consider providing programs serving multilingual populations with financial assistance to cover translation expenses.

Response: Our intent is that all marketing materials including the enrollment agreement be provided in a language the participant is able to understand. The regulation requires participant rights to be provided in writing, in English, and in other principal languages of the community, and to be explained in a manner the participant and his or her representative understands. In addition, § 460.116(c) requires that the PO display the participant rights in a prominent place in the PACE center. The State establishes the criteria POs use for determining a principal language of the community. We do not provide financial compensation for translation expenses, as we believe this is a cost of doing business for all entities in geographic areas where there are multilingual populations.

Final rule actions:

This final rule will finalize § 460.116 as published in the 1999 interim final rule.

Section 460.118 Violation of Rights

Section 460.118 requires the PO to have and implement documented, established procedures to respond to and rectify a violation of a participant right. This requirement is intended to ensure that the PO will address all violations of participant rights and not allow problems to continue.

We received no public comments on § 460.118.

Final rule actions:

This final rule will finalize § 460.118 as published in the 1999 interim final rule.

Section 460.120 Grievance Process

In accordance with sections 1894(b)(2)(B) and (f)(3) and 1934(b)(2)(B) and (f)(3) of the Act, we have established requirements at § 460.120 through § 460.124 requiring PACE organizations to establish procedures for grievances and appeals. We have adapted these requirements from Part II, section B of the Protocol. Rather than follow the Protocol's interchangeable use of the terms ''complaint,'' ''grievance,'' and ''appeal,'' we have distinguished between grievances and appeals. Our intent was to delineate between (1) a participant's grievance regarding dissatisfaction with service delivery or the quality of a service furnished and (2) a participant's action with respect to noncoverage of or nonpayment for a service. We believe that such a distinction is needed to clearly establish both a process to address a participant's dissatisfaction with service delivery or quality of care furnished and a process to address the PACE organization's refusal to furnish or pay for a particular service. The grievance process and the appeals process are similar, since both are based on the Protocol, with some minor differences due to the nature of the complaint.

A grievance is defined as a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished.

The PO must have a formal written process to evaluate and resolve grievances, whether medical or non-medical in nature, by PACE participants, their family members, or representatives. Having a formal written process to evaluate and resolve grievances is essential since all personnel (employees and contractors) who have contact with participants should be aware of and understand the basic procedures for receiving and documenting grievances in order to initiate the appropriate process for resolving participant concerns.

We retained the requirement from the Protocol that all participants must be informed of the grievance process in writing. This information must be provided to participants upon enrollment into the PACE program and at least annually thereafter. We believe it is critical that participants are fully and promptly informed of this process and periodically reminded of their rights, so they may exercise these rights from the beginning of their relationship with the PO.

The grievance process, at a minimum, must include procedures for:

(1) Filing a participant's grievance;

(2) Documenting the participant's grievance;

(3) Responding to and resolving the participant's grievance in a timely manner; and

(4) Maintaining confidentiality of the participant's grievance.

The PO's internal procedures should assure that every grievance is handled in a uniform manner and that there is communication among different individuals who are responsible for reviewing or resolving grievances. In addition, the PO must maintain appropriate documentation, so the information can be utilized in the organization's QAPI program. Requiring that grievances be responded to and resolved in a timely manner provides a protection to the participants. This action is intended to ensure that the PO addresses all participant concerns and does not allow the problem in service delivery to be unresolved. Finally, at all times, an organization must have procedures governing confidentiality to protect against unauthorized or inadvertent disclosure of information. Participant confidentiality is also intended to prevent reprisal against the participant.

It is critical that the PO continue to provide care to the participant during the grievance process because once enrolled, in accordance with § 460.154(p), participants must receive care solely through the PO. Continuing care also encourages participants to continue to voice concerns about service delivery without fear of reprisal.

The PO must discuss and provide to the participant in writing the steps, including timeframes for response, that will be taken to resolve the participant's grievance both at the time of the participant's enrollment and when a grievance is filed. This requirement assures the participant that there will be resolution of the issue. In addition, the organization acknowledges the participant's concern, tries to address the problem, and makes any necessary adjustments in service delivery. We recognize there will be occasions when a grievance may not be resolved to the satisfaction of the participant, but believe the PO should nonetheless set forth its best efforts. The PO must maintain, aggregate, and analyze information on grievance proceedings. This requirement is an integral part of fostering an environment of continuous improvement, and complements the QAPI requirements. We expect that once an organization has a quality improvement system in place, participant grievances will be analyzed and evaluated as grievances may be the first clue that a problem exists. By analyzing the number and types of grievances, a PO will be able to develop activities to monitor and improve the grievance resolution process, as well as identify and make improvements or modifications in the care.

Comment: One commenter was concerned that the definition of grievance found in § 460.120 could lead to confusion as to whether minor problems that present in day-to-day staff-participant contact during the provision of services would be interpreted as grievances and reported as such.

Response: The commenter has interpreted the requirement correctly. A grievance could identify a minor problem where someone is dissatisfied with the service provided. We would expect grievances to occur in day-to-day interactions and we expect to see a number of grievances simply because people have different opinions and expectations. Therefore, we are more concerned when grievances over such things as food or the choice of music are not recorded. We expect these grievances to be tracked, evaluated, and included in the QAPI process. For example, if there is a pattern of complaints about cold food, the issue should be addressed and if every time a particular dish is served many participants complain, then a change in the menu should be considered.

Comment: Two commenters expressed concern with the requirement to ''continue to furnish all required services.'' One commenter requested the regulatory language be revised to define ''required services,'' and the other commenter requested modifying the requirements regarding the PO's responsibility to continue to provide services during the grievance process. Both commenters recommended that we clarify that the PO must continue to furnish to participants all services required by their current treatment plan. If a change in health status necessitates a change in treatment plan, the PO must furnish to the participant all services required by the revised treatment plan.

Response: It appears that commenters may have confused grievances which related to quality of services with appeals that relate to coverage of services. ''Required services'' are those services indicated in the participant's plan of care. This requirement is a participant protection intended to avoid potential reprisal. We continue to

believe that it is appropriate for the PO to continue to provide all required services in the plan of care during the grievance process. Thus, we do not believe the clarification requested is necessary.

Comment: One commenter indicated the requirement did not specify a timeframes for the resolution of a grievance. The regulations require that the PO only has to provide written notice that includes the timeframes for response. The commenter recommended that all grievances be resolved within 30 days.

Response: Grievances cover a wide range of issues which may be resolved in minutes or may take much longer to resolve. Therefore, while we require the PO to have a written process to evaluate and resolve medical and non-medical grievances, we have not established a specific timeframe for resolution of grievances. The PO must acknowledge receipt of the grievance in writing and provide to the participant information as to the expected timeframe for response based on the specific situation. We expect that POs will make every effort to resolve grievances as expeditiously as possible accounting for the complexity of the particular grievance filed. Accordingly, we have not revised the regulation to set forth timeframes for resolutions.

Comment: One commenter asked whether we intended that service delivery encompass administrative complaints, such as failure to replace a lost handbook on a timely basis, failure to return phone calls related to requests for information, or breaches of confidentiality.

Response: We expect POs to acknowledge grievances in writing, to record, and to resolve any issue about which a participant expresses dissatisfaction (medical or non-medical), including administrative complaints. These grievances should be reviewed, analyzed, and included in the PO's QAPI plan.

Comment: One commenter recommended that PO actions on grievances be subject to monitoring at any time.

Response: In accordance with § 460.200, the PO must allow CMS and the SAA access to its data and records. In addition, POs report data for monitoring that includes grievance information. Thus, CMS and the SAA have access to and routinely review grievance information.

Final rule actions:

This final rule will finalize § 460.120 as published in the 1999 interim final rule.

Section 460.122 PO's Appeals Process

An appeal is defined as ''a participant's action taken with respect to a noncoverage of, or nonpayment for a service.'' The PO must have a formal written appeals process, with specified timeframes for response. We included the requirement from the Protocol that all participants must be informed of the appeals process in writing. This information must be provided to participants upon enrollment into the PACE program, at least annually thereafter, and whenever the IDT denies a request for services or payment. The appeals process, at a minimum, must include written procedures for:

(1) Timely preparation and processing of written denials of coverage or payment in accordance with § 460.104(c)(3);

(2) Filing a participant's appeal;

(3) Documenting the participant's appeal;

(4) Appointing an appropriately credentialed and impartial third party who was not involved in the original decision and who does not have a stake in the outcome of the appeal to review the participant's appeal;

(5) Responding to and resolving the participant's appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the PO receives an appeal; and

(6) Maintaining confidentiality of participant appeals.

The appeals process is similar to the grievance process. However, we included the requirement that an objective third party be appointed to review all appeals. In this way, information is reviewed by an individual or group that has no financial stake in the decision. This helps to prevent bias in the decision. In addition, we specified that the PO must respond to participant appeals within 30 calendar days of receipt of an appeal and established a shorter timeframe for expedited appeals. We did not include a provision for a 14-day extension of this 30-day timeframe (as allowed under the MA regulations at § 422.590(a)) in recognition of the frailty of the PACE population. We solicited comments on both the appropriateness of the 30-day timeframe and on the necessity of requiring a specific timeframe.

In § 460.122(d)(2), we adopted the Protocol requirement that the PO must give the parties involved in the appeal a reasonable opportunity to present evidence related to the dispute in person as well as in writing.

It is critical that the PO continue to furnish care to the participant during the appeal process because, in accordance with § 460.154(p), participants must receive care solely through the PO. In addition, we incorporated the Medicaid continuation of benefits provision for all Medicaid participants. Under the Medicaid continuation of benefits provision in § 460.122(e)(1), the PO may not terminate or reduce disputed services while an appeal is pending if the Medicaid participant requests that they be continued, with the understanding that the participant may be liable for the cost of those services if the appeal is not resolved in his or her favor. It is critical that all other care continue in order to maintain the participant's functional status. The goal of the program is to furnish comprehensive care to the participant and this cannot be accomplished if there is a breakdown in the provision of services.

The PO must have an expedited appeals process for situations in which the participant believes that if the service is not furnished, his or her life, health, or ability to regain maximum function would be seriously jeopardized. This process provides for prompt consideration of requests for services if the participant's health might be adversely affected if he or she had to wait for the standard appeals process to resolve the issue. As noted above, the goal of the PACE program is to maximize the participant's functioning, and the expedited appeals process ensures that all factors are evaluated so that all necessary services are being furnished and participant health is not compromised.

We included a provision at § 460.122(f)(2) pertaining to the expedited appeals process requirement that the PO must respond to the appeal as expeditiously as the participant's health condition requires, but no later than 72 hours after it receives the appeal. The 72-hour timeframe may be extended by up to 14 calendar days if the participant requests the extension or if the PO justifies to the SAA the need for additional information and how the delay is in the interest of the participant. The timeframes for responding to requests for expedited appeals are consistent with the requirements for MA expedited appeals in § 422.590(d). The PO must take appropriate action to furnish the disputed service as expeditiously as the health condition of the participant requires if, on appeal, a determination is made in favor of the participant. There may be situations in which the PO has made an incorrect or inaccurate assessment of the participant's needs or condition and has denied a service. In

these situations, it is critical that ongoing care not be delayed until the appeal is resolved, and that the participant continue to receive comprehensive care that maintains her or his functional status.

We maintained the Protocol requirement that all determinations that are wholly or partially adverse to the participant must be forwarded to CMS and the SAA. We require that the PO notify CMS, the SAA, and the participant of its actions at the time the decision is made.

We solicited comment regarding the appropriateness of a 30-day timeframe without extension, within which the PACE provider must respond to a participants' appeal, and on the necessity of requiring a specific timeframe for implementing the change in the participant's plan of care resulting from resolution of the appeal.

Comment: Several commenters supported the timeframes as published. One commenter supported the emphasis on participant rights, believed appeals would be rare and thus supported the 30-day timeframe with a shorter period for expedited appeals.

Several commenters suggested timeframes for the various components of the appeal process. Three commenters supported the 30-day timeframe in which the PO must respond to the participant's appeal. Two commenters requested the regulation specify a timeframe in which the PO must inform the participant of the determination on the appeal, while another commenter suggested that the regulation specify that services should be provided no later than 10 days after a favorable determination or immediately in the case of the expedited appeal. One commenter requested that we clarify the PO's right to implement its determination in connection with its internal appeal process.

Response: We are retaining the timeframes as required in the 1999 interim final rule. The timeframes are consistent with MA requirements in § 422.568 through § 422.570. As PACE utilizes the same timeframes as the MA requirements, we believe it is important to maintain this consistency.

Comment: One commenter stated that informing the participant of the external appeal process when the PO's internal appeal process determination is not wholly in the participant's favor was sufficient. Other commenters requested the regulation provide more detail in the denial notice provided to the participant when a request for services is denied. The commenter recommended that the notice include a description of the process used when a participant requests an item or service, the reason for the denial, the right to submit additional evidence, and information about the appeal process.

Response: Section 460.104(c)(3) requires an in-person reassessment when the participant or his or her representative believes a participant needs to initiate, eliminate, or continue a particular service. In addition, in accordance with § 460.122(b), the PO is required to have processes for timely resolution of participant requests and appeals and to provide written information on the appeals process to participants on enrollment, annually thereafter, and any time the IDT denies a request for services. We believe that the current regulation provides adequate notification requirements for the appeals process and additional changes at this time are not necessary.

Comment: We received comments requesting that we clarify what is meant by ''appropriately credentialed'' and ''impartial third party,'' as provided in § 460.122(c)(4). It was recommended that the regulatory requirement be modified to specify that the appointment be of an impartial third party credentialed in a field that is appropriate for the service at issue. Commenters questioned whether a PO's employees or contractors could serve in this capacity.

Response: An appropriately credentialed and impartial third party is an individual who was not involved in the original action and who does not have a stake in the outcome of the appeal. For example, this individual may be an outside physician or practitioner in a related field who will review the documentation related to the appeal.

To the extent that POs allow employees and contractors to review the IDT denials, it is in the context of a review committee. An employee or contractor may participate on these review committees so long as they have no connection to the original denial decision and their expertise is in the appropriate field. For example, it would not be appropriate for a social worker to review an appeal related to a physical therapy denial, or a gynecologist to review a denial of services regarding coronary surgery.

We recommend that the PO ensure that the credentialed and impartial third party reviewer make his or her determinations in a similar manner to determinations made under section 1862(a)(1)(A) of the Act. The determination is based on the participant's medical need and not on other reasons such as the cost of the disputed care, who is paying the third party reviewer's salary or fee, an individual's reputation, or other factors.

Comment: Two commenters disagreed with the regulation requirement in § 460.122(h) that CMS and the SAA be informed of every adverse determination and recommended that this requirement be deleted.

Response: We view the reporting of adverse determinations to CMS and the SAA as a participant protection. Routine reporting will enable us to track trends in coverage of services to participants and to monitor the extent to which appeals are addressed in the PO's quality improvement activities. It also alerts us to the potential for a request for an external appeal.

Comment: Several comments were submitted regarding services furnished during appeals. While one commenter recommended that we delete the requirement, other commenters indicated we should extend the protection to Medicare participants. One commenter pointed out that MA providers must continue to provide disputed services during an appeal. One commenter recommended that we require POs to continue to furnish to the participant all other services required by his or her current treatment plan. The commenter believes that in the event a change in health status necessitates a change in the treatment plan, the PO must furnish to the participant all services required by the revised treatment plan. Another commenter indicated that without the continuity of Medicare and Medicaid services, PACE participants would be subject to discrimination based on payment source.

Response: We adopted the requirement that POs continue to furnish disputed services during the appeal process to Medicaid-eligible participants in order to be consistent with the Medicaid State fair hearing (SFH) regulation at § 431.230. We did not adopt a similar requirement in the 1999 interim final rule for Medicare-eligible participants because there is no corresponding requirement for continuation of services during appeal in the Medicare Independent Review Entity (IRE) review process. For this reason, we believe it is appropriate to retain the 1999 interim final requirement at this time. We note, it is critical however, that the PO continue to furnish the non-disputed services to the participant during the appeal process, because section 1894(a)(1)(B)(1) of the Act requires that participants receive services solely through the PO and as explained in § 460.98, the required services for a participant are those services identified in their plan of care.

Comment: Commenters suggested that the appeals section apply to reductions and terminations of services in addition to denials of services.

Response: We agree with the commenters and have revised the introductory text of § 460.122 accordingly.

Comment: Commenters suggested that the expedited appeals process described in § 460.122(f) be revised. Currently, § 460.122(f) requires that POs have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain maximum function would be seriously jeopardized absent provision of the service in dispute. The commenters suggested that an expedited appeal process apply where a participant believes that his or her life, health, or ability to regain *or maintain* maximum function *could* be seriously jeopardized absent provision of the service in question.

Response: We agree with the commenters and have revised § 460.122(f) accordingly.

Final rule actions:

In this final rule, we are:

• Amending the regulatory language of the introductory paragraph of § 460.122 to clarify that for purposes of this section, a denial of services could include a denial, reduction, or termination of services.

• Revising § 460.122(f)(1) to require that a PACE organization must have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain or maintain maximum function could be seriously jeopardized, absent provision of the service in dispute.

Section 460.124 Additional Appeal Rights Under Medicare or Medicaid

As we explained in the 1999 interim final rule, the PO must inform participants in writing of their additional appeal rights under Medicaid or Medicare, assist participants in choosing which appeal process to pursue if both are applicable, and then forward the appeal to the appropriate external entity. Participants who are dually eligible for Medicare and Medicaid may utilize either the Medicare or the Medicaid managed care appeal process. In those cases where participants are covered only under one program (Medicare or Medicaid), only the applicable appeals process would apply.

Comment: We received several comments related to the additional appeal rights under Medicare and Medicaid. Several commenters indicated that the preamble description in the 1999 interim final rule does not reflect CMS's intent to allow dually eligible participants to access only one appeal route, either Medicare or Medicaid. The language does not clearly state that participants must choose one route of appeal and that the route chosen is final.

Commenters indicated that the bifurcated external appeal process was confusing, administratively burdensome, and ambiguous and that a single appeals system should be developed. These commenters also stated that the regulation should specify a timeframe for the completion of the entire appeal process suggesting a 90-day timeframe which is consistent with Medicaid requirements.

We also received comments recommending a single system of grievance, appeals, and hearings, or adapting the essentials elements of the Medicaid managed care regulations that were published in the **Federal Register** on September 29, 1998 (63 FR 52022) to the PACE program since most PACE participants are Medicaid eligible.

One commenter requested clarification on the relationship between the PO's appeal process and the external Medicare/Medicaid processes. Another commenter requested that we define ''appropriate external entity for Medicare and Medicaid,'' and respond to the following questions: First, how will the PO and participant know which appeal route is appropriate, and second, how to handle disparate decisions when a participant chooses both appeals routes.

One commenter pointed out that the reference in the regulations to the Medicare appeals process was confusing. The commenter questioned whether we intended that denials of Part A services be referred to the Part A fiscal intermediary and denials of Part B services be referred to the Part B carrier.

Lastly, other commenters indicated the reporting requirements were burdensome as all adverse determinations are to be forwarded to both CMS and the State without any guidelines or criteria to assess whether such determinations were appropriately made.

Response: Review of the comments indicated that many of the commenters misunderstood the PACE appeals process and in response to the comments, we believe a reiteration of the process would address the concerns raised. As noted previously, sections 1894(f)(3)(A) and 1934(f)(3)(A) of the Act, require that in applying certain additional beneficiary protections, we should apply Medicare and Medicaid managed care requirements while taking into consideration the differences between the population served and benefits provided under this section and under Medicare and Medicaid managed care programs. Because of this requirement, we did not intend that the PACE external appeals process involve the Medicare fee-for-service Part A intermediary or Part B carrier appeals processes. Rather, we followed the Medicare managed care process using the IRE contractor for the PACE external appeals process.

The external appeals process provides participants with an appropriate external review depending on their Medicare and Medicaid status. Medicare beneficiaries have access to the Medicare external appeals route through the IRE that contracts with CMS to resolve MA appeals, while Medicaid eligible individuals have access to the SFH process. PACE participants who are dually eligible for both Medicare and Medicaid have the choice of either process, the Medicare IRE or the Medicaid SFH process. Allowing dually eligible participants to choose to pursue an appeal through either the Medicare's IRE or Medicaid's SFH processes eliminates the possibility of conflicting determinations. Therefore, all PACE participants have one route by which to exercise their external appeal rights.

It is the PO's responsibility to assist the participants in understanding which external route is appropriate for them based on the participant's Medicare and Medicaid status. For dually eligible participants, the PO must explain the external processes of each option and assist them in initiating their choices. This is primarily a matter of personal preference as both external appeals processes are equally valid options.

Information on the Medicare IRE process is available online at *http://www.medicareappeal.com* and information on the SFH process can be obtained from the SAA. Should the participant need help with the Medicare IRE process, then in accordance with § 460.124, the PO will provide that assistance. Although Medicare does not have an external appeals process to permit challenges of disenrollment determinations, all participants may use their State's external appeals processes. As we noted in the discussion on § 460.164 (Involuntary disenrollment), the State must provide a process for Medicare-only participants for an involuntary disenrollment appeal.

Comment: Commenters asked what would happen if the PO directs the participant to the wrong entity and would the appeal rights of the participant be lost if the correct filing is not made in the required time. In

addition, one commenter stated that implementation of the 1999 interim final rule regarding appeals would be problematic for them due to a class-action litigation settlement agreement which applies a time limit on initiating appeals through the State Medicaid appeals process.

Response: CMS staff has worked closely with the POs, the SAAs, and the IRE staff responsible for PACE in order to ensure that appeals are directed to the appropriate entity. However, if an appeal should be misrouted, corrections can be accommodated.

As noted previously, dual eligible participants are allowed to choose to use either the Medicare or Medicaid external appeal processes and POs play a significant role in assisting participants in choosing the appropriate external review entity and filing the appropriate documentation. Where State law establishes a timeframe for initiating an SFH, the PO must be sensitive to those time constraints in order to ensure that the participant's rights to access the SFH is not negated by a failure to meet the State timeframes.

Comment: Another commenter recommended that Medicare participants be provided the same right as Medicare beneficiaries enrolled in an M+C plan and be allowed to go directly to an Administrative Law Judge (ALJ) hearing upon completing the internal appeals process, and not have to go through carrier or fiscal intermediary review. Another commenter indicated that the participant should not have to exhaust the internal PACE appeal process before initiating the external appeal process.

Response: According to § 422.600, beneficiaries are not permitted to circumvent the appeals process with their MA organization. Under § 422.600, beneficiaries may only be heard before an ALJ after reconsideration with their MA organization.

Comment: One commenter expressed concern that the regulation places the responsibility entirely with the PO to advise dually-eligible participants of the appropriate route of appeal without supplying guidance as to which route would best benefit the participant in different situations. This commenter believes it is essential that guidelines be established to decrease the possibility of litigation against the State or the PO and to prevent participants from accessing a second appeal route by saying they were wrongfully advised in selecting a particular route of appeal.

Response: We believe that both processes are valid options and we do not agree that a wrong choice can be made. In addition, we note that since the 1999 interim final rule was implemented, no IRE appeals and only a few SFH appeals have been filed. We will continue to monitor appeals under PACE and will propose changes in the appeals process if warranted. We have worked extensively with POs to educate them on the Medicare IRE process so that they are able to fully explain the system to participants.

Final rule action:

This final rule will finalize § 460.124 as published in the 1999 interim final rule.

Subpart H: Quality Assessment and Performance Improvement

Sections 1894(e)(3) and 1934(e)(3) of the Act require that, under a PACE program agreement, the PO, CMS, and the SAA shall jointly cooperate in the development and implementation of health status and quality of life outcome measures with respect to PACE participants. In 1999, we were considering putting into place a PACE participant assessment tool, and outcome measures that would be clinically meaningful to PACE participants and empirically valid for purposes of quality monitoring and improvement. Thus, CMS took a leadership role in developing outcome measures to be integrated into clinical and administrative practices at PACE sites.

In the 1999 interim final rule, we adopted quality QAPI requirements that are consistent with the provisions from part V of the Protocol. As noted below and as discussed in that rule (64 FR 66259), we added further requirements to prepare POs to participate in the OBCQI system that was under development pursuant to a CMS contract with the Center for Health Services and Policy Research (CHSPR) at the University of Colorado.

At the time the 1999 interim final rule was published, CHSPR was developing a core data set that was to provide the foundation for a standardized OBCQI system for PACE programs. In developing the data set for PACE, CHSPR examined existing CMS data instruments such as the Minimum Data Set (MDS) (a part of the nursing home assessment instrument), the Outcome Assessment Information Set (OASIS), (required under the home health agency conditions of participation), DataPACE (developed by On Lok, Inc., and used by the PACE demonstration programs), and the Functional Independence Measure (FIM) (an assessment data set used in rehabilitation hospitals), for data items that could be pertinent for PACE quality improvement purposes.

Since the publication of the 1999 interim final rule, the health care industry has moved beyond the problem-oriented, ''after-the-fact'' corrective approach of quality assurance to a proactive approach that focuses on continuously addressing QAPI. Consequently, many health care QAPI programs are patient-driven rather than process-driven. Given that changes in health care delivery systems are rapid and continuous, many providers requested flexibility to design QAPI programs that meet the needs of their health care settings, rather than try to comply with a ''one-size-fits-all'' program. We agree that a QAPI program should blend flexibility with appropriate accountability and in the past few years, we have been striving to balance both in a patient-centered approach. With an effective QAPI program, we believe that providers will be able to determine how its performance has affected patient experiences and outcomes. We expect a provider to focus on performance outcomes and to prioritize areas needing improvement.

While we recognize the utility of the OBCQI core outcome and comprehensive assessment data set(COCOA–B) system as a useful assessment tool for PACE participants, we have misgivings about its long-term application. Given the need for flexibility for PACE sites, we are also concerned that specifically mandated measures may compromise the discretion of POs to use other assessment tools that may be more appropriate for their settings. We decided not to impose the OBCQI requirements for POs. Therefore, POs should not expect to see the publication of specific outcome measures as was implied in the 1999 interim final rule. We are not foreclosing the possibility of requiring specific outcome measures in the future, but at this time we believe PACE organizations and their participants will benefit from a wide degree of flexibility in the QAPI approach we have chosen to present.

Section 460.130 General Rule

We require the PO to develop, implement, maintain, and evaluate an effective data-driven QAPI program. It is important that the QAPI program take into consideration the wide range of services furnished by PACE. Additionally, the program should use data to identify and improve areas of poor performance. The PO must take actions that result in improvements in its performance in all types of care.

Comment: One commenter requested that we clarify whether the requirement

to take action to improve the performance in ''all types of care'' means that the organization does not have flexibility to identify its critical processes and to prioritize and select areas of concentration in which to apply resources for improvement efforts.

Response: The requirement in § 460.130(c) states that a PO must take actions that result in improvements in its performance in all types of care. Our expectation is that POs will operate a continuous QAPI program that does not limit activity to only selected kinds of services or types of patients. We expect POs to exercise as much flexibility as is necessary in order to fully meet obligations to its participants' care. As we do not require the use of a common quality assessment tool or a set of specific outcome measures beyond the data elements for monitoring included in the program agreement, POs have the flexibility to develop the program that best meets their needs. The desired outcome of the QAPI requirement is that data-driven quality assessment serves as the engine that drives and prioritizes continuous improvements for all the PO's services.

Final rule actions:

This final rule will finalize § 460.130 as published in the 1999 interim final rule.

Section 460.132 QAPI Plan

The PO must have a written QAPI plan. Consistent with the Protocol, we require POs to have their QAPI plan annually reviewed by the PACE governing body and, if necessary, revised. Further, in this section we establish that a written plan must, at a minimum, specify how the PO proposes to (1) identify areas in which to improve or maintain the delivery of services and patient care; (2) develop and implement plans of action to improve or maintain quality of care; and (3) document and disseminate the results of the QAPI activities to the PACE staff and contractors.

We received a number of comments and questions regarding the QAPI plan.

Comment: Several commenters requested information regarding CMS' intention regarding prior approval and monitoring of the QAPI plan.

Response: POs are required to present their QAPI plan to their governing body for annual approval. CMS and the SAA must approve the QAPI plan prior to its inclusion in the program agreement and review the plan during monitoring visits.

Comment: One commenter indicated that the regulations do not establish an oversight responsibility for review of the plan by either the Federal or State government.

Response: The program agreement contains a description of the QAPI plan and CMS and the SAA review plan during monitoring visits.

Final rule actions:

This final rule will finalize § 460.132 as published in the 1999 interim final rule.

Section 460.134 Minimum Requirements for Quality Assessment and Performance Improvement Program

The requirements contained in § 460.134 are consistent with the Protocol, but provide more explicit information about the types of outcomes that must be used to monitor quality. We provided the following guidance regarding QAPI in the 1999 interim final rule. The PO's QAPI program must include, but need not be limited to, the use of objective measures to demonstrate improved performance with regard to the following:

(1) *Service utilization.* PACE demonstration programs collected utilization data such as hospitalizations and emergency room visits. This information can be used to evaluate fiscal well-being, as well as evaluate quality of care. It can also be used to target reviews of PACE centers whose utilization data suggest, for example, that participants may be receiving fewer services than necessary to achieve expected outcomes. The purpose of including utilization data in the PO's QAPI program is to help the PO ensure that participants receive the appropriate level of care through their PACE center. Additionally, using information regarding utilization of and reasons for emergency care and hospital and nursing home admissions, the PO can identify areas for improvement.

(2) *Caregiver and participant satisfaction.* Caregiver and participant satisfaction with services is an important element of a QAPI program. A PO must survey, on an ongoing basis, participants and their caregivers to determine satisfaction with the services furnished and the outcomes achieved. Given the large number of PACE participants who are cognitively impaired and the critical role caregivers play in keeping PACE participants in the community, it is important to survey caregivers about their satisfaction with the program. We expect the PO to use this information to identify opportunities to improve services and caregiver and participant satisfaction. We do not intend, at this point, to prescribe the specific tools for measuring participant and family satisfaction. It is the responsibility of the PO to survey the participants and family, but we are not specifying the survey tool they must use. The PO will be expected to demonstrate its satisfaction measurement system and how it is used as part of the overall internal QAPI system.

(3) *Outcome measures derived from participant assessment data.* These measures can be used to determine if individual and organization-level measurable outcomes are achieved compared to a specified previous time period. These measures should encompass the various areas needed to monitor care for PACE participants, including physiologic, functional, cognitive, mental health, social/behavioral, and quality of life outcomes. For example, POs should focus their quality improvement activities on outcomes such as stabilization in ability to bathe, from a baseline period to each follow-up period; improvement in dyspnea from admission into PACE to a follow-up period; improvement in transportation services over a specific time period; and improvement in caregiver stress from participant admission into PACE to a follow-up time period.

(4) *Effectiveness and safety of staff-provided and contracted services, including the competency of clinical staff, promptness of service delivery, and achievement of treatment goals and measurable outcomes.* For participants to experience the outcomes that the PACE benefit is intended to achieve, staff must demonstrate skills and competencies necessary to facilitate those desired outcomes. The PO is expected to include data-based, criterion-referenced performance measures of staff skills, to utilize these data to ensure that staff maintain skills, and to provide training as new techniques and technologies are introduced and as new staff are hired. Each PO will be expected to demonstrate that it has a system of appropriate complexity for keeping track of the skills and competencies of the staff and for effectively identifying and addressing staff training needs. These data should be an integral part of the PO's internal QAPI program that provides continuous feedback on staff performance.

(5) *Non-clinical areas.* The types of outcomes in this area include outcomes related to participants grievances, transportation services, and meals. For example, if a PO finds a high rate of grievances not resolved, the PO might target its activities to improve the grievance process.

We expect POs to use the most current clinical practice guidelines and

professional standards in the development of outcome measures applicable to the care of PACE participants. Continuous improvement is only possible through the identification and use of current information, techniques, and practices. While we are not imposing any specific standards of practice, this requirement establishes the expectation that the PO will utilize the current clinical and professional standards as a routine part of its daily operations.

In addition, we included a requirement that the PO must meet minimum levels of performance on standardized quality measures that will be established by CMS and the SAA and which are specified in the PACE program agreement. For example, we require all POs to achieve at least 80 percent flu immunization rate for their PACE participants. If a PO fails substantially to meet these specified requirements, the continuation of the PACE program agreement may be conditional on the execution of a CAP, or alternatively, some or all further payments for PACE program services may be withheld until the deficiencies have been corrected. We are not establishing minimum performance standards in this regulation. Rather, we will establish minimum performance standards in the program agreement based on analysis of available data sets that are applicable to PACE participants.

We also added a requirement that the PO take actions to ensure the accuracy and completeness of all data used for outcome monitoring. A data-driven QAPI program must be based on accurate data. The regulations require that POs set up mechanisms to check for the accuracy, timely collection, and completeness of all data.

Comment: One commenter described the efforts of the Performance Measure Workgroup lead by the NPA in 1999, which reviewed draft performance measures previously developed as a part of the NPA accreditation project. The final core set of 15 measures were accepted by the POs and States as measures valuable to track. This commenter recommended that CMS adopt these 15 measures or allow the States to negotiate quality measures with POs and CMS as part of the PACE program agreement.

Response: We believe that the decision to use outcome measures in addition to the five noted in § 460.134 is one that that a PO is in the best position to make. If a PO believes that tracking a specific outcome measure will benefit its participants and improve the level of service or the delivery of service, we would expect the organization to identify and collect information that will support its use.

Comment: One commenter asked when it will be known how the quality data, referred to in the 1999 interim final rule, will be collected by CMS and what the specific quality measures will be. The commenter also questioned how POs can be expected to comply with the PACE regulation prior to implementation of the OBCQI program minimum requirements for QAPI program.

Response: In 2001, we established requirements for submission of Data Elements for Monitoring, which is included in the PACE program agreement under Appendix L. The program agreement can be located at *http://www.cms.hhs.gov/PACE.* As discussed in more detail in Subpart L of this final rule, POs are required to submit the Data Elements for Monitoring quarterly via the Health Plan Management System (HPMS). POs are expected to collect, analyze, and track data from the five outcomes measures required in § 460.134, the Data Elements for Monitoring, and any other outcome measure where an identified improved performance will benefit their participants.

Comment: A commenter questioned whether levels of performance will vary by program based on such factors as the program's age, its enrollees' characteristics, its specific service model, and unique characteristics of the service area.

Response: As in other types of health care facilities, the participant population in PACE sites varies. These differences should not affect the QAPI process but may determine what performance indicators (that is, adverse patient events, satisfaction, wound healing, etc.) a PO uses to identify areas requiring continuous quality assessment and performance improvement.

Comment: One commenter supported CMS's plan, as explained in the 1999 interim final rule (64 FR 66259), not to impose standardized data collection requirements by implementing OBCQI, pending the outcome of work by CHSPR. The commenter also supports CMS continuing to work with States to collect data to be used in the development and implementation of outcome measures that would allow comparison between varied types of programs serving individuals with like needs as well as with cross-site comparison. Other commenters indicated that the application of numerous other data collection instruments such as those noted in the Preamble of the interim final rule, that is, the MDS, OASIS, DataPACE, etc., could divert resources from providing services to PACE enrollees.

Another commenter expressed concern that POs will be unduly subjected to data reporting and quality assessment requirements exceeding those imposed on other Medicare provider types. The commenter indicated it would be better to condense the data collection responsibilities of the PACE provider and establish a core set of minimum data and reporting requirements.

Response: We are concerned that specifically mandated measures such as the OBCQI may compromise the discretion of POs to use other assessment tools that may be more appropriate for their settings. At this time, CMS does not have any plans to establish a minimum data set for PACE. As stated in previous responses, we are not requiring POs to comply with the OBCQI system in this final rule. However, we believe some structure for quality-related data collection and reporting is necessary. We expect POs to exercise flexibility in determining the most appropriate methods and instruments for their participant caseloads. Those POs that have experience with data sets should be able to manage the data needs of their QAPI program.

We recognize that in some States, POs are already subject to OASIS reporting requirements because they are licensed as home health agencies and must comply with OASIS requirements. It was not our intent to subject POs to more reporting requirements than other providers. However, as more States develop specific licensure requirements for PACE, this reporting burden will be greatly reduced. We also recognize that some POs have experience in utilizing the draft performance measures developed by the NPA Performance Measure Workgroup. Although we are not requiring that POs use the OBCQI nor submit the COCOA–B data at this time, for POs still searching for guidelines to develop or improve their assessment tools or quality enhancement, the COCOA–B is available at *http://www.cms.hhs.gov/QualityInitiativesGenInfo.*

The commenters may have misunderstood the preamble discussion of QAPI in the 1999 interim final rule. We stated that the CHSPR was examining existing CMS data instruments such as MDS, OASIS, DataPACE and FIM for data items, which may be pertinent for PACE. We did not intend to imply that POs would have to comply with these other CMS data sets. However, States have differing requirements for PACE licensure and

with licensure and if the State requires a PO to be licensed as several provider types the PO would be responsible for the reporting requirements of each of the licensed provider types.

Comment: One commenter requested information about CMS's plan for working with States to establish outcome measures and minimum levels of performance.

Response: At this time, we have no specific plans to establish additional outcome measures or minimum levels of performance beyond the data elements for monitoring which were established in 2001 and are included in the program agreement as Appendix L. State licensure requirements are based on the State's designation of PACE as a particular provider type. The State designation determines the State and Federal requirements, which may include outcome measures or minimum levels of performance.

We believe that State licensure requirements together with QAPI program requirements and our reporting requirements related to the data elements for monitoring are sufficient to ensure quality care for PACE participants without being excessively burdensome for the POS. In 2001, we established the Data Elements for Monitoring. POs are required to submit quarterly data on each of the following 9 elements:

1. Routine Immunization
2. Grievance and Appeals
3. Enrollments
4. Disenrollments
5. Prospective Enrollees
6. Readmissions
7. Emergency (unscheduled) Care
8. Unusual Incidents for Participants and the PACE site (to include staff if participant was involved)
9. Deaths

Final rule actions:

This final rule will finalize § 460.134 as published in the 1999 interim final rule.

Section 460.136 Internal QAPI Activities

In § 460.136, we require that the PO must use a set of outcome measures to identify areas of good or problematic performance and must take actions targeted at reinforcing or improving care based on these outcome measures.

The PO also must incorporate any actions that result in performance improvement into its standards of practice for the delivery of care. A method of periodically tracking performance to assure that any improvements are sustained over time must also be incorporated in the program. The PO must use its own experience from its performance improvement program to change care behaviors and to ensure that these behaviors are sustained.

We require the PO to set priorities for performance improvement, considering the prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes. However, any identified problems that directly or potentially threaten the health and safety of participants must be corrected immediately. Prioritizing areas of improvement is essential to ensure consistency in the quality of care furnished over time. Conditions that may threaten the health and safety of participants must be immediately and directly addressed when they are identified.

Similar to the Protocol, we require the PO to designate an individual to coordinate and oversee implementation of QAPI activities. The purpose of this requirement is to ensure that the PO designates responsibility for a QAPI plan and the various activities resulting from this plan. Also, this individual is responsible for ensuring that all team members, PACE staff, and contract providers are aware of the various quality QAPI activities.

We require that the PO ensure that all team members, PACE staff, and contract providers are involved in the development and implementation of the QAPI activities and are aware of the results of these activities. The process of service delivery in PACE requires the team to identify participant problems, determine appropriate treatment objectives, select interventions and evaluate outcomes of care on an individual participant basis. The IDT is in a unique position to provide PACE management with structured feedback on the performance of the PACE program and suggest ways in which performance can be improved. Thus, we expect the PO to make full use of the IDT and other staff in contributing to its internal quality improvement program.

Finally, consistent with the Protocol, we require the PO to encourage PACE participants and caregivers to be involved in QAPI activities, including providing information about their satisfaction with services. One of the best sources of information about the strengths and weaknesses of a program is from the users of the program. In this case, it is important for PACE programs to get feedback from both PACE participants and caregivers to help identify areas that need improvement.

Comment: Many commenters expressed support for the use of an OBCQI system.

Response: We thank the commenters for their support although we are not requiring POs to comply with a specific OBCQI system at this time.

Comment: A commenter pointed out that the QAPI coordinator has a similar function similar to the medical director with regard to quality. The commenter asked if one person could hold both positions.

Response: The medical director has responsibility for patient outcomes and for the organization's QAPI program. It is the PO's choice to determine that the medical director will serve as the QAPI coordinator. The coordinator's function is to coordinate and oversee the implementation of quality assessment and performance improvement activities. We envisioned the QAPI coordinator as an individual other than the medical director. The QAPI coordinator would be responsible for day-to-day quality issues, collecting data, analyzing data, detecting trends, coordinating IDT involvement in QAPI activities, and compiling comments related to participant/caregiver satisfaction and concerns.

Final rule actions:

This final rule will finalize § 460.136 as published in the 1999 interim final rule.

Section 460.138 Committees With Community Input

Consistent with the Protocol, we require that the PO develop a committee(s) with community input to (1) evaluate data collected pertaining to quality outcome measures, (2) address the implementation of and results from the QAPI plan, and (3) provide input related to ethical decision-making including end-of-life issues and implementation of the Patient Self-Determination Act. Through this committee, the PO will be able to receive guidance regarding its QAPI program and the ethical issues faced by POs.

Comment: One commenter disagreed with the requirement, stating that it does not seem reasonable or necessary, for a small PO to be required to involve community members in one or more committees to evaluate data from the quality outcomes measures and to address implementation of the organization's QAPI plan. The commenter indicated that it should be sufficient for the SAA and CMS to evaluate the QAPI data and plan implementation on behalf of the enrollees and community.

Response: The requirement for a PO to establish committee(s) with community input was adopted from the Protocol. Section 1894(f) of the Act

requires that the Secretary ''* * * incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol.'' The use of community input is contained in that protocol. Our intention is to provide a participant protection through community involvement in the oversight of participant satisfaction and QAPI activities.

Final rule actions:

This final rule will finalize § 460.138 as published in the 1999 interim final rule.

Section 460.140 Additional Quality Assessment Activities

We require that POs participate in periodic, external quality improvement reporting requirements as may be specified by the CMS or the SAA. Examples of participation in an activity include the reporting of data items for outcome measurement purposes, participation in the survey process, and participation in a CMS-directed national quality improvement project.

Comment: One commenter asked when CMS would provide the ''external quality assessment and reporting requirements.''

Response: The only quality assessment reporting that we currently require is the Data Elements for Monitoring.

Final rule actions:

This final rule will finalize § 460.140 as published in the 1999 interim final rule.

Subpart I: Participant Enrollment and Disenrollment

The purpose of subpart I is to establish the requirements for enrollment and disenrollment of a PACE participant. We received a large number of comments related to enrollment and disenrollment in PACE.

Section 460.150 Eligibility To Enroll in a PACE Program

In accordance with sections 1894(a)(5) and (c)(1) and 1934(a)(5) and (c)(1) of the Act, we established § 460.150, to specify the requirements for eligibility to enroll in a PACE program.

Sections 1894(c)(2) and 1934(c)(2) of the Act provide that a PACE program eligible individual must have a health status comparable to the health status of individuals who participated in the PACE demonstration programs. Further, sections 1894(c)(2) and 1934(c)(2) of the Act specify that this determination will be based upon information on health status related indicators (such as medical diagnoses and measures of activities of daily living, instrumental activities of daily living, and cognitive impairment) that are part of the information collected by POs on potential PACE program eligible individuals. This provision was intended to ensure that POs continue to serve patients who are as frail as those served under the PACE demonstration program and will prevent POs from selecting enrollees who need less care and whose care is less costly.

As we explained in the 1999 interim final rule, we examined data extracted from the PACE Fact Book (Second Edition, 1996, prepared by On Lok, Inc., 1333 Bush Street, San Francisco, California, 94109) which provides a portrait of participants in the eleven fully-capitated demonstration programs as of December 31, 1995. Activities of daily living (ADLs) are personal care tasks (bathing, dressing, toileting, transferring, and eating) that a person must be able to perform to be considered independent. A person is considered to have an ADL dependency and a score of ''1'' is assigned, for each of those 5 tasks for which some or full assistance is needed to perform the task. A similar scale measured dependencies in eight instrumental activities of daily living (IADLs), which include meal preparation, shopping, housework, laundry, heavy chores, money management, taking medications, and transportation. The 2710 participants in these 11 sites at the end of 1995 had an average of 2.8 ADL dependencies (varying by site from 2.3 to 3.8) and an average of 7.5 IADL dependencies (varying from 6.9 to 7.9 by site). Additionally, these participants had an average of 7.9 medical conditions (varying from 4.9 to 11.0 by site) and an average number of 4.5 errors or unanswered questions (varying from 2.0 to 6.4) on the Short Portable Mental Status Questionnaire used to evaluate mental functioning.

The PACE Fact Book acknowledges the difficulty of maintaining a valid and consistent data set in a multisite project with sites scattered across the country. However, there are many reasons why the data would be expected to show differences across sites. Although the targeted population for all PACE demonstration programs consisted of individuals who met the NF level of care, the specific criteria used to determine if an individual needs this level of care varies by State. Actual implementation of the PACE program also differs in other ways across sites to reflect the particular community in which the site is located. Furthermore, marketing efforts vary, as do the maturity of the site and particular staffing arrangements. We are convinced that any means of determining whether individuals have a health status comparable to that of participants in the PACE demonstration programs must take into account variances among sites and differences across patients within a site. Therefore, we concluded that we could not develop a tool that would more adequately determine health status comparable to individuals in the PACE demonstration programs than the current criteria used by States to determine if an individual needs a NF level of care.

In determining how best to implement this requirement, we also considered other safeguards against selective enrollment. Sections 1894(c)(3) and 1934(c)(3) of the Act include a requirement that participants be recertified annually as requiring a NF level of care. Under the demonstration program, there was a one-time certification of a participant's meeting the NF level of care. Thus, under the demonstration program, POs could continue to serve individuals who had a short-term need for a NF level of care but whose condition had shown significant improvement. The law's annual recertification requirement ensures that participants will continue to need a NF level of care.

Additionally, we included a requirement that POs must notify CMS and the SAA of enrollment denials. CMS and the SAA can analyze this information to detect selective enrollment.

After weighing both the need to maintain State and organization flexibility to develop programs suitable to the communities in which the POs operate and the implementation of other safeguards against selective enrollment, we believe having a health status comparable to the PACE demonstration programs is inherently equivalent to needing a NF level of care. We are satisfied that applying the NF level of care requirement in conjunction with the other safeguards discussed will minimize selective enrollment while preserving program flexibility; however, we invited comments with regard to other ways to implement this provision.

Additionally, the statute requires that an individual meet any other eligibility conditions imposed under the PACE program agreement. We are aware that under the demonstration program, some PACE sites instituted some other eligibility conditions. For example, some set their minimum age limits higher than 55. However, we do not believe the intent of section 1894(a)(5)(D) of the Act was to allow for modification of the requirements of section 1894(a)(5)(A–C) of the Act, including the age criteria of 55 or older.

Thus, POs may not turn away any otherwise eligible individual who is at least age 55.

In the 1999 interim final rule, we cautioned organizations that these site-specific eligibility requirements are not intended to allow programs to discriminate against individuals with problems such as cognitive deficits, disruptive behavior, or substance abuse. Any site-specific eligibility criteria must be specified in the program agreement. We will not approve criteria that would serve as a way to selectively enroll individuals whose care is anticipated to be less costly or who are thought have easier care needs.

The eligibility requirement specified in § 460.150(c) incorporated the Protocol provision that at the point of enrollment, an individual's condition must be such that his or her health or safety would not be jeopardized by living in a community setting. We recognize that enrollment in the PACE program is not appropriate for everyone who meets the basic eligibility criteria. Determining whether or not an individual's health or safety would be jeopardized by living in the community involves assessing the individual's care support network as well as the individual's health condition. As specified in § 460.152(a)(4), this assessment is done by the PO based upon criteria developed by the SAA and specified in the program agreement.

We indicated in the statutory provisions in sections 1894(i) and 1934(j) of the Act that PACE program eligibility is not contingent upon an individual's eligibility for Medicare or Medicaid.

Comment: Two commenters disagreed with the regulatory requirement permitting enrollment of individuals 55 years of age or older. One commenter requested allowing the age limitation be established at the State's discretion. The other commenter requested more restrictive age targeting criteria which would be consistent with pre-PACE and PACE demonstration programs. This commenter would limit eligibility to those age 65 years old and older.

Response: The age requirement is consistent with sections 1894(a)(5)(A) and 1934(a)(5)(A) of the Act, which defines a PACE program eligible individual as ''55 years of age or older.''

Comments: There were numerous requests for clarification of the State responsibility related to PACE eligibility determinations. Commenters asked who determines NF level of care for PACE applicants who are not Medicaid-eligible.

Response: The SAA is responsible for determining the NF level of care for all PACE applicants, regardless of Medicaid status.

Comment: Four commenters concurred with our interpretation of health status comparable to individuals enrolled in the PACE demonstration programs. One commenter asked about the meaning of the NF certification requirement and if States have the ability to set criteria that would limit enrollment to persons who are more costly or more difficult to care for than persons who meet the State's minimum threshold level for NF level of care.

Response: Section 460.150(b) requires that an individual must meet 3 basic eligibility requirements in order to enroll in PACE. These are: (1) Be 55 years old or older, (2) be determined by the SAA to need the level of care required under the State Medicaid plan for coverage of NF services (that is, the individual's health status is comparable to the health status of individuals who participated in the PACE demonstration programs), and (3) reside in the PO's service area.

If a State establishes that its minimum threshold to qualify for a NF level of care would permit the enrollment of less frail individuals than those who participated in PACE demonstration programs (on a nationwide or State basis), we will approve the use of a more stringent or higher level of care requirement in order to ensure that the PACE permanent providers continue to serve a population that is comparable to those served under the PACE demonstration programs.

Comment: Several commenters requested clarification on the requirement that individuals with neither Medicare nor Medicaid may enroll in PACE. Commenters asked if this requirement was intended to mandate that States provide PACE as a private pay benefit or whether this would be an option. Commenters noted that establishing PACE as a private pay benefit may subject POs to State insurance laws.

Another concern was that the regulation addressed all combinations for premiums except for individuals with neither Medicare nor Medicaid. One commenter requested clarification of premium amounts for non-Medicare and non-Medicaid participants.

Response: Based on sections 1894(i) and 1934(j) of the Act, we believe the Congress intended to permit individuals with Medicare Part A, Medicare Part B, Medicaid, any combination of the above, or none of the above mentioned benefits to participate in PACE. Therefore, § 460.150(d) indicates that a potential participant is not required to be Medicare enrolled or Medicaid eligible. The statute does not specify the premium that may be charged to non-Medicare and non-Medicaid participants. However, in response to inquiring POs, we have indicated they could charge the non-Medicare and non-Medicaid participants the combined Medicare and Medicaid capitation rates as their premium.

Comment: A commenter asked if an individual who met all enrollment criteria, except the ability to live safely in a community setting could be denied enrollment. The commenter asked whether this would be the only condition under which a willing individual could be denied enrollment.

Response: Consistent with the Protocol, the only permitted reason for a denial of enrollment is when a participant's health or safety would be jeopardized by living in a community setting. The criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting are often developed by the SAA and must be included in the PACE program agreement in accordance with sections 1894(c) and 1934(c) of the Act. PACE staff must assess the potential participant to establish that the participant can be cared for appropriately in a community setting and that he or she meets all requirements for PACE eligibility specified in this part. The SAA is responsible for oversight of this process and has ultimate responsibility for the determination. If a PO denies enrollment because based on their assessment, that is, they do not believe the individual can be safely maintained in the community, the PO must notify CMS and the SAA.

Comment: When determining whether an individual can be maintained safely in the community, one commenter asked if we intended to include all possible community settings or merely the one in which the individual resides at the time of application.

Response: The intent of the requirement is that POs consider the individual's residence at the time of application. However, if the individual cannot be maintained safely in their current residence but the PO believes they could live safely in another community setting, the option of moving should be presented to the individual before enrollment is denied.

Comment: Several commenters recommended regulatory revisions that: (1) Provide the SAA flexibility to ensure that selective enrollment is avoided; (2) permit denial of enrollment to those with End-Stage Renal Disease (ESRD) (alternatively, CMS should reconsider a proposed change in financing for

enrollees with ESRD); and (3) specifically exclude conditions prohibited elsewhere in the regulation from being approved as an additional program specific eligibility requirement. Commenters noted that specific mention of important protections against discriminatory exclusion would be beneficial. Lastly, commenters requested that we provide an example of an optional eligibility criterion.

Response: The regulations include several provisions intended to prevent selective enrollment. First, participants must have a health status comparable to the health status of individuals who participated in the PACE demonstration program. This is incorporated into the requirement that eligible individuals must meet the State's NF level of care requirements. If a State establishes that its minimum threshold to qualify for a NF level of care would permit the enrollment of less frail individuals than those who participated in the PACE demonstration program (on a nationwide or State basis), the State may request the use of a more stringent or higher level of care requirements in order to ensure that the POs continue to serve a population that is comparable to that served under the PACE demonstration. Other safeguards include a requirement that participants be recertified annually as requiring a NF level of care as well as a requirement that POs must notify both CMS and the SAA of enrollment denials.

It is the SAA's responsibility to establish the criteria used by the PO in assessing an individual's ability to live safely in the community. These criteria are included in the program agreement. The PO's assessment is used by the SAA in their final enrollment/denial determination. Although we believe that the States will be open to PO assessments regarding a participant's ability to live safely in the community, the decision to permit a denial of enrollment is ultimately delegated to the State. If the PO determines that the individual must be denied enrollment, the PO must inform CMS and the SAA. In addition, the PO is required to inform the individual in writing of the reason for the denial.

We understand individuals with ESRD are among the most frail and complex persons to care for and in the past POs have had reservations about enrolling this population due to additional cost of their care. However, we believe that PACE is a care delivery model well-suited to meeting the needs of this population. Thus, we do not believe that it is appropriate for POs to deny enrollment to individuals solely based on ESRD status.

In January 2005, we implemented a risk-adjusted capitation model exclusively for ESRD. The ESRD CMS–HCC model accounts for the additional costs of providing ESRD patients with the costly and highly specialized care needed. This model is exclusively for ESRD patients and has three categories of ESRD acuity: those that are on dialysis, those that have had kidney or kidney and pancreas transplant(s), and those that have had kidney grafts.

We agree with the commenter's suggestion that any condition that is specifically excluded in statute or regulation not be included in a program agreement as an additional program specific eligibility condition. As all additional program specific eligibility conditions must be approved by CMS and the SAA, we do not believe that additional regulatory language is needed.

Although we have not yet approved any site-specific eligibility requirements, we anticipate that the most likely proposal would be to develop a disease or condition-specific program, such as programs for participants with Alzheimer's disease. Site-specific requirements may not modify the three basic eligibility requirements and may not serve as a way to selectively enroll participants. We will consider other proposals on a case-by-case basis.

Comment: Several commenters asked which IDT members are required to assess the participant to determine the participant's ability to live safely in the community. Another commenter requested that the PO's ability to safely transport a participant be considered in the determination of whether a participant could live safely in the community.

Response: We did not specify particular IDT members that must assess the participant's ability to live safely in the community because we believe that the PO is in the best position to assign this responsibility. It is our expectation that individuals' health condition and their social support system will be considered in their assessment. In addition, as transportation is a major activity, whether to the PACE center, or to off-site providers, we expect this assessment to include the PO's ability to transport individuals safely.

Comment: One commenter requested that for POs located in areas where there are a disproportionate number of Medicaid-only elderly, they be permitted a waiver or modification of the mandate to enroll all individuals meeting the eligibility requirements. The commenter indicated that a PO in this situation will have a serious financial burden from the substantial loss of revenues related to the prohibition from collecting the Medicare capitation amount from these participants.

Response: With implementation of the Part D benefit, all States will have to develop Medicaid rates that vary depending on whether the participant is dually eligible (Medicare and Medicaid eligible) or is a Medicaid-only individual. The costs utilized as the basis for the calculation of the Medicaid rate will vary for these two comparable populations due to service utilization and will result in a higher rate for the Medicaid-only population. Therefore, the Medicaid capitation payment is adjusted to account for the difference in costs between the dually-eligible individual and the Medicaid-only individual. We recognize that an organization may receive more for a dually-eligible participant, due to the receipt of both Medicare and Medicaid capitation payments rather than only the Medicaid capitation for a Medicaid-only participant. However, we believe the Medicaid capitation payments are adequately adjusted to account for the difference in costs, and we are not inclined to grant a waiver of the requirement to enroll the Medicaid-only population.

Final rule actions:

This final rule will finalize § 460.150 as published in the 1999 interim final rule.

Section 460.152 Enrollment Process

We established § 460.152 to specify the PO's responsibility during the intake process and actions required in the event a potential PACE participant is denied enrollment because his or her health and safety would be jeopardized by living in a community setting.

Although we recognize that the intake process must be flexible to meet the needs of POs and potential PACE enrollees, in the 1999 interim final rule, we specified certain steps that must, at a minimum, be included in the process. These are not intended to be sequential steps and may in fact occur concurrently. Potential participants need reliable, accurate information on the PACE delivery system in order to make a rational decision whether to enroll. There is both a legal and an ethical obligation to inform potential participants about how the PO controls and affects the delivery of health care and other services, albeit in full partnership with the participant.

The following discussion describes the information that is made available to the potential participant routinely and upon request. One-on-one assistance is

provided throughout the intake process. In all situations, the information is provided in a culturally competent manner, including providing information in a language understood by the participant.

The most basic disclosure is that all health care services must be received through the PO. Once that disclosure is made and understood by the potential participant, other key disclosures related to what is included within and what is excluded from the PACE program, what costs would be borne by the participant, how to access emergency services, and how the grievance and appeals processes work. Additional information that should be disclosed upon request includes the process that the PO uses to decide that drugs, devices, and procedures are experimental and whether the PO uses a drug formulary.

The uniqueness of the PACE model depends upon the partnership formed between the participant and the IDT. Therefore, a potential participant should also be made aware of how the team works, who is on it, and what choices exist for participant selection of a primary care physician. The participant must also know how the organization provides access to services not provided directly by the IDT. These services may include contractors who furnish specialty services, health care facilities such as hospitals and nursing homes, and providers of home health care. Also, participants may request information regarding whether there are financial incentives to PO staff and contractors that may impact care. Finally, upon request, the following information must be disclosed: Information regarding board certification and other credentialing requirements; clinical protocols; medical practice guidelines, consumer satisfaction survey results; or the results of the organization's most recent Federal or State review.

With regard to specific intake tasks, we did not include the Protocol requirement for a complete assessment by the IDT prior to the denial of enrollment based on health and safety issues. We believe that such a determination can generally be made without a complete IDT assessment. In establishing enrollment requirements, our intent was to clarify, not change, the enrollment process as described in the Protocol.

If a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in the community, we require the PO to inform CMS and the SAA as well as make the documentation available for review; notify the individual in writing of the reason for the denial; as appropriate, refer the individual to alternative services; and retain supporting documentation of the reason for the determination.

We received the following comments related to the PACE enrollment process.

Comment: Commenters asked if the State review was limited to certifying a potential participant's eligibility for NF level of care. Commenters also asked if the State was prohibited from reviewing other eligibility criteria such as the ability for the potential participant to be maintained safely in the home.

Response: In addition to certifying NF level of care, States are responsible for establishing the criteria used for the PO assessment to determine if an individual's health and safety would be jeopardized by living in a community setting. States are also responsible for oversight of the PO's intake process.

Comment: A commenter asked if Federal financial participation (FFP) is available to States for administrative costs related to the State performing preadmission screening for NF level of care determinations for participants, particularly if they are not Medicaid eligible.

Response: FFP is provided to States for all administrative costs for administering the PACE program. Because the State NF level of care determination is a statutory eligibility requirement for the PACE program, the State may claim FFP for this administrative function regardless of whether the participant is ultimately determined eligible for Medicaid or Medicare.

Comment: Commenters requested we identify which members of the IDT must conduct assessments prior to enrollment.

Response: We have not specified which IDT members must conduct assessments prior to enrollment. We believe the PO is best able to identify staff qualified to perform the assessment to determine whether the participant can live safely in the community and provide a preliminary explanation of the services that an individual would receive from the program. An initial comprehensive assessment as described in § 460.104 must be completed by all members of the IDT promptly following enrollment.

Comment: We received several comments related to denials of enrollment that we believe indicate some confusion regarding the differences between ''withdrawal'' by a participant, ''screen-out'' by the PO when the prospective enrollee does not meet eligibility requirements, and ''denial of enrollment''.

Response: We wish to clarify the difference between ''withdrawal,'' ''screen-out,'' and ''denial of enrollment.''

When a prospective enrollee begins the intake process, the PO must determine whether or not the prospective enrollee meets the three basic eligibility criteria:

(1) Age 55 or older,

(2) Lives in the service area of the PO, and,

(3) Requires the State's NF level of care.

- If the potential enrollee does not meet any of these three basic eligibility criteria, we consider the result to be a ''screen-out'' by the PO.
- If the prospective enrollee meets the three basic eligibility criteria but decides not to enroll in the PACE program, we consider the enrollee's action to be a ''withdrawal.''
- If the potential enrollee meets the three basic eligibility criteria, they are then assessed to ensure they can safely live in the community and be provided a preliminary explanation of services that would be provided. If the enrollee then chooses not to enroll, it is still considered a ''withdrawal.'' Neither screen-outs nor withdrawals are required to be reported to CMS or the SAA by our regulations.
- A ''denial of enrollment'' may occur when the person is determined to be unable to live in the community without jeopardizing his or her health and safety. The PO must report this denial of enrollment to CMS and the SAA and provide the individual with a written explanation of the denial of enrollment. Consistent with the Protocol, the only permitted reason for a denial of enrollment is that living in a community setting would jeopardize an individual's health and safety.

Comment: Commenters asked about the purpose of notifying CMS and the State of each denial of enrollment, and how this notification was to occur. We were also asked if the intent of reporting a denial of enrollment is to communicate the presence of an ''at risk'' individual living in the community, for which the State already has established reporting requirements and protocols for addressing such situations. Commenters also asked if potential participants could appeal denials of enrollment.

Response: The purpose for notifying CMS and the SAA of each enrollment denial is to prevent selective enrollment by the PO. We believe this reporting is another participant protection preventing the practice of enrolling those individuals with less expensive care needs or implementing

discriminatory practices. The CMS requirement is fulfilled through the quarterly HPMS reporting. The SAA is responsible for the oversight of the denial process and may specify additional reporting requirements.

Denials of enrollment are may be appealed by potential participants through the State fair hearing process, and this process is applicable for all enrollment denials, regardless of the participant's Medicare and Medicaid status.

Comment: Two commenters recommended that we modify requirements to explicitly permit qualified M+C (now MA) enrollees to disenroll from MA at any point in the year for the purpose of enrolling in PACE.

Response: Medicare has an operational process called the Special Election Period (SEP) which allows Medicare managed care enrollees to disenroll from MA plans at any time in order to enroll in PACE. The SEP for PACE is in the Medicare Managed Manual, section 30.4.4., and can be located on the CMS Web site at *http://www.cms.hhs.gov/manuals/downloads/mc86c02.pdf*. Moreover, after disenrolling from PACE, under the SEP, individuals are allowed two months to enroll in an MA plan or revert to the original Medicare program. As SEPs are an operational practice of the MA program, we do not believe it is appropriate to include SEP provisions in PACE regulations.

Comment: One commenter recommended that the regulation be revised to require POs to explain to potential enrollees which services or benefits are excluded and how the PACE service delivery model differs from the other service alternatives.

Response: The intake process is an extensive and interactive activity between the PO, the participant and their family or caregiver. During these encounters the PO staff explains PACE, what it encompasses and the differences between PACE and other service delivery alternatives including what services generally are not covered. The PACE benefit includes all Medicare services, all Medicaid services, and services the IDT determines is necessary for a particular participant. Therefore, we believe regulatory language requiring POs to provide information on excluded services would be inappropriate because PACE services are participant-specific and excluded services for one participant may become required services for another participant.

Comment: One commenter recommended that the information supplied to prospective participants include a review of post-eligibility treatment of income, which was not expressly included in the 1999 interim final rule.

Response: Although not specified in this section of the regulation, we require that information regarding post-eligibility treatment of income is included in the enrollment agreement (see § 460.154(g).

However, we agree with the commenter and as an additional participant protection, we are adding a requirement to § 460.152(a) that POs review post-eligibility treatment of income with prospective enrollees.

Comment: Commenters asked if the State could delegate review of denials of enrollment and review of proposed involuntary disenrollments to local departments of social services.

Response: The PO must provide written notification to individuals denied enrollment. We note that a denial occurs when an individual meets the basic eligibility criteria of age, living in the service area and requiring NF level of care but is determined to be unable to live safely in the community. The SAA is ultimately responsible for oversight of this process and for prior review of involuntary disenrollments. While the SAA can delegate these activities, the SAA must maintain adequate and appropriate oversight and review of any delegated activities/responsibilities.

Final rule actions:

In this final rule, we are adding a requirement that POs review post-eligibility treatment of income with prospective enrollees.

Section 460.154 Enrollment Agreement

While the program agreement contains the specific enrollment and disenrollment procedures to be followed by the PO, in § 460.154, we specify general requirements, which must be met by all POs. Although the statute is silent as to any general enrollment requirements, it requires that the regulations should incorporate, to the extent possible, the requirements applied to the PACE demonstration programs under the Protocol. Thus, we adopted the Protocol enrollment and disenrollment provisions with the exceptions noted below.

We removed the reference to the Member Handbook because we found the distinction between the Member Handbook and the enrollment agreement to be confusing. We define the minimum information that must be included in the enrollment agreement to incorporate those materials that would generally be expected to be included in a Member Handbook. Although some POs may use a cover sheet to obtain the participant's signature and a ''handbook'' to provide the required information, the cover sheet alone does not constitute the enrollment agreement and must be accompanied by the additional minimum information specified when provided to the participant.

In the 1999 interim final rule, we emphasized that an individual who accepts PACE as his or her sole source of services could not then make an election of hospice care under section 1812(d) of the Act and 42 CFR 418.24 or section 1905(o)(2) of the Act. However, hospice-type services are available from the PO as the PACE model of care is designed to furnish a continuum of services which meet health care needs. We included a requirement that the enrollment agreement include notification that Medicaid recipients and individuals dually-eligible for Medicare and Medicaid enrolled in PACE are not liable for any premiums, but they may be held liable for any applicable spenddown liability under 42 CFR 435.121 and 435.831 and any amounts due under the post-eligibility treatment of income process under § 460.184.

We also included a requirement for the enrollment agreement to include information on the consequences of subsequent enrollment in other optional Medicare or Medicaid programs following disenrollment from PACE. This provision was intended to ensure that participants are informed in advance of conditions that might apply if they are disenrolled from PACE and elect, for example, to enroll in another managed care plan.

We added a requirement that any changes to the information contained in the enrollment agreement must be provided to the participant in writing and fully discussed with the participant and his or her representative or caregiver. We believe it is essential that all participants are made aware of any changes in this information in order to protect and exercise their rights.

Comment: We received four comments related to the enrollment agreement. One commenter expressed concern that in § 460.154(h) our requirement that the enrollment agreement contain a notice that a Medicare participant may not disenroll from a PACE program at a Social Security office seems likely to create confusion and could be more appropriately handled by proper education of Social Security Administration staff.

Response: Social Security Administration staff are unable to make an eligibility determination for PACE enrollment. The PO and SAA make the required determinations that a prospective PACE enrollee meets the State's NF eligibility criteria and can be safely cared for in the community.

Because most Medicare beneficiaries are familiar with the Social Security office in their community as the place where they signed up for their Social Security and Medicare benefits, it is reasonable to assume that Medicare beneficiaries would think that the Social Security office is the logical place to enroll or disenroll from PACE. We included this requirement in our regulations to ensure that all PACE participants understand that, unlike other Medicare benefits, they cannot enroll in or disenroll from PACE at a Social Security office.

We are clarifying this requirement by revising the regulatory language to state that enrollees may not enroll or disenroll at a Social Security office.

Comment: Two commenters requested we modify § 460.154(k) to require POs to include in the enrollment agreement all services that are covered and not covered through the PACE providers.

Response: We disagree with the commenters; PACE services are participant-specific as determined by the IDT and specified in the participant's plan of care. Therefore, identifying covered and non-covered services could be misleading and potentially confusing for participants and their family or representative.

Comment: One commenter requested we modify § 460.154(t) to specify that the enrollment agreement contain the signature of the applicant or his or her designated representative, and the date.

Response: We agree with this commenter, and are amending § 460.154(t) to include ''or his or her designated representative'' to sign the enrollment agreement.

Final rule actions:

In this final rule we are revising:

- § 460.150(h) by clarifying that individuals may not enroll or disenroll at a Social Security office.
- § 460.154(t) to read ''The signature of the applicant or his or her designated representative and the date.''

Section 460.156 Other Enrollment Procedures

We established this section to specify the documentation that must be provided to a PACE participant who signs an enrollment agreement. Specifically, a PACE participant must be given a copy of the enrollment agreement, a PACE membership card, emergency information to be posted in his or her home which includes the phone number of the PO, and when applicable, stickers for the PACE participant's Medicare or Medicaid cards (or both) that indicate the individual is a PACE participant and include the phone number of the PO.

In addition, the PO must submit participant information to CMS and the SAA in accordance with established procedures.

We also included a requirement that, in the event there are changes in the enrollment agreement information at any time during the participant's enrollment, the PO must provide to the participant an updated copy of the information and explain the changes to the participant and their representative in a manner they understand.

Comment: One commenter requested clarification of the ''established procedures'' POs are required to use for submitting enrollment information to CMS and the SAA.

Response: The ''established procedures'' refers to CMS and SAA procedure for enrollment and payment. CMS and the SAA notify the PO how to submit information regarding enrollment.

Final rule actions:

This final rule will finalize § 460.156 as published in the 1999 interim final rule.

Section 460.158 Effective Date of Enrollment

Consistent with the Protocol, this section established that a participant's enrollment in the PACE program is effective the first day of the calendar month following the date the PO receives the signed enrollment agreement.

Comment: Three commenters indicated that unless we require that PACE enrollment be effective on the same date for both Medicare and Medicaid, there is the potential that a participant could be enrolled in Medicare a month earlier than they are enrolled in Medicaid. The commenters indicated that as written, this requirement is problematic for States that set the enrollment date for PACE on a day other than the first day of the month following the date of the signed enrollment agreement. Commenters indicated that potential PACE participants may very likely be in situations where they need to enroll before the beginning of the next month. The commenters explained that since capitation payment is tied to pull down dates for the Medicaid Management Information System and the effective date of enrollment impacts the effective date of the capitation payment, they need flexibility in establishing the effective date for Medicaid enrollment, and should be permitted to adjust that first month's capitation payment.

Response: Our regulation at § 460.158 requires that a participant's enrollment in the program is effective on the first day of the month following the date the PO receives the signed enrollment agreement. This is applicable for all participants regardless of Medicare or Medicaid eligibility. Therefore, the effective date for Medicare and Medicaid payment will be the same, even if the participant is eligible for both programs.

In an instance where there is a lag time between the signing of the enrollment agreement and its effective date, the PO may choose to provide services to the newly signed enrollee. However, any services provided are not considered ''PACE'' services until the effective date of enrollment. Therefore, services would only be covered to the extent an individual's existing health plan (for example, Medicare fee-for-service or Medicaid) provided the coverage. Should the PO choose to provide services outside the individuals existing benefits package prior to the effective date of enrollment in PACE, the PO would be liable for the cost of providing these services.

A State may choose to pay the PO for services for a participant prior to the effective date of enrollment whether on a fee-for-service or pro-rated capitated basis. However, the participant's effective date of enrollment as a PACE participant is not established until the first of the following month.

Comment: A commenter asked what the PO's responsibilities are for covering nursing home care in the event that a participant's condition necessitates such placement before the effective date of enrollment.

Response: Section 460.150(c) requires that at the time of enrollment into PACE, an individual must be able to live in a community setting without jeopardizing his or her safety. If a participant's condition or situation changes prior to the effective date of enrollment such that they can no longer be maintained safely in the community, the PO, with SAA concurrence, may deny the enrollment. Since the enrollment was never implemented, there is no need to involuntarily disenroll the enrollee. However, once the enrollment status has become effective, a participant may not be disenrolled due to health status.

Final rule actions:

This final rule will finalize § 460.158 as published in the 1999 interim final rule.

Section 460.160 Continuation of Enrollment

In this section, we specify that a PACE participant's enrollment continues until death regardless of changes in health status unless the PACE participant voluntarily disenrolls in accordance with § 460.162 or is involuntarily disenrolled in accordance with § 460.164.

We incorporated the statutory requirement contained in sections 1894(c)(3) and 1934(c)(3) of the Act for an annual recertification of need for NF level of care. We believe that the law contemplated that reevaluations would be conducted by the SAA for all participants, whether Medicaid eligible or not.

The statute provides that the annual recertification may be waived for those individuals for whom the SAA determines there is no reasonable expectation of improvement or significant change in condition. As a waiver may not be granted until the first annual recertification is due, a participant for whom this requirement is waived would have been receiving services under the PACE program for at least a year. We believe it is unlikely, especially in view of the average age and frailty of PACE participants, that a person who has not shown significant improvement in the past year would show enough improvement in the future to no longer need a NF level of care. The law permits a waiver ''during a period in accordance with regulations'' in those cases where the SAA determines there is no reasonable expectation of improvement. Therefore, we provided in the 1999 interim final rule that such a waiver should be for the life of the participant. However, the reasons for the waiver must be explicitly documented in the medical record. We indicated that we did not provide a mechanism for reinitiating the recertification process once a waiver was granted, and we invited comments on this issue.

Finally, sections 1894(c)(4) and 1934(c)(4) of the Act allow for the continuation, or deemed eligibility, of participants who are determined, through the annual recertification process, to no longer meet the NF level of care requirement but who, in the absence of continued coverage under PACE, would reasonably be expected to again meet the NF level of care within the next 6 months. We indicated that the determination is made by the SAA, which may solicit input from the PACE organization and that the deemed eligibility continues until the next annual recertification. While it is the SAA's responsibility to determine the need for NF level of care, the PO has a detailed knowledge of the day-to-day care and service requirements of the participants and would, therefore, be better able to predict a participant's reaction to the loss of PACE services. We invited comments on whether this responsibility should be shared or carried out solely by either the SAA or the PO.

Comment: Eight commenters supported differing requirements related to continuation of enrollment. The commenters generally agreed with annual recertification of NF eligibility. Half of the commenters supported deeming the annual recertification a State responsibility after working with the PO to make the determination. The remaining commenters viewed deeming a PO responsibility subject to State review or a joint State/PO activity.

One commenter did not support annual recertification, stating that disenrolling a participant from the program penalizes the participant and IDT team for reaching their goals.

Five commenters responded to our request for input regarding whether deemed eligibility should continue until the next annual recertification. They unanimously agreed that the period of deemed eligibility should continue for 12 months until the next annual recertification is due.

Response: With the publication of the 1999 interim final rule and the transition of PACE programs from demonstration programs to permanent provider status, the provisions regarding continued enrollment in the program changed. Under the demonstration program, the NF level of care determination was a one-time certification prior to enrollment and PACE participants were not recertified as needing a NF level of care. While sections 1894(c)(3) and 1934(c)(3) of the Act, implemented a new annual certification requirement, the law balanced this requirement with an important beneficiary protection in the continued eligibility provisions of section 1894(c)(4) and 1934(c)(4) of the Act. The continued eligibility provisions take into account that a participant's condition may have improved such that he or she no longer meets the NF level of care solely due to the services being received from the PACE program. Thus, being disenrolled from the program could result in a decline in which the person quickly needs a NF level of care once again and would be eligible to re-enroll in the program. The continued eligibility provisions at § 460.160(b)(2) avoid this unnecessary and disruptive cycling in and out of eligibility by allowing participants to remain in the program even though they do not currently meet the NF level of care requirement if a determination is made that, in the absence of PACE services, they would reasonably be expected to meet the requirement within the next 6 months.

In the 1999 interim final rule, we solicited comments on whether the determination of continued eligibility should be a responsibility that should be shared or carried out solely by either the State administering agency or the PACE organization. In considering the comments received, and in light of the fact that it is the State's responsibility to determine the need for nursing facility level of care, we have concluded that all States should develop appropriate criteria and implement a process whereby continued eligibility determinations can be made. However, we recognize that the PO has knowledge of the care and service requirements of the individual participants and should be consulted in making the determination of continued eligibility based on these criteria. For this reason, we are revising § 460.160(b)(3)(i) to specify that the SAA must establish criteria, in consultation with the PO, make a determination of deemed continued eligibility based on a review of the participant's medical record and plan of care.

With regard to the comments on annual recertification, we understand the argument presented by the commenter that disenrolling a participant who does not meet the NF level of care at the time of recertification penalizes the participant and the IDT for reaching their goals. However, the annual recertification required at § 460.160(b) is a statutory requirement (sections 1894(c)(2)–(4) and 1934(c)(2)–(4) of the Act). The recertification process is an important safeguard to ensure that PACE programs continue to serve individuals who have a health status comparable to those who participated in the demonstration program. We believe the provisions allowing the waiver of this requirement on a case-by-case basis as well as the use of the deemed continued eligibility provisions provide important flexibility and safeguards for States in administering the program and would not result in penalizing the participant or the PO.

Regarding whose responsibility it is to determine or deem a participant's continued eligibility, we believe that establishing whether a participant meets

the State's criteria for NF level of care is a State responsibility. We believe this activity includes pre-enrollment or post-enrollment eligibility. We also acknowledge that due to the gravity of continued eligibility determinations, the SAAs should solicit input and assistance from the PO in making these determinations, but the SAA retains the ultimate responsibility.

Comment: Several commenters agreed that a mechanism for reinitiating the recertification process once a waiver had been granted was not necessary because waivers would only be granted in cases where the possibility of improvement is extremely remote.

Response: We agree with the commenters and therefore have not developed a mechanism for reinitiating the recertification process once a waiver has been granted.

Final rule actions:

In this final rule we are revising paragraph (b)(3)(i) to clarify that the SAA must establish criteria for use in making deemed eligibility determinations.

Section 460.162 Voluntary Disenrollment

In accordance with sections 1894(c)(5)(A) and 1934(c)(5)(A) of the Act, this section specifies that a PACE participant may voluntarily disenroll from the program without cause at any time. We received no public comments on § 460.162.

Final rule actions:

This final rule will finalize § 460.162 as published in the 1999 interim final rule.

Section 460.164 Involuntary Disenrollment

In accordance with sections 1894(c)(5)(B) and 1934(c)(5)(B) of the Act, we established this section to specify the conditions under which a PACE participant can be involuntarily disenrolled from a PACE program. The Protocol, in Part III, section D.1, describes various circumstances under which a participant may be involuntarily disenrolled.

The statutory language at sections 1894(c)(5)(B) and 1934(c)(5)(B) of the Act provides that a participant may only be involuntarily disenrolled for nonpayment of premiums on a timely basis or for engaging in disruptive or threatening behavior. In our regulations at § 460.164(a)(1), we adopted the requirement that a participant may be involuntarily disenrolled if they fail to pay or to make satisfactory arrangements to pay any premium due the PO after a 30-day grace period.

We also incorporated the following reasons for involuntary disenrollment from the Protocol:

(a) The participant moves out of the PO's program service area or is out of the service area for more than 30 days unless the PO agrees to a longer absence due to extenuating circumstances;

(b) The PO is unable to offer health care services due to loss of State licensure or contracts with outside providers.

We added as a reason for involuntary disenrollment that the PO agreement with CMS and the SAA is not renewed or is terminated. We also incorporated, at § 460.164(a)(4), as a reason for involuntary disenrollment the statutory provision regarding the annual recertification of NF level of care. In all of these situations the disenrollment is not a subjective determination made by the PO but is necessary due to the application of objective criteria.

We did not incorporate the following reasons for disenrollment from the Protocol: the participant refuses to provide accurate financial information, provides false information, or illegally transfers assets. As these situations would affect the determination of Medicaid eligibility, we believe they would actually prevent enrollment in the first place. However, if the individual is already enrolled when these situations occur or are discovered, they may affect the participant's payment responsibility and thus lead to either voluntary disenrollment or involuntary disenrollment based on failure to pay premiums.

In order to incorporate the statutory provision regarding disruptive or threatening behavior, we felt the need to balance two concerns: (1) To protect participants who are exhibiting difficult behaviors from being disenrolled by the PO, and (2) to provide a safeguard for the PO, by permitting them to disenroll a competent but noncompliant participant whose behavior disrupts the organization's ability to furnish adequate services to that individual for reasons beyond the organization's control. Therefore, after consulting with SAAs, we defined a person who engages in disruptive or threatening behavior as:

a. A person whose behavior is jeopardizing his or her health or safety or that of others; or

b. A person with decision-making capacity who consistently refuses to comply with his or her individual plan of care or the terms of the enrollment agreement.

However, in accordance with paragraphs (c)(5)(B)(ii) of sections 1894 and 1934 of the Act, a PO may not involuntarily disenroll a PACE participant on the grounds that the individual has engaged in noncompliant behavior if such behavior is related to a mental or physical condition of the individual unless the individual's behavior is jeopardizing his or her health or safety or that of others. The term ''noncompliant behavior'' includes repeated noncompliance with medical advice and repeated failure to keep appointments.

While we believe this definition provides a necessary safeguard, we are not suggesting that a participant should be disenrolled at the first sign of difficulty. We caution organizations to use this authority only as a last resort when all reasonable remedies (which must be documented in the medical record) have been exhausted.

Based on sections 1894(c)(5)(B)(iii) and 1934(c)(5)(B)(iii) of the Act, we specified that proposed involuntary disenrollments are subject to a timely review and final determination by the SAA prior to the effective date of the proposed disenrollment. This provision protects the participant from being inappropriately disenrolled and provides for the continuation of services until a final determination is made. We invited comments on whether the regulations should specify a timeframe in which the review must be conducted and, if so, what an appropriate timeframe would be.

We received a large number of comments regarding involuntary disenrollment.

Comment: Several commenters requested that we expand the reasons for involuntary disenrollment to include the failure to pay any allowable fees and share of costs including amounts required as part of a participant's spenddown liability and post-eligibility treatment of income amounts.

Response: Sections 1894(c)(5)(B) and 1934(c)(5)(B) of the Act explicitly state that the PO may involuntarily disenroll a participant for only one payment-related issue, which is nonpayment of premiums.

However, CMS has the authority to provide BIPA 903 waivers in instances where the POs are unable to comply with regulatory requirements (see § 460.26). We have approved several BIPA 902 grandfathering requests and BIPA 903 waiver requests regarding this issue. However, to retain flexibility in application of these waivers, we are not expanding the reasons for involuntary disenrollment for non-payment of premiums in this final regulation.

Comment: Three commenters requested that we eliminate the requirement for State review of an

involuntary disenrollment due to failure to pay a premium.

Response: We believe the commenters' concern about the SAA review of a proposed involuntary disenrollment due to failure to pay premiums may be that the process would cause further delay and present a financial hardship for the POs. The intent of this requirement is oversight by the SAA to ensure that the disenrollment documentation reflects adequate grounds for involuntary disenrollment. The review was established as a check in the process to ensure an important participant protection. We are confident the SAAs have established procedures that ensure the State review is completed prior to the effective date of the proposed disenrollment.

Comment: One commenter requested that we include the disruptive or threatening behavior of family members, where they are involved in health care or decisions at the participant's request, as a reason for involuntary disenrollment.

Response: It is not our intention to jeopardize the safety of those providing care. However we expect POs to make every effort to resolve such situations before considering disenrollment. Sections 1894(c)(5) and 1934(c)(5)of the Act specify the reasons a PACE Program eligible individual may be disenrolled, including ''for engaging in disruptive or threatening behavior, as defined in such regulations (developed in close consultation with State administering agencies).''

In consultation with SAAs, we have defined disruptive or threatening behavior in our regulations at § 460.164(b) as including consistent refusal by a competent participant to comply with the plan of care. If PO staff or contractors cannot furnish necessary care because of the threatening behavior of someone other than the participant, then we expect the PO to establish alternative arrangements that would not disrupt the PO's ability to provide adequate services and to include those arrangements in the participant's plan of care. Such arrangements might include providing services at the PACE center, arranging for alternative living arrangements, or obtaining the participant's agreement to control the actions of the caregiver or family member during the time PO staff are on the premises. Should the participant refuse to cooperate with the plan of care and all efforts fail, as a last resort the PO may submit a proposal to involuntarily disenroll a competent participant for refusal to comply with their plan of care, as provided in § 460.164(b). As required by § 460.164(d) and (e), all pertinent documentation must be submitted to the SAA for review before the PO may implement an involuntary disenrollment.

Comment: One commenter agreed that the breakdown in the physician/IDT and participant relationship is not a reason for involuntary disenrollment.

Response: We appreciate the commenters support. We believe that a breakdown in the IDT/participant relationship is an unacceptable reason for involuntary disenrollment and would undermine the participant's right to participate in treatment decisions. Our expectation in this situation is that the PO would work with the participant and the IDT to establish a mutually acceptable resolution. Should the participant remain dissatisfied after the PO attempts to reestablish an acceptable working relationship, it would be the participant's right to voluntarily disenroll. We view this breakdown as an incident the PO would review as a part of its QAPI plan.

Comment: Commenters supported a variety of timeframes for SAA review of involuntary disenrollments. Recommended timeframes included no required timeframe, in a timely manner, 72 hours, up to 30 days (depending on the cause of the disenrollment, especially where the participant's health and safety may be in jeopardy or the participant has not paid their premiums). Commenters suggested that the involuntary disenrollment be deemed approved if the SAA does not respond within a reasonable timeframe.

Response: Our experience to date has been that States have developed adequate procedures and are in a position to know when a particular situation warrants an expedited review. While we understand the concerns behind the suggestion that involuntary disenrollments should be deemed approved if the SAA has not responded within an appropriate timeframe, we are not including this provision in this final rule. We view the State review as an important beneficiary protection and are concerned that a specific timeframe might unduly constrain or limit the State's ability to provide an adequate review. Therefore, we are retaining § 460.164(e) and will require SAA review in a timely manner for involuntary disenrollments.

Comment: One commenter suggested we give the State the authority to consider all relevant evidence in their review of proposed involuntary disenrollment, not to limit review to the sufficiency of reasons shown in the records.

Response: Documentation provided to the SAA by the PO should include all relevant information supporting their reason for initiating an involuntary disenrollment. Our regulations do not preclude the SAA from requesting additional documentation if it feels that the organization has not provided adequately documented grounds for disenrollment.

Comment: One commenter expressed support for CMS' attempt to distinguish between behavior that jeopardizes health and safety and noncompliant behavior. They requested further clarification as to whether a PO may disenroll a participant for noncompliant behavior if the behavior is not related to a mental or physical condition of the participant. The commenter questioned whether noncompliant behavior would be considered disruptive behavior if the participant is competent and the noncompliance was addressed in the participant's care plan.

Response: We note that § 460.164(b) does not distinguish between disruptive behavior and noncompliant behavior, but rather defines noncompliant behavior as disruptive behavior, consistent with the statute. The PO may involuntarily disenroll a participant for noncompliance with their plan of care provided the noncompliance is not related to a mental or physical condition.

Comment: Two commenters requested that we eliminate noncompliance as a reason for involuntary disenrollment. Other commenters were concerned that we unduly expanded the definition of disruptive or threatening behavior to include a competent participant who consistently refuses to comply with his or her individual plan of care or terms of the PACE enrollment agreement.

Another commenter indicated that this type of disenrollment violates the participant's right to refuse treatment. Therefore, they requested that noncompliance be eliminated as a reason to disenroll a participant.

Response: We disagree with the commenters' suggestion that we delete noncompliance as a reason to involuntarily disenroll. We do not believe that a disenrollment based upon noncompliance by a competent participant violates their right to refuse treatment.

The competent participant actively participates in establishing their plan of care, and it is at this juncture that the participant should raise any objections to the components of their plan of care and refuse treatment. At the time the participant refuses the proposed treatment, the IDT should present and discuss other treatment options. If the

participant has issues with the treatment after the establishment of the plan of care, there should be discussion with his or her IDT. Because of the cooperative nature of establishing the plan of care, once the participant has agreed with the plan of care they are committed to following it. If the participant later refuses to comply with the agreed upon plan of care and the IDT and the participant are unable to agree to an alternative treatment, the PO can involuntarily disenroll that participant. We believe that the noncompliant behavior will disrupt the provision of care to the participant and jeopardize their health or safety.

Additionally, potential participants are informed of the terms of the enrollment agreement during the enrollment process and signing of the enrollment agreement indicates the person's willingness to comply with those terms. We believe we must provide this safeguard to allow POs to disenroll competent but willfully noncompliant participants if their behavior disrupts the organization's ability to furnish adequate services and safeguard the participant's health and safety.

Comment: One commenter questioned the requirement that the State review involuntary disenrollments initiated by the PO without respect to the enrollee payer status and asked if the SAA review was considered to be a final determination that can be appealed.

Response: As specified in § 460.164(e), the SAA must review all proposed involuntary disenrollments, regardless of payer status, in order to determine that the PO has adequately documented acceptable grounds for disenrollment. This was one of the issues specifically discussed with the State workgroup in developing the 1999 interim final rule. At that time, the States correctly predicted that this provision would not lead to a major increase in workload. If the State supports the PO's decision to involuntarily disenroll the PACE participant, the participant may pursue an external appeal. States must provide an alternative to the Medicaid State Fair Hearing process for Medicare-only participants because Medicare's independent review entity does not hear involuntary disenrollment appeals.

The SAA review of involuntary disenrollments is a final determination, which would allow a Medicaid-eligible participant to pursue a Medicaid Fair Hearing. POs should contact their SAA for details on their State's Fair Hearing process. Medicaid regulations regarding the State Fair Hearing process are located at 42 CFR 431.200 through 431.250.

Comment: One commenter indicated that there is no need for SAA review of proposed disenrollments due to nonpayment of premiums.

Response: As a participant protection, we believe the SAA should review all involuntary disenrollments, including involuntary disenrollment related to nonpayment or failure to make satisfactory arrangements to pay premiums.

Final rule actions:

In this final rule, we are finalizing § 460.164 as published in the 1999 interim final rule.

Section 460.166 Effective Date of Disenrollment

We require that the PO must use the most expedient process allowed for by Medicare and Medicaid procedures to ensure that the disenrollment date is coordinated between Medicare and Medicaid for participants who are dually eligible for both programs and that reasonable advance notice is given to the participant. In addition, until such time the enrollment is terminated, PACE participants must continue to use PO services and remain liable for any premiums, and the PO must continue to furnish all needed services.

Comment: One commenter recommended that an involuntary disenrollment should not be effective until Medicare and/or Medicaid eligibility has actually been established and alternative providers are available to provide the services in the participant's care plan.

Response: We believe the disenrollment date must be the same for Medicare and Medicaid participants. We intend that no disenrollment would become effective until the participant is appropriately reinstated into other Medicare and Medicaid programs and alternative services are arranged.

Final rule actions:

In this final rule, we are finalizing § 460.166 as published in the 1999 interim final rule.

Section 460.168 Reinstatement in Other Medicare and Medicaid Programs

We established this section to prescribe the PO's responsibility to facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment. We require that the PO make appropriate referrals and ensure that medical records are made available to new providers in a timely manner. In addition, we require that the PO work with the SAA and CMS to reinstate the participant in other Medicare and Medicaid programs for which the individual is eligible.

We received no comments on this section.

Final rule actions:

This final rule will finalize § 460.168 as published in the 1999 interim final rule.

Section 460.170 Reinstatement in PACE

Section 460.170 provides that a previously disenrolled participant may be reinstated in the PACE program. However, we did not adopt the Protocol provision limiting a participant to a one-time-only reinstatement following a voluntary disenrollment. We believe that frail elderly individuals may experience living arrangement changes that take them in and out of a PO's service area and result in unavoidable disenrollments. However, we included the Protocol provision that a PACE participant may be reinstated in the PACE program with no break in coverage if the reason for the disenrollment was failure to pay premiums and the PACE participant pays the premium before the effective date of the disenrollment.

Comment: One commenter recommended that the State be granted the flexibility to set criteria for multiple re-enrollments of participants after involuntary disenrollment. Two other commenters indicated that it would be appropriate to restrict the number of times an individual may be reinstated.

One commenter suggested a one-time reinstatement or, alternatively, that the PO be granted the discretion to determine whether to reinstate a participant multiple times based upon the unique circumstances of the previous disenrollment. The commenter recommended that the PO identify the circumstances for reinstatement and establish policies and procedures prior to implementation of the PACE program.

Response: We believe the decision to allow participants the ability to be reinstated repeatedly is appropriate in some cases, especially for participants who voluntarily disenroll. Therefore, we are not inclined to limit the number of allowable reinstatements. However, if a participant has been involuntarily disenrolled, and wishes to re-enroll in the PO, the issue that caused the involuntary disenrollment must be resolved, before the participant can be reinstated.

Final rule actions:

This final rule will finalize § 460.170 as published in the 1999 interim final rule.

Section 460.172 Documentation of Disenrollment

We established § 460.172 to specify that a PO must have procedures to document the reasons for all voluntary and involuntary disenrollments, make the documentation available for review by CMS and the SAA, and use the information on voluntary disenrollments in the PO's internal QAPI plan.

Comment: One commenter recommended that the information on all disenrollments be used in quality assurance.

Response: It is our intent to use only the voluntary disenrollment information in QAPI as these disenrollments are more likely to be impacted by participant impressions of the quality of their care and their satisfaction. Involuntary disenrollment is not usually initiated because a participant is unhappy with their care but rather the participant has not met their responsibilities to the PO. Therefore, we only require that voluntary disenrollment information be used in QAPI.

Final rule actions:

This final rule will finalize § 460.172 as published in the 1999 interim final rule.

Subpart J: Payment

The 1999 interim final rule described Medicare payment as follows. Sections 1894(d) and 1934(d) of the Act requires that payment to a PO be based on a capitation amount. The Medicare capitation amount is based upon the M+C (now MA) payment rates established under section 1853 of the Act. The Medicaid capitation amount is negotiated between the State and the PO.

The following basic principles distinguish the PACE financing model.

- Obligation for payments is shared by Medicare, Medicaid, and individuals who do not participate in Medicare and Medicaid.
- Medicare, Medicaid, and private payments for acute, long-term care, and other services are pooled.
- The capitation rates paid by Medicare and Medicaid are designed to result in cost savings relative to expenditures that would otherwise be paid for a comparable NF-eligible population not enrolled under the PACE program.
- The PO accepts the capitation payment amounts described in this section as payment in full from Medicare and Medicaid.

Section 460.180 Medicare Payment to PACE Organizations

Section 1894(d)(1) of the Act requires that POs be paid monthly payments of a capitation amount for each eligible enrolled PACE program individual, in the same manner and from the same sources as payments that are made to a M+C (now MA) organization under section 1853 of the Act. In accordance with section 1894(d)(2) of the Act, PACE capitation amounts are based upon payment rates established for the purposes of payment under section 1853 of the Act and shall be adjusted to take into account the comparative frailty of PACE enrollees and other factors the Secretary determines appropriate. Payments of a capitated amount are to be adjusted in the manner described in section 1853(a)(2) or section 1876(a)(1)(E) of the Act; that is, retroactively adjusted to take into account any difference between the actual number of participants and the estimated number of participants to be enrolled in determining the amount of the advance payment.

Consistent with the basic methodology applied to M+C (now MA) plans at the time of publication of the 1999 interim final rule, Medicare paid monthly payments based on an interim per capita rate per participant. Under that methodology, separate rates were established for Part A and Part B. The PO received payments based on each participant's entitlement to Medicare Part A and Part B. Therefore, if the participant was entitled to Part A benefits, but was not enrolled under Part B, the PO received only the monthly capitation rate established for Part A. For Medicare Part A-only participants who are also eligible for Medicaid, the State is obligated to pay Medicare Part B premiums under section 1902(a)(10) of the Act. Therefore, POs needed to verify at the time of enrollment whether the participant was dually eligible for Medicare and Medicaid and whether the participant has Medicare Part A and Part B. As required in 1999 and still currently required, payment for a participant begins upon the effective date of enrollment (see § 460.158).

Under section 1894(d)(2) of the Act, the capitation amount should be adjusted to take into account the comparative frailty of PACE participants and other factors the Secretary determines to be appropriate. As explained below, a frailty factor and an adjustment factor for PACE participants who have ESRD were applied to the appropriate demographic payment rate.

Under the PACE demonstration program, the Medicare capitation rate for each PO was calculated using CMS' standard Adjusted Average Per Capita Cost (AAPCC) methodology (also referred to as the demographic rate methodology) developed in accordance with the 1982 Tax Equity and Fiscal Responsibility Act to pay risk-based health maintenance organizations for Medicare enrollees. However, instead of using the usual adjustments for age, sex, welfare status, institutional status, employment status, and disability, there was one frailty adjuster of 2.39 for all PACE participants except those diagnosed with ESRD. Therefore, in accordance with 1894(d)(2) of the Act, as of January 1, 1998, the Medicare capitation rate paid to PACE demonstration programs was calculated using the M+C (now MA) AAPCC rates with an additional frailty adjuster of 2.39 to account for the higher costs related to caring for this frail population.

Subsequently, the BBA mandated M+C (now MA) plans to implement a risk adjusted methodology starting January 1, 2000. However, PACE payment continued to be based on the frailty adjusted demographic rate methodology until refinements to the risk adjustment methodology specific to PACE were completed. Implementation of the risk adjustment payment methodology with PACE specific adjustments began January 1, 2004.

Changes to PACE payment methodology are proposed in the annual Advance Notice of Methodological Changes for Medicare Advantage Payment Rates (Advance Notice), along with changes to MA methodology. After publication of the Advance Notice, the public is given a two-week period to provide comments. The final changes are described in the Announcement of Medicare Advantage Payment Rates (Announcement). The Announcement is published the first Monday in April, and the Advance Notice is published 45 days before that. Any changes that have been made to PACE payment methodology since the publication of the 1999 proposed rule were dealt with through that process.

Many of the changes to the PACE payment methodology since 1999 are based on the January 1, 2004 implementation of the CMS-Hierarchical Conditions Category (CMS–HCC) based MA risk adjustment payment methodology with refinements for PACE. These changes are reflected throughout § 460.180. The risk adjustment payment methodology, history and authority are initially described in the Advance Notice and

Announcement for calendar year 2004, with the refinements described in subsequent Advance Notices and Announcements. Advanced Notices and Announcements can be found on the CMS Web site at *http://www.cms.hhs.gov.*

The purpose of risk adjustment is to use health status indicators to improve the accuracy of payments and establish incentives for plans to enroll and treat less healthy Medicare beneficiaries. The risk adjustment model was phased-in for all MA plans. The gradual phase-in provided a safeguard against abrupt changes in payments and effects related to risk adjustment. However, due to the additional refinements that were made to the PACE payment, the implementation of the risk adjustment phase-in was delayed for PACE. The phase-in schedule for PACE will lag the phase-in of MA risk adjustment by one year. The additional refinements to the risk adjustment model for PACE, mentioned above, surrounded the frailty adjuster. A deferral was needed so that CMS could study the applicability and impact of risk adjustment on capitated payments for the frail elderly.

On January 1, 2004, PACE began the phase-out of the demographic payment methodology adjusted by the 2.39 frailty adjuster and phase-in of the new MA risk-adjusted payment methodology. To ease the transition, the rates will blend a gradual decreasing amount of the demographic payment methodology adjusted by the 2.39 frailty adjuster and a gradual increasing amount of the new MA risk-adjusted payment methodology. The blended phase-in rates for PACE are provided in the following table.

Calendar year	Percent frailty adjusted demographic rate (AAPCC times 2.39)	Percent risk adjusted rate (CMS–HCC times frailty score)
2004	90	10
2005	70	30
2006	50	50
2007	25	75
2008	0	100

The demographic payment methodology referenced above, which is the payment methodology that is being phased out, was used at the time of the interim final rule in 1999. Under that methodology, the Medicare capitation rate paid to PACE demonstration programs was calculated using the MA AAPCC rates with an additional frailty adjuster of 2.39 to account for the higher costs related to caring for this frail population.

As discussed above, section 1894(d) of the Act mandated that the Medicare capitated payments to POs be based on MA rates and be adjusted to account for the comparative frailty of PACE enrollees. The CMS–HCC payment approach described herein is a further refinement to the risk adjustment payment methodology to ensure that capitated payments to POs that serve frail community-based populations are accurate.

The CMS–HCC payment model described above is the basis of the new PACE payment. The individual participant risk score for MA and PACE is calculated using the appropriate CMS–HCC model (community, long-term institutionalized, ESRD or new enrollee) based on the participant's status. Risk adjustment explains the future Medicare expenditures of individuals based on diagnoses and demographics. The risk score is computed for each participant for a given year and applied prospectively. The risk score generally follows the beneficiary for one calendar year. But risk adjustment does not explain all of the variations in expenditures for frail community populations. We determined that it was appropriate to augment risk adjustment with a frailty adjustor for functionally impaired community residents in PACE. The purpose of the PACE frailty adjustment is to predict the Medicare expenditures of community populations with functional impairments that are unexplained by risk adjustment. Therefore, we developed a payment approach that adjusts the risk adjustment payment to an organization according to the frailty of the organization's enrollees. To clarify, the PACE frailty adjustment currently is made in addition to the risk adjustments made under the MA payment methodology.

The PACE frailty adjustment is based on activities of daily living (ADLs), a proxy for functional impairment, and applies only to community-based and short-term institutionalized participants (that is, the frailty adjustment for long-term institutionalized participants is zero).

The prospective frailty adjustment was designed to adjust for the average difference between the predicted and actual expenditures for each group. The prior year's functional impairment data are used to predict the next year's payment adjustment. Functional data are submitted to CMS, where they are calculated to establish the PO's frailty score, which is then applied to each participant's risk adjusted payment. The frailty adjustment approach is applied in conjunction with the CMS–HCC risk adjustment model. The frailty adjustment and factors were initially described in the CY 2004 Advance Notice and Announcement of MA Payment Rates. The CY 2004 Advance Notice and Announcement of MA Payment Rates can be found on the CMS Web site at: *http://www.cms.hhs.gov/MedicareAdvtgSpecRatesStats/Downloads.* We continue to refine our risk adjusted payment methodology to ensure that capitated payments to POs are accurate and take into account the comparative frailty of PACE enrollees. Any changes to our current PACE payment methodology will be described in subsequent Advance Notices and Announcements.

Comment: We received numerous comments, recommendations and concerns related to the Medicare payment methodology provided in the 1999 interim final rule. Overall, the commenters disapproved with changing the established payment methodology, discontinuing the 2.39 frailty adjustment, and speculation regarding how the Principal Inpatient-Diagnostic Cost Group (PIP–DCG) methodology risk adjustment payment methodology would work, including the rate amounts and how an MA payment methodology would be appropriate for calculating the PACE capitation payments. They also requested we continue to explore methods to capture the frailty status of PACE participants. Several commenters also inquired how ESRD payment would be calculated.

Response: The PIP–DCG risk adjustment methodology has been replaced by the CMS–HCC risk

adjustment model, that provides numerous adjustments related to participant demographics, characteristics, and diagnosis. CMS provided extensive technical assistance and training to the NPA and POs prior to the phase-in of risk adjustment for PACE. We also provided guidance and training on the ESRD payment methodology.

We believe that the comments presented have been answered to the satisfaction of the commenters. Further information and specific MA risk adjustment rate updates and MA documentation pertinent to risk adjustment methodology can be found on the CMS Web site at *http://www.cms.hhs.gov.* Annual rate updates are also published in the Advanced Notice of Methodological Changes for Calendar Year (CY)—Medicare Advantage (MA) Payment Rates and are also located on the CMS Web site.

End-Stage Renal Disease (ESRD) Adjustment Under the PACE Demonstration Program

Under the PACE demonstration program, POs were paid in two ways for Medicare ESRD participants. Each month for each ESRD participant, the PACE program was paid the AAPCC Part A and Part B ESRD rate. The rate was not adjusted by the 2.39 frailty factor. Instead, PACE programs received additional payment each month for the actual cost of services in excess of the AAPCC ESRD payment rate. As section 1894(d) of the Act does not authorize payment of actual cost, we conducted an analysis of 1994 Medicare claims data for ESRD patients. The analysis shows that Medicare expenditures for ESRD patients who are 75 or older are significantly higher than expenditures for all ESRD patients. This finding was fairly constant over time. The group of ESRD patients who are 75 or older tend to be very frail and in most cases would be considered NF-eligible. This group of elderly ESRD patients were used as a proxy for ESRD patients who are NF-eligible. ESRD patients who are 75 or older have 46 percent higher Part A expenditures relative to all ESRD patients, while their Part B expenditures are 36 percent higher. We applied this information to calculate adjusters for ESRD patients enrolled in PACE. Thus, the Part A ESRD adjuster was 1.46 and the Part B ESRD adjuster was 1.36. These ESRD adjustment factors were established at the time the 1999 interim final rule was published as an interim measure pending development of a risk adjustment methodology.

New ESRD Risk Adjustment Model

Simultaneous with the implementation of the CMS–HCC model for risk adjustment, we have implemented a new approach to improve payments on behalf of enrollees with ESRD. The approach is the same for both PACE and MA plans. Section 605 of BIPA required CMS to adjust the approach to computing ESRD payment rates to reflect the method used in the ESRD social HMO (S/HMO) demonstration program then in place. We interpreted this to mean that ESRD payments to MA organizations should employ the same basic approach used under the ESRD demonstration referenced in section 605. To implement the BIPA provision for 2002, CMS increased the base rates by three percent and began adjusting payments with age and sex factors, while continuing to review other options.

Effective January 2005, MA enrollees with ESRD were incorporated into diagnosis-based risk adjustment using a different version of the CMS–HCC model. (A list of coefficients for each disease group can be found at *http://www.cms.hhs.gov.*) The new ESRD payment model aligned us further with the method used in the ESRD S/HMO demonstration program by allowing us to capture co-morbidity information in addition to demographic information and basic disease markers for ESRD beneficiaries. ESRD status is recognized in the payment year. The data for 100 percent of ESRD beneficiaries were used to develop the model. The CMS–HCC model for ESRD is described in the Advance Notice and Announcement for Calendar Year 2005, which is available on the CMS Web site. Any updates will be described in future Advance Notices and Announcements.

In this final rule, we are revising § 460.180(b)(4) to reflect the new ESRD risk adjustment model.

We are also revising § 460.180(b)(1) to require that the PACE program agreement contain the ''methodology'' for establishing the monthly capitation rather than the ''amount'' of the monthly capitation. Section 1894(d)(2) of the Act, requires that capitation amount be specified in the program agreement. As such, under the new risk adjustment methodology, specifying the capitation amount in the program agreement is operationally impractical. We believe that continuing to include the capitation amount would require CMS, the SAA, and the PO to establish and sign new program agreements each time a new individual enrolled in the PACE program. We believe that the change from including the capitation amount to the methodology used to calculate the risk adjusted capitation payment amount is consistent with the statutory intent that the program agreement should specify how the PO will be paid. Because of the change in the MA payment methodology enacted by the Congress, it is no longer feasible to include the amount of payment. We will therefore include the payment methodology in the program agreement as a way to give effect to the intent of the PACE statute.

Under the demographic rate methodology, the capitation amount per person was the same for all participants (except participants with ESRD) and was multiplied by the number of participants. Under the new risk adjusted methodology each participant receives a individualized diagnosis-related payment. There is no way for CMS, the SAA, or the PO to predict what diseases or number of diseases future participants will have. Therefore, we have replace the capitation amount with the methodology for calculating the capitation amount in the PACE program agreement in Appendix M.

Comment: Commenters suggested that the actual fee-for-service cost factors be utilized in developing the new MA capitation rates and that the regulation should include language which allows alternatives to the MA methodology. Commenters also requested that CMS continue to explore methodology options and test the validity of various methods of capturing the true frailty status of PACE participants.

Response: Section 1894(d) of the Act directs that PACE payment be based on MA payment rates, adjusted for frailty of PACE enrollees and other factors as appropriate. The differences in the cost of caring for the community based frail population led to the implementation of a frailty adjustor being added to the risk adjustment methodology of the CMS–HCC model.

Comment: In the 1999 interim final rule, we also solicited comment related to the data collection that would be required to develop a specific risk adjustment methodology for PACE.

Numerous commenters presented their concerns that CMS sets Medicare payments to PACE providers based on the rate CMS pays to a MA organization. The commenters questioned whether the MA payment methodology is an appropriate foundation for calculating capitation payments for PACE providers considering the inherent problems with applying the PIP–DCG methodology to PACE and the decision to delay implementation of risk adjustment for PACE. They also believe that a risk-adjustment methodology that relies on

inpatient diagnosis as a determinant for payment is an inappropriate payment methodology for innovative programs such as PACE that diligently strive to minimize inpatient days through aggressive preventative and primary care and serve a frail elderly population with multiple chronic and complex health conditions.

Response: The Congress, through BIPA, required the implementation of a payment model for M+C organizations using not only diagnoses from inpatient hospital stays, but also from ambulatory settings, beginning in 2004. In addition, as described previously, CMS applies a frailty adjuster to an individual participant's risk-adjusted payment to account for the frailty of PACE participants.

Comment: The commenters also indicated that risk adjustment for PACE must account for PACE participants' functional status and cognitive impairment as well as other factors that may systematically impact Medicare utilization and costs in the fee-for-service environment and the need to base payment methodology (and related reporting requirements) for PACE programs on Medicare expenses incurred by comparable individuals outside PACE, not utilization of Medicare covered expenses by PACE participants themselves.

Because the 1999 interim final regulation was not specific in regard to the manner in which MA rates will be established in the future or the manner in which CMS will adjust MA rates for frailty and other factors determined by CMS to be appropriate, they requested that any process that CMS employs to modify the current rate-setting methodology for PACE, include consistent and timely communication with POs.

They also recommended that CMS consult with NPA regarding the reasonableness and impact of proposed changes well in advance of a final determination regarding a particular rate-setting approach and its implementation.

Response: In response to our solicitation for comment we received numerous comments on the data collection required to develop a PACE-specific risk adjustment methodology. The 1999 interim final rule discussed a MA payment methodology that no longer applies to PACE payment since that MA payment methodology is in the process of being phased out as required by BIPA.

Implementation of a new risk adjusted payment methodology based on the CMS–HCC model began in 2004. The transition to 100 percent payment using the new risk adjusted payment methodology will occur over a 5-year period. Implementation of the MA risk adjustment payment methodology for PACE programs was delayed until 2004 to provide CMS with sufficient time to evaluate differences in cost of care for the frail elderly community dwelling population.

In response to the commenters, the risk adjustment methodology for PACE, includes a frailty adjustment based on the functional status of the PO's participant population.

After the development of the MA risk adjustment model and of PACE specific modifications to the MA payment methodology, CMS had discussions with NPA regarding implementation of the new PACE payment methodology.

Comment: A commenter asked if the Medicare capitation rate would be based on the location of the program or the residence of the participant if the program spanned more than one county.

Response: The Medicare capitation rate is based on the county in which the participant resides.

Final rule actions:

In this final rule, we are amending § 460.180 to:

- Reflect statutory changes in the capitation payment methodology used to determine payment amounts for MA plans, and thus payment amounts for POs; and
- Require that the PACE program agreement contain the payment methodology for establishing the monthly capitation rate, rather than specifying a payment amount, in accordance with the changes to the MA capitation payment methodology.

Section 460.182 Medicaid Payment

Section 1934(d) of the Act requires a State to make prospective monthly capitated payments for each PACE program participant eligible for medical assistance under the State plan. The capitation payment amount must be specified in the PACE program agreement and be less, taking into account the frailty of PACE participants, than the amount that would otherwise have been paid under the State plan if the individuals were not enrolled in a PACE program.

A national Medicaid rate-setting methodology for PACE has not been established. Rather, each State that elects PACE as a Medicaid State plan option must develop a payment amount based on the cost of comparable services for the State's nursing-facility-eligible population. Generally, the amounts are based on a blend of the cost of nursing home and community-based care for the frail elderly. The monthly capitation payment amount is negotiated between the PO and the SAA and can be renegotiated on an annual basis.

As the statutory requirements do not differ from the Protocol requirements regarding Medicaid payments under the PACE demonstration program, the regulations mirror the Protocol requirements. We received three comments pertaining to Medicaid payment.

Comment: One commenter stated that considering the relationship between PACE payments and M+C (now MA) methodologies, there should be ample safeguards to assure that PACE entities can reasonably be expected to provide high quality services at these (Medicaid) payment levels. The commenter was also concerned that Medicaid payments are set at the state, not national level, and suggested we should examine the variation in state payments in relation to outcomes.

Response: We believe this commenter was indicating their opinion that the Medicaid payment amount in conjunction with the Medicare payment was ample to provide the highest quality care.

Medicaid costs vary depending on the State plan and home and community-based services offered in the State. The Medicaid capitation payment must be less than the amount that would otherwise have been paid under the State plan if the participant were not enrolled in a PACE program. As costs and benefits vary by State, we do not believe it would be appropriate to set Medicaid rates at a national level.

Comment: A commenter indicated that to date POs have operated with a fixed rate that does not change based on the participant's health status and suggested testing alternative approaches. The commenter offered to assist CMS with testing an alternative approach involving a rate change (at specified intervals) if there is significant change in a participant's health status. The commenter also requested that waivers be considered to facilitate testing this payment approach.

Response: We appreciate the commenter's offer, however, the statute does not address risk adjustment for Medicaid rates in PACE. As explained above, CMS does not want to impose a rate setting methodology on States. States have flexibility to implement a risk adjusted payment methodology that would recognize differences in health status among participants should they choose to do so consistent with the requirements of 1934(d)(2) of the Act.

Comment: The third commenter asked if the requirement at § 460.182(b) precludes the establishment of multiple

rate cells, with different payment levels that may change based on an annual reassessment, that address the frailty level and health status of the participant.

Response: States are afforded the flexibility to establish various payment levels reflective of frailty levels as long as payment is prospective and does not change before the annual renegotiation of the Medicaid capitation rate due to a change in health status. Section 460.182(b)(4) permits capitation rates to be renegotiated on an annual basis. It would be the responsibility of the State Medicaid Agency to ensure that payments for participants are accurately made for the appropriate payment level.

Comment: A commenter asked if the requirement at § 460.182(c) precludes risk sharing on losses and profits on the Medicaid services.

Response: Under sections 1894 and 1934(f)(2)(B)(v) of the Act, the PO must be at full financial risk. The State may not share risk with the PO.

Accordingly, § 460.182(c) states that the PO must accept the capitation payment as payment in full for Medicaid participants and may not bill, charge, collect, or receive any other forms of payment from the SAA. Therefore, the PO cannot share the risk with the State under stop-loss provisions.

POs are permitted to purchase stop-loss insurance from entities in the form of reinsurance, which is discussed in § 460.80(c)(2). States can offer stop-loss or reinsurance as a product to be purchased by the PO. Stop-loss provisions should be established based on the total costs for a participant and may not be based on a particular aspect of the benefit package.

Final rule actions:

This final rule finalizes § 460.182 as published in the 1999 interim final rule.

Section 460.184 Post-Eligibility Treatment of Income

Section 1934(b)(1)(A)(i) of the Act states that a PO shall provide, to eligible individuals, all covered items and services without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. Section 1934(i) of the Act permits States to use post-eligibility treatment of income in the same manner as it is applied for individuals receiving services under a waiver under section 1915(c) of the Act.

The post-eligibility treatment of income provision reduces the amount of Medicaid payments to a PO by the amount remaining after specified deductions are made from the income of the PACE participant. The income that remains after these deductions are applied is the amount a participant is liable to pay toward the cost of the PACE services. Therefore, an argument could be made that sections 1934(b) and (i) of the Act are in conflict since under section 1934(i) of the Act, PACE participants may incur limited liability for part of the cost of their services. However, we have concluded that the type of Medicaid participant liability permitted by section 1934(i) of the Act is not cost sharing prohibited by section 1934(b)(1)(A)(I) of the Act.

Section 1902(a)(17) of the Act permits an individual (or family) who has more income than allowed for Medicaid eligibility to reduce excess income by incurring expenses for medical or remedial care to establish Medicaid eligibility. However, this spenddown process is used in establishing Medicaid eligibility rather than being the type of cost sharing prohibited by section 1934(b)(1)(A)(I) of the Act.

We interpret section 1934(b)(1)(A)(i) of the Act, to refer to deductibles, copayments, coinsurance or other cost sharing beyond participant liabilities related to Medicaid eligibility. Any other reading of the law would make section 1934(i) of the Act merely surplusage and not meaningful. Therefore, to give significance to these sections of the Act, we provided in § 460.184, which implements section 1934(i) of the Act, references to 42 CFR 435.726 and 435.735. Sections 435.726 and 435.735 lay out the post-eligibility treatment of income requirements that may be applied to PACE participants in the same manner as applied to individuals receiving home and community-based services.

Conforming Amendments

The BBA made conforming amendments to sections 1924(a)(5) and 1903(f)(4)(C) of the Act pertaining to eligibility for medical assistance. Section 1924(a)(5) of the Act, was revised to indicate that special treatment of income and resources for institutionalized spouses in determining eligibility for medical assistance is applied to individuals receiving services under a PACE program under sections 1934 or 1894 of the Act. Further, section 710 of the Omnibus Appropriation Bill (Pub. L. 105–277) enacted October 21, 1998, permits PACE program eligible individuals enrolled in a PACE program under section 1934 of the Act to be eligible for Medicaid under the optional categorically needy eligibility group at section 1902(a)(10)(A)(ii)(IV) of the Act. Under this authority, States can determine eligibility for PACE enrollees using institutional rules, including use of the special income level group described at section 1902(a)(10)(A)(ii)(IV) of the Act.

We received no public comments on § 460.184.

Final rule actions:

This final rule will finalize § 460.184 as published in the 1999 interim final rule.

Section 460.186 PACE Premiums

Neither section 1894 nor section 1934 of the Act addresses the premiums a PO can charge a PACE participant. As a result, we have adopted most of the PACE premium requirements in this section from Part VI, section D of the Protocol. It is important to note that the term ''premiums'' as used in this regulation does not include spenddown liability under 42 CFR 435.121 and 435.831, or post-eligibility treatment of income under § 460.184. This use of the word premiums is narrower than the way the word is used in the Protocol, where a participant's ''share of cost'' responsibility under Medicaid is referred to as a type of premium. In addition, POs may continue to collect any liability due them under Medicaid spenddown and post-eligibility processes, but that liability is not a premium.

We specify that a participant's monthly premium responsibility depends upon his or her eligibility under Medicare and Medicaid.

The Protocol says that the premium for Medicare-only participants is equal to the Medicaid capitation amount. Nearly all Medicare participants have both Part A and Part B, and the capitation amount that Medicare pays is the sum of the Part A and Part B capitation rates. However, section 1894(a)(1) of the Act permits an individual who is entitled to Medicare benefits under Part A or enrolled under Part B to enroll in the PACE program. For those rare persons who are eligible under only one part, the Medicare capitation amount will be only the portion for that part. Such a participant is required to make up the difference, that is, pay an additional premium amount equal to the missing piece of the Medicare capitation amount. We specify the premiums for Medicare-only participants as follows—

- For a participant who is entitled to Medicare Part A and enrolled under Medicare Part B, but is not eligible for Medicaid, the premium equals the Medicaid capitation amount.
- For a participant who is entitled to Medicare Part A, but is not enrolled under Part B and is not eligible for Medicaid, the premium equals the

Medicaid capitation amount plus the Medicare Part B capitation rate.

• For a participant who is enrolled only under Medicare Part B and is not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part A capitation rate.

We specify that no premium may be charged to a participant who is dually eligible for both Medicare and Medicaid or one who is only eligible for Medicaid.

We received four comments regarding PACE premiums.

Comment: Commenters requested clarification on the premiums for those with neither Medicare nor Medicaid. One commenter recommended that POs not be permitted to establish private pay premiums for Medicare covered services in excess of the Medicare capitation amount. Two commenters suggested that private pay premiums for non-Medicaid eligible participants be no less than the Medicaid capitation rate.

Response: We believe it was congressional intent to permit individuals with Medicare Part A, Part B, Medicaid, any combination of the above or none of the above to participate in PACE based on sections 1894(i) and 1934(j) of the Act. Therefore, POs must enroll any individual who meets the enrollment criteria even if they participate in neither Medicare nor Medicaid.

However, as we noted previously, the statute does not address the amount a private pay PACE enrollee can be charged in premiums. Therefore, we will leave the premium amount to the discretion of the POs, based on their individual population and service needs.

Comment: One commenter recommended that, through the waiver process, POs be allowed to explore alternate methods of establishing premiums for non-Medicaid participants, who have Medicare so long as the premiums are set to be actuarially equivalent to, those established for the Medicaid populations.

Response: In accordance with BIPA 903, the 2002 interim final rule provides a waiver process that can be accessed by a PO, that is unable to meet a regulatory requirement or, if they are an experienced PO, waivers to explore alternative practices (see § 460.26 and § 460.28 regarding waiver process). Additional information regarding the waiver process is on the PACE Web site, *www.cms.hhs.gov/PACE.*

As explained above, CMS requires that the premium for Medicare-only participants enrolled in both Medicare Part A and Part B be equal to the Medicaid capitation amount. The PO does not have the discretion to establish a higher premium amount for these participants. CMS specifies the premium amount that may be charged to these PACE participants so that premiums correlate with (Medicaid) costs and are equal for participants with the same eligibility. CMS and States go through an extensive process to calculate Medicaid rates that take into account the frailty of PACE participants. Therefore, the Medicaid capitation rate, should be an acceptable amount for a premium.

Final rule actions:

This final rule will finalize § 460.186 as published in the 1999 interim final rule.

Subpart K: Federal/State Monitoring

Section 460.190 Monitoring During Trial Period

Sections 1894(e)(4)(A) and 1934(e)(4)(A) of the Act provide for annual close oversight during the trial period, which is a PO's first 3 contract years. We established § 460.190 to address the requirements for monitoring during the trial period. During the trial period, CMS in cooperation with the SAA conducts comprehensive annual reviews of a PO.

In accordance with the statute and as specified in § 460.190 the review includes an on-site visit to the PO, a comprehensive assessment of the organization's fiscal soundness, a comprehensive assessment of the organization's capacity to furnish all PACE services to all enrolled participants, a detailed analysis of the organization's substantial compliance with all significant requirements of sections 1894 and 1934 of the Act and these regulations, and any other elements that CMS or the SAA find necessary.

No public comments were received on § 460.190.

Final rule actions:

This final rule will finalize § 460.190 as published in the 1999 interim final rule.

Section 460.192 Ongoing Monitoring After Trial Period

In accordance with paragraph (e)(4)(B) of sections 1894 and 1934 of the Act, we specified that at the conclusion of the trial period, CMS, in cooperation with the SAA, would continue to conduct reviews of a PACE program, as appropriate. These reviews must take into account the performance level of the PO with respect to the quality of care provided and compliance of the organization in meeting the PACE program requirements. Such reviews include an on-site visit at least every two years.

No public comments were received on § 460.192.

Final rule actions:

This final rule will finalize § 460.192 as published in the 1999 interim final rule.

Section 460.194 Corrective Action

We require the PO to take action to correct deficiencies identified during the reviews. CMS or the SAA will monitor the effectiveness of corrective actions. Failure to correct deficiencies can result in sanctions or terminations in accordance with subpart D.

Comment: One commenter inquired how it would be determined whether the CMS or the State would monitor a CAP.

Response: CMS works in partnership with the SAA to monitor POs. Information received by either agency in response to the CAP is shared with the other agency. As indicated in § 460.194, either CMS or the SAA will monitor the CAP. The determination of which agency will monitor the CAP will vary depending on the issues addressed by the CAP. Since CMS and the SAA have their own regulations, each agency is monitoring for deficiencies in relation to their regulations as well as any general deficiency they identify that needs correction. CMS and the SAA discuss the monitoring review findings and the actions that need to be taken, to assure the PO has corrected or is in the process of correcting the deficiencies, prior to releasing the official CAP report to the PO. During those discussions, they will decide who will be the lead for monitoring the progress of the CAP. One of the factors involved in that decision is the number of follow-up visits that will be required and the proximity of the SAA and CMS offices. Often times, quarterly calls between CMS, the SAA, and the PO can include specific CAP items on the agenda. Follow-up visits can be conducted by the SAA, CMS, or the results can be reviewed at the next monitoring visit.

Final rule actions:

This final rule will finalize § 460.194 as published in the 1999 interim final rule.

Section 460.196 Disclosure of Review Results

In accordance with paragraph (e)(4)(C) of sections 1894 and 1934 of the Act, we specified requirements for disclosing the results of monitoring reviews. CMS and the SAA promptly report the results of reviews under § 460.190 and § 460.192 to the PO, along with any recommendations for changes to the organization's program. The results are made available to the public upon

request. In addition, we require that the PO post a notice of the availability of the results of the most recent review and any CAPs or responses related to the most recent review. The PO must also make the results available for examination in a place readily accessible to participants.

Comment: One commenter stated that access to the information by the public would be greatly expanded by requiring the SAA to post the results of PACE monitoring reviews on the agency's Web sites.

Response: We believe the decision regarding whether the State posts the results of PACE monitoring reviews is a State determination. We encourage access to information for the public but do not believe it is necessary to dictate specific methods in regulations.

Comment: Another commenter questioned if the definition for ''promptly'' means within 45 days.

Response: CMS and the SAA expect to complete the analysis of monitoring review findings and provide them to the PO within 30 days after completion of the review and, if this timeframe is not possible, then as close to 30 days as possible. Due to the in-depth review performed by the CMS and SAA monitoring review teams, it is not always possible to complete an extensive report quickly. Therefore, we have decided to retain the term promptly and not provide a specific timeframe.

Final rule actions:

This final rule will finalize § 460.196 as published in the 1999 interim final rule.

Subpart L: Data Collection, Record Maintenance, and Reporting

The purpose of subpart L is to establish the requirements for data collection, record maintenance, and reporting. This subpart describes in detail the manner in which POs must collect, maintain and report data including participant health outcomes, organization financial information, and medical records.

Section 460.200 Maintenance of Records and Reporting of Data

In accordance with sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act, we require POs to collect data, maintain records, and submit reports. We describe data and records to include participant health outcome data, financial books and records, medical records, and personnel records. We require the documents to be accessible to CMS and the SAA upon request and be stored in a manner consistent with the PO's written policies that protect them from loss, destruction, unauthorized use or inappropriate alteration.

We established several requirements intended to safeguard the privacy of any information that identifies a particular participant. The PO must establish written policies and implement procedures to ensure that information from, or copies of, records are released only to authorized individuals and that original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas. In addition, a participant's written consent must be obtained before the release of identifiable information to persons not otherwise authorized to receive it. The written consent may limit the degree of information and the persons to whom information may be released. Participants are guaranteed timely access to review and copy their own medical records and may request amendments to their records. Finally, the PO must abide by all Federal and State laws regarding confidentiality and disclosure of participant mental health and medical records and other health information.

The Protocol did not specify a minimum record retention timeframe. In order to enable adequate oversight and to be consistent with the requirements established for M+C plans, we require POs to retain records for the longest of the following periods: the period specified by State law; six years from the date of the last entry made in the record; or for medical records of disenrolled participants, six years after the date of disenrollment. If any litigation, claim, financial management review, or audit is started before the expiration of the retention period, we are requiring that those records be retained until completion of the litigation, or until claims or audit findings involving the records have been resolved and final action taken.

We note that for purposes of Medicare Part D, POs are required to retain Part D related records for a period of 10 years in accordance with 42 CFR 423.505(d).

Comment: One commenter asked when data collection, maintenance, and reporting requirements would be issued by CMS and the SAA.

Response: In the fall of 2001 the PACE demonstration programs were instructed to submit Data Elements for Monitoring on a quarterly basis via the HPMS. This reporting requirement remains in effect for POs.

Prior to signing the program agreement, which contains these reporting requirements, POs are provided with instructions on the HPMS: The HPMS Connectivity Guide, HPMS User's Guide and HPMS Connectivity for States. These materials can also can be found on the PACE Web site at *http://www.cms.hhs.gov/PACE/09_AdditionalResources.asp*.

The Data Elements for Monitoring include information on the number of grievances and appeals; reasons for disenrollment; and vaccination rates for flu and pneumonia.

Appendix M of the PACE program agreement indicates that Medicare payment is also reliant on information reported to CMS. As discussed in the payment section, the risk score for PACE participants is based on the CMS–HCC, which is based on the diagnostic information submitted by the PO. The PO's frailty score is based on the responses received from community-dwelling participants on the Modified HOS (Health Outcomes Survey), which identifies participant difficulty in performing ADLs.

To the extent the SAA establishes additional reporting requirements, the requirements would be identified in a separate contract between the SAA and the PO.

Final rule actions:

This final rule will finalize § 460.200 as published in the 1999 interim final rule.

Section 460.202 Participant Health Outcomes Data

In the 1999 interim final rule, we modified the requirement in Part VII, section B of the Protocol for data collection and reporting. We require POs to maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure their performance and to develop their QAPI. As discussed above, POs are expected to collect data for monitoring and report it at quarterly intervals via HPMS. HPMS information may be used by CMS, SAAs, and POs.

Each PO must collect, evaluate, and report the data as part of managing its QAPI. These data will assist the PO in its efforts to identify opportunities to improve participant care and outcomes, and to evaluate the results of its performance improvement activities.

Additionally, we have a requirement that the PO must furnish data and information in the manner and at the time intervals specified by CMS and the SAA, pertaining to its participant care activities. The items to be collected are specified in the PACE program agreement and will be subject to the confidentiality requirements specified in § 460.200.

Finally, we require that each PO conduct an annual satisfaction survey of its participants and caregivers. The

findings should be used by the PO to identify opportunities for improvement.

Comment: Four commenters commented on health outcomes data, and although they were supportive of requirements for participant health outcomes data, they maintain that flexibility is important in developing State or site specific systems. Commenters asked that CMS focus on the specific data elements that will be required but leave the decision about which tool to use to the States or providers.

One commenter indicated that it is important for States to know, up front, the participant health outcome data reporting requirements to assist them in making PACE a State plan option.

Response: Although the reporting requirements discussed above were not available when we published the 1999 interim final rule, we established the requirement shortly after publication. We also provided training to the POs. States should now be aware of the reporting requirements for PACE.

Comment: One commenter indicated that if encounter data were going to be used for uses other than risk adjustment, then a broader range of data requirements would be needed. This commenter was interested in CMS developing consistency in reporting requirements in order to minimize the reporting burden for POs.

Response: Currently, encounter data is only being used to determine reimbursement under the risk adjustment payment methodology. As discussed in the QAPI section, we are no longer pursuing development of a standardized assessment tool for PACE.

Comment: Several commenters stressed the importance of streamlining all Federal and State reporting requirements. Two commenter opposed CMS' application of a broad range of reporting requirements to POs which were developed for, and are more appropriate to, managed care entities and more limited provider types, such as, home health agencies or nursing homes. One commenter discouraged whole scale application of these types of requirements and encouraged the development of OBCQI requirements unique to PACE providers.

Response: At the time we published the 1999 interim final rule, several PACE demonstration programs were licensed under State law as home health agencies. In these cases, the POs were subject to the additional reporting requirements based upon their licensure. We understand many States are now developing licensure programs for PACE. When this occurs, the POs would no longer be required to submit additional OASIS information. The encounter and functional status reporting are necessary for PACE payment under risk adjustment methodology.

Final rule actions:

This final rule will finalize § 460.202 as published in the 1999 interim final rule.

Section 460.204 Financial Recordkeeping and Reporting Requirements

In § 460.204, we require that a PO must provide CMS and the SAA with accurate financial reports that are prepared using an accrual basis of accounting and verifiable by auditors.

In addition, we require that the PO maintain an accrual accounting recordkeeping system that accurately documents all financial transactions, provides an audit trail to source documents, and generates financial statements.

Further, except as stipulated under Medicare principles of reimbursement set forth in 42 CFR part 413, a PO must follow standardized definitions and accounting, statistical, and reporting practices that are widely accepted in the health care industry.

We also require that a PO must permit CMS and the SAA to audit or inspect any books and records of original entry that pertain to any aspect of services performed, reconciliation of participants' benefit liabilities or determination of Medicare and Medicaid amounts payable.

We note the statute does not provide for risk-sharing arrangements between CMS and POs. It places the organization at full financial risk for all services, thus our emphasis is on the need for accurate accounting records.

Comment: One commenter recommended that CMS require POs that are a subdivision of a larger parent organization, to maintain a balance sheet, statement of income and expenses, and documentation of the sources and uses of its funds that is separate and distinct from the parent organization's financial record keeping.

Response: We agree. We believe it is important for us to receive the financial information for the PO in order to determine the PO's solvency. However, where the PO's financial solvency is based on a guarantee by the PO's parent organization, we request this information as well.

Final rule actions:

This final rule will finalize § 460.204 as published in the 1999 interim final rule.

Section 460.208 Financial Statements

CMS, in cooperation with the SAA, has the responsibility of assessing fiscal soundness as described in § 460.80. The financial information required to assess the fiscal soundness of a PO is information from basic financial statements, balance sheets, statement of revenues and expenses, and sources and uses of funds statement. An organization that has completed its trial period is required to submit financial statements annually. An organization that is in the trial period is required to submit quarterly financial statements in addition to the annual certified financial statements. An organization may use the ''Annual Statement'' (also known as the ''orange blank''), which was developed by the National Association of Insurance Commissioners for reporting by HMOs. For information contact NAIC 2301 McGee Street, Suite 800 Kansas City, MO 64108 (816–842–3600).

We require that, not later than 180 days after the end of the organization's fiscal year, the PO submit the annual financial statement that includes appropriate footnotes. This financial statement must be certified by an independent certified public accountant. At a minimum, the certified financial statement must include a certification statement, a balance sheet, a statement of revenues and expenses, and a source and use of funds statement.

Throughout the trial period, we require that not later than 45 days after the end of each quarter of the organization's fiscal year, a PO must submit a quarterly financial statement. Quarterly financial statements are not required to be certified by an independent certified public accountant.

At the conclusion of the trial period, CMS or the SAA may require a PO to submit monthly or quarterly financial statements, or both, if CMS or the SAA determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness. These additional reports do not have to be certified by a certified public accountant.

Sections 1894(e)(3) and (4) and 1934(e)(3) and (4) of the Act require CMS and the SAA to work in consultation to determine what data, cost and financial reports the PO must submit so these agencies can monitor the cost and effectiveness of a PO and perform necessary reviews.

We consulted with representatives from various State organizations that serviced PACE demonstration programs. We have determined that data collection

and financial reporting requirements vary among the State organizations. The data collection and financial reports we require for purposes of assessing fiscal soundness can also assist the SAA in their monitoring and oversight requirements. Of course, States have the authority to request any data and reports that they consider to be necessary in implementing the PACE program. We solicited comments on consistency in reporting requirements in the 1999 interim final rule.

Comment: Two commenters asked whether financial statements and reports should be routed to CMS via the SAA or if they should go to CMS and the SAA simultaneously.

Response: Financial reports should go to CMS and the SAA simultaneously.

Comment: Commenters asked whether there is any flexibility in CMS requirements at § 460.208 for submission of financial reporting documents to CMS and the State, if the State establishes a different reporting cycle.

Response: The financial statements are due to CMS within the required timeframes of 45 days from the end of the quarter (during the trial period) and 180 days after the fiscal year end. There is no flexibility in CMS' timeframes, but States may have discretion regarding their timeframes for reporting requirements if they are different than the Federal requirements.

Comment: Several commenters asked if CMS has standard reporting formats and if States have flexibility to develop their own financial reporting documents.

Response: CMS does not have a standard format for financial reporting for POs. As specified in § 460.204, financial reports are required to be prepared using an accrual basis of accounting and must be verifiable by qualified auditors.

There is flexibility for States to develop their own financial reporting formats if they choose to do so.

Final rule actions:

This final rule will finalize § 460.208 as published in the 1999 interim final rule.

Section 460.210 Medical Records

The participant's medical record presents a total picture of the care provided. The medical record is a useful tool in diagnosing, treating and caring for the participant. The medical record: (1) Facilitates communication among the various health care professionals providing services to the participant; (2) provides a focal point for coordinating the actions of the IDT; (3) provides an accurate picture of the participant's progress in achieving care goals; and (4) provides the team members with data for evaluating and documenting the quality and appropriateness of care delivered. Because care for the PACE population will be provided by a variety of sources (for example, PACE center employees, contracted personnel, hospital staff, nursing home staff, etc.), it is critical that all information on the participant be documented in the medical record to ensure quality and continuity of care. As a result, in the 1999 interim final rule, we retained with few modifications the minimum elements specified in the Protocol to be included in the participant's medical record.

To facilitate continuity of care, we require in § 460.210 that the PO maintain a single comprehensive medical record for each participant at the PACE center they attend. Participant medical records should be complete, accurately documented, easily retrievable, systematically organized, and available to all staff. We recognize that a PO may have more than one PACE center, however, participant medical records must be located at the PACE center where the participant receives services so that staff has access to pertinent information. This requirement also should prevent time lost in obtaining records and facilitate timely review and documentation of the medical record.

At a minimum, the participant medical record must include:

- Appropriate identifying information;
- Documentation of all services furnished, including:

+ A summary of emergency care and other inpatient or long-term care services. (We included this last phrase to ensure that any services furnished to the participant outside the scope of the PACE center's direct care is documented in the medical record. It is critical to the continuity of care that the IDT be informed of all outside services furnished to the participant. Once the participant returns to the PACE center, the course of treatment can be reevaluated and adjusted based on any changes in the participant's status.);

+ Services furnished by employees of the PACE center; and

+ Services furnished by contractors and their reports (This item is intended to ensure that anyone who furnishes services to the participant, employees of the PO or contractors, shares the information with the IDT for documentation in the medical record. Again, this requirement is intended to facilitate communication between providers.);

+ Interdisciplinary assessments, reassessments, plans of care, and treatment and progress notes that are signed and dated;

+ Laboratory, radiological and other test reports (This change from the Protocol clarifies that all tests should be included in the participant medical record.);

+ Medication records;

+ Hospital discharge summaries, if applicable;

+ Reports of contact with informal support (for example, representatives/ care givers, legal guardian, or next of kin);

+ Enrollment Agreement signed by the participant;

+ Physician orders;

+ Disenrollment justification, if applicable;

+ Advance directives, if applicable (For example, when a participant has executed an advance directive, that fact should be prominently displayed. If the PO cannot implement an advance directive as a matter of conscience that fact also should be prominently displayed and explained to prospective enrollees.);

+ A signed release permitting disclosure of personal information; and

+ Accident and incident reports. (Accident and incident reports were included because we believed they may be an indicator of changes in the participant's functional status, problems or changes in the participant's home environment, or physical problems with the PACE center or its staff.)

We also require the PO to provide for the prompt transfer of copies of appropriate medical record information between treatment facilities to ensure continuity of care whenever a participant is temporarily or permanently transferred to another facility. Examples of appropriate medical record information include, but are not limited to, the reason for the transfer, the name and phone number of the attending physician, participants' demographics, active diagnosis and treatment plan including current medications and ADL status, special dietary considerations, etc. It is essential that the medical history and plan of care follow the participant. This requirement is intended to ensure communication between providers. We solicited comments on whether a specific timeframe for the transfer of participant medical record information should be required.

We included a requirement for authentication of the medical record to ensure that the appropriate individuals have reviewed and completed the participant's medical records. All

entries must be legible, clear, complete, and appropriately authenticated and dated.

Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry.

Comment: Three commenters indicated that it is inappropriate for accident and incident reports to be kept in the medical record. They suggest that changes in a participant's health status resulting from an accident and other incident not be noted in the medical record. Rather the commenter believed that accident or incident reports should be maintained in a secure, confidential location that is available to CMS and the SAA for review.

Response: Our intent at the time of drafting the 1999 interim final rule was that POs would record changes in health status resulting from accidents or incidents in the medical record and all records would be consolidated into one medical record. However, we agree with the commenters that specific accident or incident reports should be maintained in a secure confidential location and should be available to CMS and the SAA for review. We believe the purpose of including such items in the medical record is served by noting the change in medical condition. We do not think that the origin of the change is required in the medical record but agree that accident and incident reports should be available to CMS and the SAA for purposes of program review. Changes in participant health status and related participant assessments and modifications to care plans are required to be included in the medical record. We will, however, no longer require that accident and incident reports be filed in participant medical records.

Therefore, we are amending § 460.210 by deleting paragraph (b)(13) from the required content of medical record.

Comment: Two commenters responded to our request for comments regarding whether to impose specific timeframes for the transfer of participant medical record information between the PO and another treatment facility or provider. One commenter did not recommend the imposition of a timeframe for transfer of records, while the other commenter recommended implementing a timeframe requirement only when providing the participant with a copy of their medical record when requested.

Response: We believe that a comprehensive treatment history equips providers to deliver appropriate care. We also believe that POs are cognizant of the importance of prompt transfer of medical records in order to assist other providers and facilities in coordinating PACE participant care.

Therefore, we believe that POs will provide for the prompt transfer of appropriate medical record information between treatment facilities to ensure continuity of care whenever a participant is temporarily or permanently transferred to another facility and a timeframe for doing so is not necessary. Accordingly, we are not imposing a timeframe for transferring medical records in this final rule.

Comment: Two commenters questioned whether the PO must maintain a hardcopy of all electronically maintained medical records. The commenters requested clarification of the requirement for electronic record integrity and back-up.

Response: CMS does not require the hardcopy backup of electronic medical records. We are not mandating a specific system for electronic medical record backup but the PO needs to develop and maintain a backup system for their electronic medical records to ensure that they can reproduce their medical records should there be a systems dysfunction or physical destruction such as a fire. The electronic medical records should be periodically and systematically backed-up, secure, and located off site in case of a physical disaster. The PO must be able to provide a copy of participants medical records upon request by CMS or the SAA.

Final rule actions:

This final rule will amend § 460.210 by deleting paragraph (b)(13) ''Accident and incident reports'' from the required contents of the medical record.

IV. Provisions of Final Rule

Part 460 Authority Citation

We are adding sections 1894(f) and 1934(f) of the Social Security Act to the authority citation for part 460 because they specifically require the Secretary to promulgate regulations for these sections.

Subpart A—Basis, Scope, and Definitions

Section 460.2 Basis—No Change

Section 460.4 Scope and Purpose—No Change

Section 460.6 Definitions

We are amending this section to redefine the term ''PACE center'' as ''a facility which includes a primary care clinic, areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining which serves as the focal point for coordination and provision of most PACE services.'' We are also amending this section by adding the definition of ''PACE program''.

Subpart B—PACE Organization Application and Waiver Process

Section 460.10 Purpose—No Change

Section 460.12 Application Requirements

The October 2002 interim final with comment removed and reserved § 460.12(a)(2). In this final rule, we are redesignating § 460.12(a)(3) as § 460.12(a)(2). We are also removing the cross reference to § 460.14 in newly redesignated paragraph (a)(2)(i) of § 460.12, and the cross reference to § 460.16 in newly redesignated paragraph (a)(2)(ii) of § 460.12, since § 460.14 and § 460.16 are being removed in this rule.

Section 460.14 Priority Consideration

In this final rule, we are deleting § 460.14 which no longer applies since August 5, 2000 timeframe has passed and all PACE demonstration programs have transitioned to permanent providers. We are reserving this section.

Section 460.16 Special Consideration

In this final rule, we are deleting § 460.16 which no longer applies since the August 5, 2000 timeframe has passed and all PACE demonstration programs have transitioned to permanent providers. We are reserving this section.

Section 460.18 CMS Evaluation of Application—No Change

Section 460.20 Notice of CMS Determination—No Change

Section 460.22 Service Area Determination—No Change

Section 460.24 Limit on Number of PACE Program Agreements—No Change

Section 460.26 Submission and Evaluation of Waiver Requests

In this final rule, we are amending § 460.26 by redesignating paragraph (a) as paragraph (a)(1) and adding paragraph (a)(2) permitting non-operational entities submitting a PACE provider application to submit a waiver request at the same time. The waiver request must be submitted as a separate document and follow all other requirements as stated in this section. We are also amending paragraphs (b) and (b)(1) by adding ''or PACE applicant.''

Section 460.28 Notice of CMS Determination on Waiver Requests

We are amending (a)(2) by adding ''or PACE applicant,'' thereby requiring

CMS to notify the PO or PACE applicant in writing of the decision to deny the submitted wavier request.

Subpart C—PACE Program Agreement

Section 460.30 Program Agreement Requirement—No Change

Section 460.32 Content and Terms of PACE Program Agreement

We are amending paragraph (a)(12) to require the PACE program agreement to include the Medicaid capitation rate and the methodology used to calculate the Medicare capitation rate.

Section 460.34 Duration of Program Agreement—No Change

Subpart D—Sanctions, Enforcement Actions, and Termination

Section 460.40 Violations for Which CMS May Impose Sanctions—No Change

Section 460.42 Suspension of Enrollment or Payment by CMS—No Change

Section 460.46 Civil Money Penalties—No Change

Section 460.48 Additional Actions by CMS or the State—No Change

Section 460.50 Termination of PACE Program Agreement—No Change

Section 460.52 Transitional Care During Termination—No Change

Section 460.54 Termination Procedures—No Change

Subpart E—PACE Administrative Requirements

Section 460.60 PACE Organizational Structure

In this final rule, we are amending § 460.60(d)(3) by changing ''60'' to ''14'' days. Together with the following deletions of paragraphs (d)(4) and (d)(5) of this section, we are reducing administrative burden for POs.

We are deleting paragraph (d)(4) that states ''changes in organizational structure must be approved in advance by CMS and the SAA.''

We are also deleting paragraph (d)(5) that states, ''changes in organizational structure approved by CMS and the SAA must be forwarded to the consumer advisory committee, described in § 460.62(c) for dissemination to participants as appropriate.''

Section 460.62 Governing Body

In this final rule, we are clarifying the requirements for community involvement on issues relating to participants. We are revising the name of the ''Consumer Advisory Committee'' to be the ''Participant Advisory Committee'' to more adequately reflect the intent of the PO having an advisory committee that is comprised of participants and participant representatives who are focused on their issues. The Participant Advisory Committee provides the Participant Representative with issues as recorded in minutes of their meeting to present at the PO governing body meeting required in the new paragraph (c)(3).

Section 460.64 Personnel Qualifications for Staff With Direct Participant Contact

We are amending the title of § 460.64 and the personnel qualifications to clarify that the qualifications apply to all PACE staff with direct participant contact and decrease the burden in hiring and contracting for adequate numbers of staff members. We are removing the educational requirements and other qualifications at § 460.64(c) that we established for professions where no States require licensure, certification, or registration. All PACE staff with direct participant contact must meet the general personnel qualifications.

The amended requirements also clarify that physicians must meet the requirements for Federally-defined qualifications for a physician in addition to the general personnel requirements.

Section 460.66 Training

We are clarifying the training requirement for personal care attendants by requiring that their competency must be exhibited before performing personal care services independently.

Section 460.68 Program Integrity

We are amending the conflict of interest prohibitions. We provided a mechanism for disclosure and recusal in the event that a PO experiences any direct or indirect conflict of interest by a member of the governing body or an immediate family member.

Section 460.70 Contracted Services

We are reducing operational burden by amending this regulation to remove the requirement that POs submit each signed contract for inpatient care.

Section 460.71 Oversight of Direct Participant Care

We are amending this requirement to be consistent with the general personnel qualifications by clarifying that all direct participant care staff and contractors be free of communicable diseases and have all immunizations up to date before performing direct participant care.

Section 460.72 Physical Environment

We are amending this requirement to clarify that POs must perform the manufacturers' recommended maintenance.

Section 460.74 Infection Control—No Change

Section 460.76 Transportation Services—No Change

Section 460.78 Dietary Services

In this section, we are clarifying that each participant's dietary requirements are determined by assessment and included in the participant's plan of care. It also clarifies that the PO must ensure that each participant receives meals that are specific to their dietary needs. If the PO needs to provide meals, which are included in the participant's plan of care, the meals must be nourishing, palatable, well-balanced, and meet the participant's daily nutritional and special dietary needs.

Section 460.80 Fiscal Soundness—No Change

Section 460.82 Marketing Materials—No Change

Subpart F—PACE Services

Section 460.90 PACE Benefits Under Medicare and Medicaid—No Change

Section 460.92 Required Services

We are amending the list of required services to clarify that the PACE benefit package include all Medicare-covered items and services, Medicaid-covered items and services specified in the State's approved Medicaid plan, and other services determined necessary by the IDT to improve and maintain the participant's overall health status.

Section 460.94 Required Services for Medicare Participants

We are amending the requirement to clarify that payment for PACE program services is for services that are provided to the PACE participants.

Section 460.96 Excluded Services

We are correcting a technical error published in § 460.96(e)(1) by replacing the word ''through'' with the word ''and'' so that paragraph (e) reads ''Services furnished outside of the United States, except as follows: (1) In accordance with § 424.122 and § 424.124 of this chapter.''

Section 460.98 Service Delivery

We are expanding participant rights by amending this requirement to include sexual orientation in the list of

categories under which PO must not discriminate.

Section 460.100 Emergency Care

We are defining urgent care and post-stabilization care outside of the service area.

We are also expanding participant protection by amending this requirement to clarify that the PO must explain to the participant or caregiver that they can obtain emergency care without prior authorization.

Section 460.102 Interdisciplinary Team

We are clarifying the position and responsibilities of the social worker on the IDT by amending it to ''Master's level social worker (MSW).'' This will make the requirement consistent with other Medicare regulations.

Section 460.104 Participant Assessment

We are amending this provision to require that the in-person assessment and reassessments be performed by both a physical therapist and an occupational therapist, thus clarifying one discipline cannot replace the other discipline.

We are clarifying that a MSW performs assessments and reassessments.

We are also redesignating paragraph (c)(3) as new paragraph (d) and changing the heading from ''Reassessment based on change in participant status or at the request of the participant or designated representative'' to ''Unscheduled reassessments.'' We are identifying separate requirements in paragraph (d) for reassessments based on a change in participant status or requested by a participant or his or her representative.

We are decreasing the operational burden by removing the requirement that all reassessments be performed by the IDT minus the personal care attendant, driver, and PACE center manager. We are amending this requirement to require the IDT members listed in paragraph (a)(2) to perform in-person reassessments for change in status and permit the IDT to determine which IDT members must perform reassessments when requested by the participant or their designated representative. However, we added a requirement that if a significant change in the participant's health or psychosocial status occurs, the in-person reassessment must be performed by the entire IDT minus the personal care attendant, driver, and PACE center manager.

Section 460.106 Plan of Care—No Change

Subpart G—Participant Rights

Section 460.110 Bill of Rights—No Change

Section 460.112 Specific Rights to Which a Participant Is Entitled

We are amending this requirement by expanding the Participant's rights to include sexual orientation in the list of categories that a PO must not discriminate against.

Also we are revising paragraph (b)(1)(iii) to require the disclosure of all PO services and services delivered by contracted providers at the time a participants needs necessitate the disclosure and delivery of such information to allow the participant to make an informed choice.

Section 460.114 Restraints—No Change

Section 460.116 Explanation of Rights—No Change

Section 460.118 Violation of Rights—No Change

Section 460.120 Grievance Process—No Change

Section 460.122 PACE Organization's Appeals Process

We are amending this requirement to clarify that noncoverage of services including denials, reduction, or termination of services are included as a basis for appeal.

We are also expanding participant protections by changing ''would'' be seriously jeopardized to ''could'' be seriously jeopardized and revising ''regain'' maximum function to ''regain or maintain'' maximum function.

Section 460.124 Additional Appeal Rights Under Medicare or Medicaid—No Change

Subpart H—Quality Assessment and Performance Improvement—No Change

Subpart I—Participant Enrollment and Disenrollment

Section 460.150 Eligibility To Enroll in the PACE Program—No Change

Section 460.152 Enrollment Process

We are expanding participant protection by amending the requirement that POs must explain and provide information related to post-eligibility treatment of income during the intake process.

Section 460.154 Enrollment Agreement

We are clarifying the requirement that a participant may not enroll or disenroll at a Social Security office.

We are also expanding participant protection by amending this requirement allowing the participant or their designated representative to sign and date the reenrollment agreement.

Section 460.156 Other Enrollment Procedure—No Change

Section 460.158 Effective Date of Enrollment—No Change

Section 460.160 Continuation of Enrollment

We are revising paragraph (b)(3)(i) to clarify that the SAA must establish criteria for use in making deemed eligibility determinations.

Section 460.162 Voluntary Disenrollment—No Change

Section 460.164 Involuntary Disenrollment—No Change

Section 460.166 Effective Date of Enrollment—No Change

Section 460.168 Reinstatement in Other Medicare and Medicaid Programs—No Change

Section 460.170 Reinstatement in PACE—No Change

Section 460.172 Documentation of Disenrollment.—No Change

Subpart J—Payment

Section 460.180 Medicare Payments to POs

We are amending this section to reflect the new Medicare risk adjustment payment methodology and are requiring that the PACE program agreement contain the ''methodology'' for establishing the monthly capitation rather than the ''amount'' of the monthly capitation rate.

Section 460.182 Medicaid Payment—No Change

Section 460.184 Post-Eligibility Treatment of Income—No Change

Section 460.186 PACE Premiums—No Change

Subpart K—Federal/State Monitoring

Section 460.190 Monitoring During Trial Period—No Change

Section 460.192 Ongoing Monitoring After Trial Period—No Change

Section 460.194 Corrective Action—No Change

Section 460.196 Disclosure of Review Results—No Change

Subpart L—Data Collection, Record Maintenance, and Reporting

Section 460.200 Maintenance of Records and Reporting Data—No Change

Section 460.202 Participant Health Outcomes Data—No Change

Section 460.204 Financial Recordkeeping and Reporting Requirements—No Change

Section 460.208 Financial Statements—No Change

Section 460.210 Medical Records

We are amending this section by removing the requirement that accident and incident reports be contained in the medical record. The origin of a change in the status of a medical condition is not required in the medical record, but should be available for CMS and the SAA for review.

V. 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Section 460.30 Program Agreement Requirement

Section 460.30(c) states that CMS may only sign program agreements with PACE organizations that are located in States with approved State plan amendments electing PACE as an optional benefit under their Medicaid State plan.

The burden associated with this requirement is the time and effort for a State to develop its State plan amendment to elect PACE as an optional Medicaid benefit. We estimate that 25 States will each take 10 hours to complete this requirement for a total annual burden of 250 hours. We estimate the total burden for these requirements to be 358 hours.

Section 460.68 Program Integrity

Section 460.68(b)(1) requires PACE organizations to develop written policies and procedures for handling direct or indirect conflict of interest by a member of the governing board or an immediate family member.

The burden associated with this requirement is the time and effort for a PACE organization to develop written policies and procedures for handling direct or indirect conflict of interest by a member of the governing board or an immediate family member. We estimate that each organization will spend 1 hour developing and writing these policies and procedures. There will be approximately 54 organizations for a total annual burden of 54 hours.

Section 460.68(b)(2) requires that in the event of a direct or indirect conflict of interest the PACE organization must document the disclosure of the exact nature of the conflict.

We estimate each organization will spend 30 minutes documenting a conflict of interest disclosure. There will be approximately 54 organizations for a total burden of 27 hours.

Note: The following ICRs are subject to the PRA. However, we believe that the burden associated with these ICRs is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

Section 460.52 Transitional Care Following Termination

Section 460.52(b) states that an entity whose PACE program agreement is terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the individual's medical records available to new providers.

Section 460.70 Contracted Services

Section 460.70(a) states that the PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization.

Section 460.70(c) states that a list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.

Section 460.72 Physical Evironnment

Section 460.72(c)(1) states that the PACE organization must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that are likely to threaten the health or safety of the participants, staff or the public.

Section 460.72(c)(4) states that the organization must have a documented plan to obtain emergency medical assistance from sources outside the center when needed.

Section 460.74 Infection Control

Section 460.74(b) states that the PACE organization must establish, implement, and maintain a documented infection control plan.

Section 460.82 Marketing

Section 460.82(a) states that a PACE organization must inform the public about its program and give prospective participants the following written information: An adequate description of the PACE organization's enrollment and disenrollment policies and requirements; PACE enrollment procedures; description of benefits and services; premiums; and other information necessary for prospective participants to make an informed decision about enrollment.

Section 460.82(d) states that marketing materials must inform a potential participant that he or she must receive all needed health care (other than emergency or urgently needed services) from the PACE organization or from an entity authorized by the PACE organization. All marketing materials must state clearly that PACE participants may be fully and personally liable for the costs of unauthorized or out-of-PACE program agreement services.

Section 460.98 Service Delivery

Section 460.98(a) states that a PACE organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year.

Section 460.100 Emergency Care

Section 460.100(a) states that a PACE organization must establish and maintain a written plan to handle emergency care.

Section 460.102 Interdisciplinary Team

In summary, *section 460.102(d)* states that the interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24 hour care delivery. Each team member must regularly inform the interdisciplinary team of the medical, functional, and psychosocial condition of each participant; and document changes in a participant's condition in the participant's medical record consistent with documentation policies established by the medical director.

Section 460.104 Participant Assessment

In summary, *section 460.104(d)* states that the interdisciplinary team must explain why it denies a participant's request for services, inform participants of additional appeal processes available, and document all assessment and reassessment information in the participant's medical record.

Section 460.106 Plan of Care

Section 460.106(f) states that the team must document the plan of care, and any changes made to it, in the participant's medical record.

Section 460.110 Bill of Rights

Section 460.110(a) states that a PACE organization must have a written participant bill of rights designed to protect and promote the rights of each participant.

Section 460.110(b) states that upon enrollment, the organization must inform a participant in writing of her or his rights and responsibilities, and all rules and regulations governing participation.

Section 460.112 Specific Rights to Which a Participant Is Entitled

Section 460.112(b)(1) states that a participant has the right to be fully informed in writing of the services available from the PACE organization.

Section 460.112(b)(2) states that a participant has the right to have the enrollment agreement fully explained in a manner understood by the participant.

Section 460.112(e)(2) states that a participant has the right to have the PACE organization explain advance directives and to establish them, if the participant so desires.

Section 460.112(e)(3) states that a participant has the right to be fully informed of his or her health and functional status by the interdisciplinary team and to participate in the development and implementation of the plan of care.

Section 460.112(e)(6) states that a participant has the right to be given reasonable advance notice, in writing, of any transfer to another treatment setting, and the justification for it, due to medical reasons or for the participant's welfare, or that of other participants. The PACE organization must document the justification in the participant's medical record.

Section 460.116 Explanation of Rights

Section 460.116(a) states that a PACE organization must have written policies and implement procedures to ensure that the participant, his or her representative, if any, and staff understand these rights.

Section 460.116(b) states that upon enrollment, the staff must fully explain the rights to the participant and his or her representative, if any, in a manner understood by the participant.

Section 460.122 PACE Organization's Appeals Process

Section 460.122(d) states that a PACE organization must give all parties involved in the appeal appropriate written notification and a reasonable opportunity to present evidence related to the dispute in person, as well as in writing.

Section 460.152 Enrollment Process

Section 460.152(a)(1) requires that at a minimum, the intake process must include the following steps: the PACE staff must explain to the potential participant and his or her representative or caregiver: the PACE program; the requirement that the PACE organization is the participant's sole service provider; monthly premiums, if any; any Medicaid spend-down obligations, and post-eligibility treatment of income, if any.

Section 460.152(a)(2) states that the potential participant must sign a release to allow the PACE organization to obtain his or her medical and financial information and eligibility status for Medicare and Medicaid.

Section 460.152(b)(1) states that if a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting, the PACE organization must notify the individual in writing of the reason for denial.

Section 460.152(b)(2) states that if a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting, the PACE organization must refer the individual to alternative services, as appropriate.

Section 460.152(b)(3) states that if a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting, the PACE organization must maintain supporting documentation of the reason for the determination.

Section 460.154 Enrollment Agreement

Section 460.154 states that if the potential participant meets the eligibility requirements and wants to enroll, he or she or their representative must sign an enrollment agreement in accordance with the requirements in this section.

Section 460.156 Other Enrollment Procedures

Section 460.156(c) states that if there are changes in the enrollment agreement information at any time during the participant's enrollment, the PACE organization must give an updated copy of the information to the participant; and explain the changes to the participant and his or her representative or caregiver in a manner they understand.

Section 460.168 Reinstatement in Other Medicare and Medicaid Programs

Section 460.168(a) states that in order to facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment, the PACE organization must make appropriate referrals and ensure medical records are made available to new providers in a timely manner.

Section 460.172 Documentation of Disenrollment

Section 460.172(a) states that a PACE organization must have a procedure in place to document the reasons for all voluntary and involuntary disenrollments.

Section 460.200 Maintenance of Records and Reporting of Data

Section 460.200(e) states that a PACE organization must safeguard the confidentiality of any information that identifies a particular participant; establish and implement procedures that govern the use and release of a participant's information before releasing personal information that is not required by law to be released.

Section 460.200(f)(1) states that a PACE organization must retain records for the longest of the following periods: the period of time specified in State law; six years from the last entry date; or for medical records of disenrolled participants, six years after the date of disenrollment.

Section 460.204 Financial Recordkeeping and Reporting Requirements

Section 460.204(b) states that a PACE organization must maintain an accrual accounting recordkeeping system.

Section 460.210 Medical Records

Section 460.210(a) states that a PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards.

Section 460.210(c) states that the PACE organization must promptly transfer copies of medical record information between treatment facilities.

Section 460.210(d) states that all entries must be legible, clear, complete, and appropriately authenticated and dated. Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry.

Note: We believe the following requirements are not subject to the PRA in accordance with CFR 1320.3(c)(4) since they do not require information from ten or more entities on an annual basis.

Section 460.60 PACE Organizational Structure

Section 460.60(d)(3) states that a PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 14 days before the change takes effect.

Section 460.82 Marketing

Section 460.82 states that once a PACE organization is under a PACE program agreement, any revisions to existing marketing information and any new information is subject to CMS' time period for approval. CMS approves or disapproves marketing information within 45 days after receipt from the organization.

Note: In accordance with 5 CFR 1320.4(a)(2), we believe the following ICRs are exempt from the PRA since it is in response to an administrative action, investigation, or audit against specific individuals or entities.

Section 460.68 Program Integrity

Section 460.68(c) states that a PACE organization must have a formal process in place to gather information related to paragraphs (a) and (b) of this section, and must be able to respond in writing to a request for information from CMS within a reasonable amount of time.

Section 460.172 Documentation of Disenrollment

Section 460.172(b) states a PACE organization must make documentation available for review by CMS and the State administering agency.

Section 460.192 Ongoing Monitoring After Trial Period

Section 460.192(a) states that at the conclusion of the trial period, CMS, in cooperation with the State administering agency, will continue to conduct reviews of a PACE organization, as appropriate, taking into account the performance level of the organization with respect to the quality of care provided and the organization's compliance with all requirements of this part.

Section 460.194 Corrective Action

Section 460.194(a) states that a PACE organization must take action to correct deficiencies identified during reviews.

Section 460.200 Maintenance of Records

Section 460.200(f)(2) states that if litigation, a claim, a financial management review, or an audit arising from the operation of the PACE program is started before the expiration of the retention period, specified in paragraph (f)(1) of this section, the PACE organization must retain the records until the completion of the litigation, or resolution of the claims or audit findings.

Section 460.204 Financial Recordkeeping and Reporting Requirements

Section 460.204(d) states that a PACE organization must permit CMS and the State administering agency to audit or inspect any books and records of original entry that pertain to the following: any aspect of services performed; reconciliation of participant's benefit liabilities; or determination of Medicare and Medicaid amounts payable.

Section 460.208 Financial Statements

Section 460.208(c) states that if CMS or the State administering agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, CMS or the State administering agency may require a PACE organization to submit monthly or quarterly financial statements, or both.

Note: There is additional burden associated with Sections 460.12, 460.26, 460.30(a) & (b), 460.70, 460.71, 460.72, 460.82, 460.102, 460.104, 460.116, 460.120(b) & (e), 460.122, 460.124, 460.132, 460.152, 460.156, 460.160, 460.164, 460.190, 460.196, 460.202, 460.208, 460.22, 460.32, 460.52, 460.60(d)(1) & (2), 460.68, 460.80, 460.104, 460.118, 460.120, 460.122, 460.132, 460.200, 460.204; however, that burden is currently approved under OMB # 0938–0790 with an expiration date of 2/28/2009.

In the 2002 IFC, § 460.12 was redesignated as § 460.30(c) and the burden was approved at that time. It continues to be currently approved under OMB#0938–0790 with an expiration date of February 28, 2009.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attn.: Melissa Musotto, CMS–1201–F, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850. Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, CMS–1201–F, *carolyn_lovett@omb.eop.gov.* Fax (202) 395–6974.

VI. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

First, Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

Next, the RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1

year. Individuals and States are not included in the definition of a small entity. Although PACE organizations (POs) are nearly always small entities, the industry is limited in scope with a growth rate of new POs averaging fewer than six per year. Currently, there are 36 POs that have program agreements. In addition, the requirements contained in this rule are largely similar to the requirements that have been applicable to the existing organizations through the 1999 and 2002 interim final rules. Other entities that have contemplated or already have started developing PACE programs have been aware of those requirements and would have designed their potential programs to comply with them. Because the basic effect of this rule is to finalize prevailing industry standards, its impact is not significant.

While we do not have data on which to base an estimate of overall costs or savings to the Medicare and Medicaid programs, we believe that any incremental difference would be so small as to be negligible. PACE services substitute for services that would otherwise be covered, and payment rates are adjusted so that the total payment level is less than the projected payment that would have been made if the participants were not enrolled in PACE. Thus, the overall result should be a slight savings for this small population. PACE services substitute for services that would otherwise be covered, and payment rates are adjusted so that the total payment level is less than the projected payment that would have been made if the participants were not enrolled in PACE. Thus, the overall result should be a slight savings for this small population. Because this rule will not have a significant economic impact on a substantial number of small entities, we are not preparing an analysis for the RFA.

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 and relating to Medicare payment, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. In terms of Medicaid payment, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act, because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Next, 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. Consistent with our approach in the 1999 and 2002 PACE interim final rules, we are not preparing an analysis of section 202. Even as we factor in the growth rate of PACE since the two previous interim final rules, the mandates of this rule do not require spending $100 million or more in any 1 year. This rule will have no consequential effect on State, local, or Tribal governments or on the private sector.

Finally, 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. Under Executive Order 13132, this regulation will not significantly affect the States beyond what is required and provided for under the BBA. It follows the intent and letter of the law and does not usurp State authority beyond what the BBA requires. This regulation describes the processes that must be undertaken by CMS, the States, and POs in order to implement the PACE benefit.

As noted previously, sections 4801 and 4802 of the BBA clearly describe a cooperative relationship between the Secretary and the States in the development, implementation, and administration of the PACE benefit. The following are some examples of areas in which we engaged in partnership with States to establish policy and procedures:

1. Establishing procedures for entering into, extending, and terminating PACE agreements—sections 1894(e)(1)(A) and 1934(e)(1)(A) of the Act.

2. Establishing procedures for excluding service areas already covered under other PACE program agreements in order to avoid unnecessary duplication of services and also to avoid impairing the financial and service viability of the existing program—sections 1894(e)(2)(B) and 1934(e)(2)(B) of the Act.

3. Establishing procedures for the POs to make available PACE program data—sections 1894(e)(3)(A)(i)(III) and 1934(e)(2)(A)(i)(III) of the Act.

4. In conjunction with the PO, developing and implementing health status and quality of life outcome measures—sections 1894(e)(3)(B) and 1934(e)(3)(B) of the Act.

5. The statute requires the Secretary and State to conduct a comprehensive annual review—sections 1894(e)(4)(A) and 1934(e)(4)(A) of the Act.

6. Establishing the frequency of the monitoring reviews—sections 1894(e)(4)(B) and 1934(e)(4)(B) of the Act.

7. Establishing a mechanism for communicating CMS Secretary's findings and State action when a PO is failing to comply with Federal requirements—sections 1894(e)(6)(A) and 1934(e)(6)(A) of the Act.

8. Establishing the entity responsible for the annual eligibility recertification—sections 1894(c)(3) and 1934(c)(3) of the Act; and continuation of eligibility requirements—sections 1894(c)(4) and 1934(c)(4) of the Act.

For this reason, we obtained State input in the early stages of policy development through conference calls with State Medicaid Agency representatives. The 8 agencies that volunteered to participate in these discussions represented a balanced view of States; some with PACE demonstration program experience and some that were not involved with PACE at that time, but were interested in providing input to establish a new long term care optional benefit. The calls were very productive in understanding the variety of State concerns inherent in implementing a new program. In addition, in order to formulate processes to operationalize the PACE benefit, we maintained ties with State representatives through conference calls to obtain information on a variety of topics including the applications review and approval process, data collection needs, and enrollment/disenrollment issues, join CMS/State onsite surveys. We are committed to continuing this dialogue with States after publication of this regulation to ensure this cooperative atmosphere continues as the PACE matures.

Since this regulation finalizes costs associated with PACE and does not impose any new costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

List of Subjects in 42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services confirms as final the interim final rules amending 42 CFR Chapter IV, published on November 24, 1999 (64 FR 66234) and October 1, 2002 (67 FR 61496), as final with the following changes:

PART 460—PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 1. The authority citation for part 460 is revised to read as follows:

Authority: Secs. 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

§§ 460.72, 460.74, 460.98, and 460.102 [Amended]

■ 2. In the following paragraphs in part 460, remove the word ''center'' and add the phrase ''PACE center'' in its place:
■ § 460.72(b)(1) at the end of the first sentence
■ (b)(2)(ii)
■ (b)(4)
■ § 460.74(c)(1)
■ § 460.98(d) heading
■ (d)(3)
■ (e) heading and in the body of the paragraph § 460.102(a)(1)

Subpart A—Basis, Scope, and Definitions

■ 3. Section 460.6 is amended by revising the definition of ''PACE center'' and by adding a definition of ''PACE program'' to read as follows:

§ 460.6 Definitions.

* * * * *

PACE center is a facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.

* * * * *

PACE program means a program of all-inclusive care for the elderly that is operated by an approved PACE organization and that provides comprehensive healthcare services to PACE enrollees in accordance with a PACE program agreement.

* * * * *

§ 460.12 [Amended]

■ 4. Section 460.12 is amended by—
■ A. Redesignating paragraph (a)(3) as paragraph (a)(2).
■ B. In newly redesignated paragraph (a)(2)(i), removing the phrase '', as provided in § 460.14.''
■ C. In newly redesignated paragraph (a)(2)(ii), removing the phrase '', as provided in § 460.16.''

§ 460.14 [Removed and Reserved]

■ 5. Section 460.14 is removed and reserved.

§ 460.16 [Removed and Reserved]

■ 6. Section 460.16 is removed and reserved.

■ 7. Section 460.26 is amended as follows:
■ A. Redesignating paragraph (a) as paragraph (a)(1).
■ B. Adding paragraph (a)(2).
■ C. Revising paragraph (b) introductory text.
■ D. Revising paragraph (b)(1).
The revisions read as follows:

§ 460.26 Submission and evaluation of waiver requests.

(a)(1) A PACE organization must submit its waiver request through the State administering agency for initial review. The State administering agency forwards the waiver requests to CMS along with any concerns or conditions regarding the waiver.

(2) Entities submitting an application to become a PACE organization may submit a waiver request. The entity must submit its waiver request through the State administering agency for initial review. The State administering agency forwards the waiver requests to CMS along with any concerns or conditions regarding the waiver. The waiver request is submitted as a document separate from the application but may be submitted in conjunction with and at the same time as the application.

(b) CMS evaluates a waiver request from a PACE organization or PACE applicant on the basis of the following information:

(1) The adequacy of the description and rationale for the waiver provided by the PACE organization or PACE applicant, including any additional information requested by CMS.

* * * * *

■ 8. Section 460.28 is amended by revising paragraph (a)(2) to read as follows:

§ 460.28 Notice of CMS determination on waiver requests.

(a) * * *

(2) Denies the request and notifies the PACE organization or PACE applicant in writing of the basis of the denial.

* * * * *

■ 9. Section 460.32 is amended by revising paragraph (a)(12) to read as follows:

§ 460.32 Content and terms of PACE program agreement.

(a) * * *

(12) The Medicaid capitation rate and the methodology used to calculate the Medicare capitation rate.

* * * * *

§ 460.60 [Amended]

■ 10. Section 460.60 is amended as follows:
■ A. Paragraph (d)(3) is revised.
■ B. Paragraphs (d)(4) and (d)(5) are removed.
The revisions read as follows:

§ 460.60 PACE organizational structure.

* * * * *

(d) * * *

(3) A PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 14 days before the change takes effect.

■ 11. Section 460.62 is amended by—
■ A. Revising paragraph (b).
■ B. Revising paragraph (c).
The revisions read as follows:

§ 460.62 Governing body.

* * * * *

(b) *Participant advisory committee.* (1) A PACE organization must establish a participant advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee.

(2) The participant advisory committee must provide the liaison to the governing body with meeting minutes that include participant issues.

(c) *Participant representation on the governing body.* (1) A PACE organization must ensure participant representation on issues related to participant care. This shall be achieved by having a participant representative on the governing body.

(2) The participant representative is a liaison of the participant advisory committee to the PACE organization governing body.

(3) *Duty of the participant representative.* The participant representative must present issues from the participant advisory committee to the governing body.

■ 12. Section 460.64 is revised to read as follows:

§ 460.64 Personnel qualifications for staff with direct participant contact.

(a) *General qualification requirements.* Each member of the PACE organization's staff that has direct participant contact, (employee or contractor) must meet the following conditions:

(1) Be legally authorized (for example, currently licensed, registered or certified if applicable) to practice in the State in which he or she performs the function or action;

(2) Only act within the scope of his or her authority to practice;

(3) Have 1 year of experience with a frail or elderly population;

(4) Meet a standardized set of competencies for the specific position description established by the PACE organization and approved by CMS before working independently.

(5) Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.

(b) *Federally-defined qualifications for physician.* In addition to the qualification specified in paragraph (a) of this section, a physician must meet the qualifications and conditions in § 410.20 of this chapter.

■ 13. Section 460.66 is amended by adding paragraph (c) to read as follows:

§ 460.66 Training.

(c) Personal care attendants must exhibit competency before performing personal care services independently.

■ 14. Section 460.68 is amended by–

■ A. Revising paragraph (b).

■ B. Redesignating paragraph (d) as paragraph (c).

■ C. Revising the heading of newly redesignated paragraph (c).

The revisions read as follows:

§ 460.68 Program integrity.

* * * * *

(b) *Direct or indirect interest in contracts.* The PACE organization shall identify members of its governing body or any immediate family member having a direct or indirect interest in any contract that supplies any administrative or care-related service or materials to the PACE organization.

(1) PACE organizations must develop policies and procedures for handling any direct or indirect conflict of interest by a member of the governing body or by the member's immediate family.

(2) In the event of a direct or indirect conflict of interest by a member of the PACE organization's governing body or his or her immediate family member, the board member must—

(i) Fully disclose the exact nature of the conflict to the board of directors and have the disclosure documented; and

(ii) Recuse himself or herself from discussing, negotiating, or voting on any issue or contract that could result in an inappropriate conflict.

(c) *Disclosure and recusal requirements.* * * *

§ 460.70 [Amended]

■ 15. Section 460.70 is amended by—

■ A. Removing paragraph (d).

■ B. Redesignating paragraph (e) as paragraph (d).

■ C. Redesignating paragraph (f) as paragraph (e).

■ 16. Section 460.71 is amended by republishing paragraph (b) introductory text and revising paragraph (b)(4) to read as follows:

§ 460.71 Oversight of direct participant care.

* * * * *

(b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:

* * * * *

(4) Are free of communicable diseases and are up to date with immunizations before performing direct patient care.

* * * * *

§ 460.72 [Amended]

■ 17. Section 460.72 is amended by revising paragraph (a)(3) to read as follows:

§ 460.72 Physical environment.

(a) * * *

(3) Equipment maintenance.

(i) A PACE organization must establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations.

(ii) A PACE organization must perform the manufacturer's recommended maintenance on all equipment as indicated in the organization's written plan.

* * * * *

■ 18. Section 460.78 is amended by revising paragraph (a)(1) introductory text to read as follows:

§ 460.78 Dietary services.

(a) *Meal requirements.* (1) Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PACE organization must ensure, through the assessment and care planning process, that each participant receives nourishing, palatable, well-balanced meals that meet the participant's daily nutritional and special dietary needs. Each meal must meet the following requirements:

* * * * *

Subpart F—PACE Services

■ 19. Section 460.92 is revised to read as follows:

§ 460.92 Required services.

The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(a) All Medicare-covered items and services.

(b) All Medicaid-covered items and services, as specified in the State's approved Medicaid plan.

(c) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

■ 20. Section 460.94 amended by revising paragraph (b)(5) to read as follows:

§ 460.94 Required services for Medicare participants.

* * * * *

(b) * * *

(5) Section 411.15(g) and § 411.15(k) of this chapter that may prevent payment for PACE program services that are provided to PACE participants.

■ 21. Section 460.96 is amended by revising paragraph (e)(1) to read as follows:

§ 460.96 Excluded services.

* * * * *

(e) * * *

(1) In accordance with § 424.122 and § 424.124 of this chapter.

* * * * *

■ 22. Section 460.98 is amended by revising paragraph (b)(3) to read as follows:

§ 460.98 Service delivery.

* * * * *

(b) * * *

(3) The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment.

* * * * *

■ 23. Section 460.100 is amended by:

■ A. Revising paragraph (d).

■ B. Republishing the introductory text to paragraph (e).

■ C. Adding paragraph (e)(3) containing definitions of ''Post stabilization care'' and ''Urgent care.''

The revisions read as follows:

§ 460.100 Emergency care.

* * * * *

(d) *Explanation to participant.* The organization must ensure that the participant or caregiver, or both, understand when and how to get access to emergency services and that no prior authorization is needed.

(e) *On-call providers.* The plan must provide for the following:

* * * * *

(3) *Definitions.* As used in this section, the following definitions apply:

(i) Post stabilization care means services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized. They are not emergency services, which POs are obligated to cover. Rather, they are non-emergency services that the PO should approve before they are provided outside the service area.

(ii) Urgent care means the care provided to a PACE participant who is out of the PACE service area, and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or function is not in severe jeopardy.

■ 24. In § 460.102, paragraph (b)(3) is revised to read as follows:

§ 460.102 Interdisciplinary team.

* * * * *

(b) * * *

(3) Master's-level social worker.

* * * * *

§ 460.104 [Amended]

■ 25. Section 460.104 is amended by—

■ A. Revising paragraph (a)(2).

■ B. Revising paragraph (c)(1)(iii).

■ C. Revising paragraph (c)(2).

■ D. Redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively.

■ E. Redesignating paragraph (c)(3) as new paragraph (d) and revising it.

The revisions read as follows:

§ 460.104 Participant assessment.

(a) * * *

(2) As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team must evaluate the participant in person, at appropriate intervals, and develop a discipline-specific assessment of the participant's health and social status:

(i) Primary care physician.

(ii) Registered nurse.

(iii) Master's-level social worker.

(iv) Physical therapist.

(v) Occupational therapist.

(vi) Recreational therapist or activity coordinator.

(vii) Dietitian.

(viii) Home care coordinator.

* * * * *

(c) * * *

(1) * * *

(iii) Master's-level social worker.

* * * * *

(2) *Annual reassessment.* On at least an annual basis, the following members of the interdisciplinary team must conduct an in-person reassessment:

(i) Physical therapist.

(ii) Occupational therapist.

(iii) Dietitian.

(iv) Home care coordinator.

(d) *Unscheduled reassessments.* In addition to annual and semiannual reassessments, unscheduled reassessments may be required based on the following:

(1) *A change in participant status.* If the health or psychosocial status of a participant changes, the members of the interdisciplinary team, listed in paragraph (a)(2) of this section, must conduct an in-person reassessment.

(2) *At the request of the participant or designated representative.* If a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment.

(i) The PACE organization must have explicit procedures for timely resolution of requests by a participant or his or her designated representative to initiate, eliminate, or continue a particular service.

(ii) Except as provided in paragraph (d)(2)(iii) of this section, the interdisciplinary team must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant's condition requires, but no later than 72 hours after the date the interdisciplinary team receives the request for reassessment.

(iii) The interdisciplinary team may extend the 72-hour timeframe for notifying the participant or designated representative of its decision to approve or deny the request by no more than 5 additional days for either of the following reasons:

(A) The participant or designated representative requests the extension.

(B) The team documents its need for additional information and how the delay is in the interest of the participant.

(iv) The PACE organization must explain any denial of a request to the participant or the participant's designated representative orally and in writing. The PACE organization must provide the specific reasons for the denial in understandable language. The PACE organization is responsible for the following:

(A) Informing the participant or designated representative of his or her right to appeal the decision as specified in § 460.122.

(B) Describing both the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in § 460.122.

(C) Describing the right to, and conditions for, continuation of appealed services through the period of an appeal as specified in § 460.122(e).

(v) If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with § 460.122.

* * * * *

■ 26. Section 460.112 is amended by—

■ A. Revising the introductory text of paragraph (a).

■ B. Revising paragraph (b)(1)(iii).

The revisions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) *Respect and nondiscrimination.* Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

* * * * *

(b) * * *

(1) * * *

(iii) At the time a participant's needs necessitate the disclosure and delivery of such information in order to allow the participant to make an informed choice.

* * * * *

■ 27. Section 460.122 is amended by—

■ A. Revising the introductory text to the section.

■ B. Revising paragraph (f)(1).

The revisions read as follows:

§ 460.122 PACE organization's appeals process.

For purposes of this section, an appeal is a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a

service including denials, reductions, or termination of services.

* * * * *

(f) *Expedited appeals process.* (1) A PACE organization must have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain or maintain maximum function could be seriously jeopardized, absent provision of the service in dispute.

* * * * *

Subpart I—Participant Enrollment and Disenrollment

■ 28. Section 460.152 is amended by adding paragraph (a)(1)(vi) to read as follows:

§ 460.152 Enrollment process.

(a) * * *

(1) * * *

(vi) Post-eligibility treatment of income.

* * * * *

■ 29. Section 460.154 is amended by—

■ A. Revising paragraph (h).

■ B. Revising paragraph (t).

The revisions read as follows:

§ 460.154 Enrollment agreement.

* * * * *

(h) Notification that a Medicare participant may not enroll or disenroll at a Social Security office.

* * * * *

(t) The signature of the applicant or his or her designated representative and the date.

■ 30. Section 460.160 is amended by revising paragraph (b)(3) to read as follows:

§ 460.160 Continuation of enrollment.

* * * * *

(b) * * *

(3) *Continued eligibility criteria.* (i) The State administering agency, must establish criteria to use in making the determination of ''deemed continued eligibility.'' The State administering agency, in consultation with the PACE organization, makes a determination of deemed continued eligibility based on a review of the participant's medical record and plan of care. These criteria must be applied in reviewing the participant's medical record and plan of care.

(ii) The criteria used to make the determination of continued eligibility must be specified in the program agreement.

Subpart J—Payment

■ 31. Section 460.180 is amended by—

■ A. Revising paragraph (a).

■ B. Revising paragraphs (b)(1) through (b)(4).

The revisions read as follows:

§ 460.180 Medicare payment to PACE organizations.

(a) *Principle of payment.* Under a PACE program agreement, CMS makes a prospective monthly payment to the PACE organization of a capitation amount for each Medicare participant in a payment area based on the rate it pays to a Medicare Advantage organization.

(b) *Determination of rate.* (1) The PACE program agreement specifies the methodology used to calculate the monthly capitation amount applicable to a PACE organization.

(2) Except as specified in paragraph (b)(4) of this section, the monthly capitation amount is based on the Part A and Part B payment rates established for purposes of payment to Medicare Advantage organizations. As used in this section, ''Medicare Advantage rates'' means the Part A and Part B rates calculated by CMS for making payment to Medicare Advantage organizations under section 1853(c) of the Act.

(3) CMS will adjust the monthly capitation payment amount derived under paragraph (b)(2) of this section based on a risk adjustment that reflects the individual's health status. CMS will ensure that payments take into account the comparative frailty of PACE enrollees relative to the general Medicare population.

(4) For Medicare participants who require ESRD services, the monthly capitation amount is based on the Medicare Advantage ESRD risk adjustment model.

* * * * *

Subpart L—Data Collection, Record Maintenance, and Reporting

§ 460.210 [Amended]

■ 32. Section 460.210 is amended by removing paragraph (b)(13).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

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

Dated: September 26, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 14, 2006.

Michael O. Leavitt,

Secretary.

[FR Doc. E6–20544 Filed 12–7–06; 8:45 am]

BILLING CODE 4120–01–P

Federal Register

Friday,
December 8, 2006

Part III

Department of Energy

Office of Energy Efficiency and Renewable Energy

10 CFR Parts 430 and 431

Energy Conservation Program: Test Procedures and Technical Amendment to Energy Conservation Standards for Certain Consumer Products and Certain Commercial and Industrial Equipment; Final Rule

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

10 CFR Parts 430 and 431

[Docket No. EE–RM/TP–05–500]

RIN 1904–AB53

Energy Conservation Program: Test Procedures for Certain Consumer Products and Certain Commercial and Industrial Equipment; Technical Amendment to Energy Conservation Standards for Certain Consumer Products and Certain Commercial and Industrial Equipment

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The Energy Policy Act of 2005 (EPACT 2005) includes amendments to the Energy Policy and Conservation Act (EPCA) to provide for new Federal energy efficiency and water conservation test procedures, and related definitions, for certain consumer products and certain commercial and industrial equipment. The amendments direct the Department of Energy (DOE) to establish new test procedures for many of these products and certain equipment, in most cases EPACT 2005 requires the new test procedures to be ''based on'' certain identified testing practices generally accepted by industry and other government agencies. Today, DOE adopts test procedures for eleven types of products for which EPACT 2005 identified specific test procedures on which the federally-mandated test procedures are to be based. In addition, DOE adopts test procedures for three other products for which EPACT 2005 did not specify specific test procedures, and for which test procedures have not previously been established. Furthermore, DOE is adopting a new version of the current test procedure for small commercial package air-conditioning and heating equipment, which will not change the existing requirements.

DOE is also adopting technical corrections to the October 18, 2005, final rule, 70 FR 60407, which DOE described in detail in the July 25, 2006, notice of proposed rulemaking in this proceeding (July 2006 proposed rule), 71 FR 42178, 42195–96. However, DOE is not finalizing the procedures for sampling during compliance testing, and compliance certification and enforcement that were included in the July 2006 proposed rule. Such procedures will be addressed in a subsequent final rule.

DATES: *Effective Date:* This final rule is effective January 8, 2007. The incorporation by reference of certain publications in the final rule is approved by the Director of the Federal Register as of January 8, 2007.

FOR FURTHER INFORMATION CONTACT: James Raba, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–8654. E-mail: *jim.raba@ee.doe.gov.* Francine Pinto, U.S. Department of Energy, Office of the General Counsel, GC–72, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9507. E-mail: *Francine.Pinto@ hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The following standards are incorporated by reference: Environmental Protection Agency (EPA), ''ENERGY STAR Testing Facility Guidance Manual: Building a Testing Facility and Performing the Solid State Test Method for ENERGY STAR Qualified Ceiling Fans,'' Version 1.1, December 9, 2002; U.S. Department of Energy (DOE) ''ENERGY STAR Program Requirements for [Compact Fluorescent Lamps] CFLs,'' Version 3.0; Environmental Protection Agency (EPA), ''ENERGY STAR Program Requirements for Residential Light Fixtures,'' Version 4.0; U.S. Department of Energy (DOE) ''ENERGY STAR Program Requirements for [Compact Fluorescent Lamps] CFLs,'' August 9, 2001; Environmental Protection Agency (EPA), ''ENERGY STAR Program Requirements for Dehumidifiers,'' effective January 1, 2001; Air-Conditioning and Refrigeration Institute (ARI) Standard 810–2003, ''Performance Rating of Automatic Commercial Ice-Makers;'' American National Standards Institute (ANSI)/American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 29–1988 (RA 2005), ''Methods of Testing Automatic Ice Makers;'' American Society for Testing and Materials (ASTM) Standard F2324–03, ''Standard Test Method for Prerinse Spray Valves;'' Environmental Protection Agency (EPA), ''ENERGY STAR Program Requirements for Exit Signs,'' Version 2.0; Environmental Protection Agency (EPA), ''ENERGY STAR Program Requirements for Traffic Signals,'' Version 1.1; Institute for Transportation Engineers (ITE), ''Vehicle Traffic Control Signal Heads: Light Emitting Diode (LED) Circular Signal Supplement,'' June 27, 2005; American National Standards Institute (ANSI)/American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 32.1–2004, ''Methods of Testing for Rating Vending Machines for Bottled, Canned and Other Sealed Beverages;'' American National Standards Institute (ANSI)/Association of Home Appliance Manufacturers (AHAM) HRF–1–2004, ''Energy, Performance and Capacity of Household Refrigerators, Refrigerator-Freezers and Freezers,'' (Revision of ANSI/AHAM HRF–1–2002); Air-Conditioning and Refrigeration Institute (ARI) Standard 340/360–2004, ''Performance Rating of Commercial and Industrial Unitary Air-Conditioning and Heat Pump Equipment;'' Air-Conditioning and Refrigeration Institute (ARI) Standard 1200–2006, ''Performance Rating of Commercial Refrigerated Display Merchandisers and Storage Cabinets;'' American National Standards Institute (ANSI)/Association of Home Appliance Manufacturers (AHAM) HRF–1–2004, (Revision of ANSI/AHAM HRF–1–2002), ''Energy, Performance and Capacity of Household Refrigerators, Refrigerator-Freezers and Freezers;'' Environmental Protection Agency (EPA), ENERGY STAR ''Test Methodology for Determining the Energy Performance of Battery Charging Systems,'' December 2005; and California Energy Commission (CEC) ''Test Method for Calculating the Energy Efficiency of Single-Voltage External Ac-Dc and Ac-Ac Power Supplies,'' August 11, 2004.

I. Background
II. Summary of Today's Action
III. Discussion of Comments and Final Rule—Energy Conservation Test Procedures for Certain Consumer Products and Certain Commercial and Industrial Equipment
A. Ceiling Fans
1. Highly Decorative Ceiling Fans
2. Hugger Ceiling Fans
3. Products Manufactured for Export
4. Burden Imposed by Test Procedure
B. Ceiling Fan Light Kits
1. Ceiling Fan Light Kits with Medium Screw Base Sockets
2. Ceiling Fan Light Kits with Pin-Based Sockets for Fluorescent Lamps
3. Ceiling Fan Light Kits with Sockets Other than Medium Screw Base or Pin-Based
C. Dehumidifiers
D. Medium Base Compact Fluorescent Lamps
E. Torchieres
1. Definition of a Torchiere
2. Design Standard
3. Enforcement of Design Standard
F. Unit Heaters
1. Definitions
2. Automatic Vent Dampers
G. Automatic Commercial Ice Makers
1. Test Procedure

2. Additional Product Classes
H. Commercial Prerinse Spray Valves
1. Performance Test
I. Illuminated Exit Signs
J. Traffic Signal Modules and Pedestrian Modules
1. Definitions of Nominal and Maximum Wattage
2. ITE VTCSH Test Procedure Version
3. Pedestrian Modules
K. Refrigerated Bottled or Canned Beverage Vending Machines
1. ANSI/AHAM HRF–1–2004 Refrigerated Volume Calculation
2. Voltage
L. Commercial Package Air-Conditioning and Heating Equipment
M. Commercial Refrigerators, Freezers, Refrigerator-Freezers and Ice-Cream Freezers
1. Use of ARI Standard 1200–2006 Test Procedure for Equipment for which EPCA Prescribes Standards
2. Use of ARI Standard 1200–2006 Test Procedure for which EPACT 2005 Directs DOE to Develop Test Procedures
3. Ice-Cream Freezer Rating Temperature
4. ANSI/AHAM Standard HRF–1
N. Battery Chargers
1. Scope of Coverage
2. Modes of Test, including Active Mode
3. Definitions
4. Test Method
O. External Power Supplies
1. Scope of Test Procedure
2. Power Factor
3. Test Method
P. General Comments and Final Rule
IV. Corrections to the Recent Technical Amendment to DOE's Energy Conservation Standards
V. Procedural Requirements
A. Review Under Executive Order 12866
B. Review Under the Regulatory Flexibility Act
C. Review Under the Paperwork Reduction Act of 1995
D. Review Under the National Environmental Policy Act of 1969
E. Review Under Executive Order 13132
F. Review Under Executive Order 12988
G. Review Under the Unfunded Mandates Reform Act of 1995
H. Review Under the Treasury and General Government Appropriations Act, 1999
I. Review Under Executive Order 12630
J. Review Under the Treasury and General Government Appropriations Act, 2001
K. Review Under Executive Order 13211
L. Review Under Section 32 of the Federal Energy Administration (FEA) Act of 1974
M. Congressional Notification
VI. Approval of the Office of the Secretary

I. Background

The Energy Policy Act of 2005 (EPACT 2005) (Pub. L. 109–58) was enacted on August 8, 2005. Subtitle C of Title I of EPACT 2005 includes provisions that amend part B of Title III of the Energy Policy and Conservation Act (EPCA) (42 U.S.C. 6291–6309), which provides for an energy conservation program for consumer products other than automobiles, as well as part C of Title III of EPCA (42 U.S.C. 6311–6317), which provides for a program, similar to that in part B, for certain commercial and industrial equipment. EPACT 2005 prescribes new or amended energy conservation standards and test procedures and directs DOE to undertake rulemakings to promulgate such requirements.

On October 18, 2005, DOE issued a final rule that placed into Title 10 of the Code of Federal Regulations (CFR) the energy conservation standards and related definitions that EPACT 2005 prescribed (hereafter referred to as the October 2005 final rule). 70 FR 60407. DOE also announced that it was not exercising the discretionary authority provided in EPACT 2005 for the Secretary of Energy (the Secretary) to revise product or equipment definitions and energy conservation standards set forth in the statute, but that it might exercise this authority later. *Id.*

In the July 2006 proposed rule, DOE proposed test procedures for measuring energy efficiency and water use efficiency and related definitions for various consumer products and commercial and industrial equipment covered by EPACT 2005's amendments to EPCA. Table 1 identifies most [1] of the products and equipment these amendments cover, and shows the ones for which DOE proposed to adopt test procedures, the sections of EPACT 2005 and EPCA that authorize and require these test procedures, and the sections in the CFR where DOE proposed to place them.

TABLE 1.—TEST PROCEDURES AND GENERAL REQUIREMENTS—AUTHORITY AND PLACEMENT

Product or equipment type	EPACT 2005 section	EPCA section	USC section	10 CFR section
Ceiling fans	135(b)(1)	323(b)(16)(A)(i)	42 U.S.C. 6293(b)(16)(A)(i).	430.23(w).
Ceiling fan light kits	135(b)(1)	323(b)(16)(A)(ii)	42 U.S.C. 6293(b)(16)(A)(ii).	430.23(x).
Dehumidifiers	135(b)(1)	323(b)(13)	42 U.S.C. 6293(b)(13)	430.23(z).
Medium base compact fluorescent lamps	135(b)(1)	323(b)(12)	42 U.S.C. 6293(b)(12)	430.23(y).
Battery chargers	135(c)(4)	325(u)	42 U.S.C. 6295(u)	430.23(aa).
External power supplies	135(c)(4)	325(u)	42 U.S.C. 6295(u)	430.23(bb).
Torchieres*	135(c)(4)	325(x)	42 U.S.C. 6295(x)	N/A.
Unit heaters**	135(c)(4)	325(aa)	42 U.S.C 6295(aa)	Part 431, Subpart N.
Automatic commercial ice makers	136(f)(1)	343(a)(7)(A)	42 U.S.C. 6314(a)(7)(A)	Part 431, Subpart H.
Commercial prerinse spray valves	135(b)(1)	323(b)(14))	42 U.S.C. 6293(b)(14)	Part 431, Subpart O.
Illuminated exit signs	135(b)(1)	323(b)(9)	42 U.S.C. 6293(b)(9)	Part 431, Subpart L.
Traffic signal modules and pedestrian modules	135(b)(1)	323(b)(11)	42 U.S.C. 6293(b)(11)	Part 431, Subpart M.
Refrigerated bottled or canned beverage vending machines.	135(b)(1)	323(b)(15)	42 U.S.C. 6293(b)(15)	Part 431, Subpart Q.
Very large commercial package air-conditioning and heating equipment.	136(f)(1)	343(a)(4)	42 U.S.C. 6314(a)(4)	Part 431, Subpart F.
Commercial refrigerators, freezers, and refrigerator-freezers.	136(f)(1)	343(a)(6)	42 U.S.C 6314(a)(6)	Part 431, Subpart C.

[1] EPACT 2005 specified test procedures, standards, and other amendments for a variety of consumer products and commercial equipment. Table 1 includes those products for which EPACT 2005 specified particular test procedures or methods on which the test procedures to be promulgated by DOE were to be based as well as certain products for which EPACT 2005 directed DOE to develop test procedures.

TABLE 1.—TEST PROCEDURES AND GENERAL REQUIREMENTS—AUTHORITY AND PLACEMENT—Continued

Product or equipment type	EPACT 2005 section	EPCA section	USC section	10 CFR section
Ice-cream freezers; commercial refrigerators, freezers, and refrigerator-freezers with a self-contained condensing unit and without doors; and commercial refrigerators, freezers, and refrigerator-freezers with a remote condensing unit.	136(f)(1)(B)	343(a)(6)(A)(i)	42 U.S.C. 6314(a)(6)(A)(i).	Part 431, Subpart C.

* For torchieres, EPACT 2005 establishes a design standard, which does not require a test procedure.
** DOE is adopting definitions and other general provisions for unit heaters.

II. Summary of Today's Action

Today's final rule adopts test procedures for various consumer products and commercial and industrial equipment as required by sections 135 and 136 of EPACT 2005. Sections 135 and 136 of EPACT 2005 amended EPCA to require DOE to promulgate certain test procedures or identified certain test methods on which the DOE test procedures are to be based. These sections direct DOE to establish test procedures based on specifications of the Federal ENERGY STAR program and industry consensus standards that the statute identifies.[2] Each of these ENERGY STAR specifications and industry standards, however, contains not only energy test procedures, but also provisions that are irrelevant in determining the energy use, water use, or efficiency of the products to which they apply. DOE is adopting only those sections of the ENERGY STAR specifications and industry consensus standards that specify test procedures relevant to the measurement of energy efficiency or water consumption. DOE is incorporating these sections by reference into its rules in some cases with clarifying changes or additions that do not alter the substance of the test procedure. DOE is placing the test procedures and related definitions for consumer products in 10 CFR part 430 (''Energy Conservation Program for Consumer Products Other than Automobiles''), and the test procedures and definitions for commercial and industrial equipment in 10 CFR part 431 (''Certain Industrial Equipment'').

In addition, DOE recently incorporated the energy conservation standards prescribed by EPACT 2005 into 10 CFR Parts 430 and 431. 70 FR 60407 (October 18, 2005). In the July 2006 proposed rule, DOE identified several provisions of these technical amendments that do not accurately reflect the provisions of EPACT 2005, and discussed the changes and clarifications needed to correct these inaccuracies. 71 FR 42195–96. The technical amendments as discussed in the July 2006 proposed rule are included in today's final rule. 71 FR 42196–97.

Finally, today's final rule does not include certification, compliance, and enforcement procedures for the consumer products and commercial and industrial equipment covered by this final rule. As discussed in the July 2006 proposed rule, DOE previously proposed certification, compliance, and enforcement provisions for commercial heating, air-conditioning and water heating products in a notice of proposed rulemaking published on December 13, 1999 (hereafter referred to as the ''December 1999 proposed rule''). 64 FR 659598. That rulemaking is still pending, and DOE recently published a supplemental notice of proposed rulemaking that seeks comment on alternatives to certain aspects of those proposals (hereafter referred to as the April 2006 supplemental notice). 71 FR 25103. The certification, compliance, and enforcement procedures in the July 2006 proposed rule for the EPACT 2005 consumer products and commercial and industrial equipment were modeled after the December 1999 proposed rule and existing requirements for consumer products found in 10 CFR Part 430. In the July 2006 proposed rule and in the April 2006 supplemental notice, DOE discussed how it would decide to publish two final rules or a single final rule with the certification, compliance, and enforcement provisions for consumer products and commercial and industrial equipment. 71 FR 42193. DOE has reviewed the comments on the July 2006 proposed rule and April 2006 supplemental notice and has decided the issues are so interrelated that a single final rule is the more appropriate approach. However, due to the issues raised, DOE believes it would be best to issue the final rule for certification, compliance, and enforcement provisions for consumer products and commercial and industrial equipment in a separate **Federal Register** notice. Therefore, today's final rule takes no action on any certification, compliance, and enforcement provisions for consumer products and commercial and industrial equipment, including those provisions that were proposed in the July 2006 proposed rule.

III. Discussion of Comments and Final Rule—Energy Conservation Test Procedures for Certain Consumer Products and Certain Commercial and Industrial Equipment

A. Ceiling Fans

Section 135(c)(4) of EPACT 2005 includes an amendment to section 325 of EPCA (42 U.S.C. 6295) to add subsection (v)(1), which includes requirements to develop a test procedure for ceiling fans. Further, amended section 323(b) of EPCA directs DOE to base this test procedure on the ''ENERGY STAR Testing Facility Guidance Manual: Building a Testing Facility and Performing the Solid State Test Method for ENERGY STAR Qualified Ceiling Fans, Version 1.1'' published by the Environmental Protection Agency (EPA). (42 U.S.C. 6293(b)(16)(A)(i)).

In the July 2006 proposed rule, DOE proposed to adopt this ENERGY STAR test procedure, along with additional requirements on power measurement and sensors and sensor software used for performing the airflow test. 71 FR 42180–42181, 42203, 42204–42205. As discussed in the July 2006 proposed rule, DOE proposed these additional requirements to ensure the validity of the methods used and because the Guidance Manual is too restrictive in their software requirements. 71 FR 42180. DOE did not receive any comments regarding this proposal. DOE is incorporating by reference into Appendix U to Subpart B of 10 CFR Part 430, the applicable ENERGY STAR test

[2] Section 135(b)(1) of EPACT 2005, for example, directs that the test procedure for refrigerated bottled or canned vending machines ''shall be based on American National Standards Institute/American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 32.1–2004, entitled 'Method of Testing for Rating Vending Machines for Bottled, Canned or Other Sealed Beverages'.'' (42 U.S.C. 6293(b)(15))

procedure requirements, with the minor modifications described above, and in the July 2006 proposed rule. DOE has determined the test methods in the ENERGY STAR document, as modified, comply with the requirements of section 325(v)(1) of EPCA (42 U.S.C. 6295(v)(1)) and section 323(b)(3) of EPCA (42 U.S.C. 6293(b)(3)).[3]

However, stakeholders did submit comments on the following four issues: (1) A request that DOE define and exempt from the standards highly decorative ceiling fans; (2) a question with regard to whether hugger-type ceiling fans are covered by the test procedure; (3) a question as to whether ceiling fans built for export are covered by the standard; and (4) a comment on the recordkeeping associated with testing ceiling fans.

1. *Highly Decorative Ceiling Fans.* The American Lighting Association (ALA) and Emerson Electric (Emerson) requested that DOE define and establish highly decorative ceiling fans as an exempted product. (ALA, No. 14 at pp. 5–6, No. 18.8 at p. 67 and No. 97 at pp. 3–4; Emerson, No. 18.8 at pp. 63–64) [4] ALA suggested a definition of highly decorative ceiling fans based on a fan blade length to width ratio of less than 3:1. (ALA, No. 14 at pp. 5–6, and No. 97 at pp. 3–4) ALA also commented that traditional ceiling fans typically have their highest rotational speeds at more than 200 RPM, and for highly decorative fans, the highest speeds are typically less than 175 RPM. (ALA, No. 97 at pp. 3–4) In this comment, ALA recommended addition to the definition that highly decorative ceiling fans have ''a maximum of 175 RPM at high speed down flow.'' (ALA, No. 97 at p. 4) American Council for an Energy-Efficient Economy (ACEEE) submitted a comment stating that it agrees a definition for ''highly decorative fans'' is needed. (ACEEE, No. 59 at p. 2) However, ACEEE expressed concern over the definition provided by ALA. They believe that ALA's proposed definition is too broad and would expand the highly decorative ceiling fan exemption to products that should be covered by the standard. (ACEEE, No. 59 at p. 2)

DOE recognizes that EPCA, as amended by section 135(c)(4) of EPACT 2005, provides that if DOE sets energy conservation standards for ceiling fans, it must consider ''establishing separate or exempted product classes for highly decorative fans for which air movement performance is a secondary design feature.'' (42 U.S.C. 6295(v)(1)) However, today's final rule does not establish standards for ceiling fans beyond the design standards in EPACT 2005. (42 U.S.C. 6295(ff)) Thus, the requirement for DOE to consider whether highly decorative fans should be a separate regulated or exempted product class is not relevant at this time. In the future, should DOE amend the energy conservation standards for ceiling fans, it will address whether to establish a separate or exempted product class for highly decorative ceiling fans.

DOE also notes that the provision in EPCA that establishes ceiling fan design standards (section 325(ff) and codified in 10 CFR 430.32(s)(1) by the October 2005 final rule, 70 FR 60409, 60413) does not contain an exemption for highly decorative fans. Specifically, section 325(ff) of EPCA (42 U.S.C. 6295(ff)) requires all ceiling fans to have speed controls separate from lighting controls, adjustable speed controls, and the capability of reversible fan action for most fans. The only exemptions identified in this section apply to the reversible fan action requirement, and are for ''fans sold for industrial applications, outdoor applications, and cases in which safety standards would be violated by use of the reversible mode.'' Section 325(ff) does not provide for separate treatment or exemption of highly decorative ceiling fans under these design standards. Therefore, the design standards apply to highly decorative ceiling fans, unless an exemption specified in section 325(ff) applies. These standards go into effect for ceiling fans manufactured on or after January 1, 2007.

2. *Hugger Ceiling Fans.* Hunter Fans (Hunter) expressed its view that hugger fans are exempt from DOE's test procedure, (Hunter, No. 18.8 at p. 69), while Pacific Gas and Electric (PG&E) was concerned about such an exemption from DOE's test procedure. (PG&E, No. 18.8 at p. 74) Hugger ceiling fans are typically understood to be ceiling fans that are not suspended from the ceiling; instead, they are set flush to the ceiling. Under section 135(a) of EPACT 2005, EPCA defines ''ceiling fan'' as ''a nonportable device that is suspended from a ceiling for circulating air via the rotation of fan blades.'' (42 U.S.C. 6291(49)) Since the statutory definition defines ceiling fan as ''suspended from a ceiling'' and a hugger fan is not suspended, a hugger fan is not subject to EPCA requirements (including test procedures) applicable to ceiling fans.

3. *Products Manufactured for Export.* Hunter asked whether ceiling fans manufactured for export are subject to EPCA requirements. (Hunter, No. 18.8 at p. 71)

EPCA does not apply to products manufactured, sold, or held for sale for export from the United States and that when distributed, either bear or are in a container that bears, a ''stamp or label stating that such covered product is intended for export.'' (42 U.S.C. 6300) If such a product is in fact distributed in commerce for use in the United States, the product is subject to EPCA. *Id.*

4. *Burden Imposed by Test Procedure.* ALA and Emerson commented on the burden associated with testing and recordkeeping for ceiling fans. (ALA, No. 14 at pp. 6–7 and No. 97 at pp. 4–5; Emerson, No. 18.8 at p. 65) ALA estimates that the costs associated with complying with EPCA for one ALA member is $152,114. (ALA, No. 14 at p. 7) ALA also prepared an estimate of the costs for a ''typical ALA member,'' which totals $142,755. (ALA, No. 97 at p. 5) ALA commented that it is concerned about the burden being imposed on small businesses, and requests that DOE review the impacts. (ALA, No. 14 at p. 7)

DOE notes that the EPACT 2005 design standards, as codified in the October 2005 final rule (70 FR 60413), do not require use of a test procedure for the purpose of demonstrating compliance. These requirements, which include separate controls for fan and lights, adjustable speed controls and the capability of reversible action, are design requirements and do not require a test procedure.

With regard to the test procedure established today, DOE has yet to establish an accompanying standard. Furthermore, EPCA required DOE to establish a test procedure and to base that test procedure on an existing ENERGY STAR test method (version 1.1). (42 U.S.C. 6293(b)(16)(A)(i)) DOE's actions to propose and adopt this test method are directly in response to the statutory requirements. Any additional burdens that may be imposed through the use of this test procedure are in

[3] As outlined and further detailed in the July 2006 proposed rule, test procedures under EPCA for consumer products must be designed to ''measure energy efficiency, energy use, * * * or estimated annual operating cost.'' (42 U.S.C. 6293(b)(3))

[4] A notation in the form ''ALA, No. 14 at pp. 5–6'' identifies a written comment the Department has received and has included in the docket of this rulemaking. This particular notation refers to a comment (1) by the American Lighting Association (ALA), (2) in document number 14 in the docket of this rulemaking (maintained in the Resource Room of the Building Technologies Program), and (3) appearing on pages 5 and 6 of document number 14. Likewise, ''Public Meeting Transcript, No. 18.8 at p. 67,'' for example, would refer to page 67 of the transcript of the ''Public Meeting on Test Procedures and Certification, Compliance, and Enforcement Requirements for Consumer Products and Certain Commercial and Industrial Equipment,'' held in Washington, DC, September 26, 2006, which is document number 18.8 in the docket of this rulemaking.

connection with the statutory requirement. Therefore, DOE does not believe that today's final rule, nor the October 2005 final rule codifying the EPACT 2005 design standards, imposes any testing burden on manufacturers, beyond that resulting from EPCA as established by Congress.

DOE notes that on June 21, 2006, the Federal Trade Commission (FTC) published a notice of proposed rulemaking concerning a labeling requirement for ceiling fans. 71 FR 35584. As proposed, the representation of air flow performance of ceiling fans would require the use of DOE's test procedure finalized today.

B. Ceiling Fan Light Kits

Section 135(c)(4) of EPACT 2005 amended section 325 of EPCA (42 U.S.C. 6295) to add subsection (v)(1), which directs the Secretary to prescribe, by rule, test procedures for ceiling fan light kits. Additionally, section 135(b)(1) of EPACT 2005 amended section 323(b) of EPCA (42 U.S.C. 6293(b)) to add subparagraph (16)(A)(ii), which states that test procedures for ceiling fan light kits ''shall be based on'' the test methods ''referenced in the ENERGY STAR specifications for Residential Light Fixtures and Compact Fluorescent Light Bulbs,'' as in effect on August 8, 2005. In the July 2006 proposed rule, DOE proposed test procedures for three types of ceiling fan light kits: (1) Ceiling fan light kits with medium screw base sockets; (2) ceiling fan light kits with pin-based sockets for fluorescent lamps; and (3) ceiling fan light kits other than those with medium screw base sockets or with pin-based sockets for fluorescent lamps, including candelabra screw base sockets. 71 FR 42180–82, 42205. The classification of ceiling fan light kits in the July 2006 proposed rule is consistent with the classification established in subsection 325(ff) of EPCA. (42 U.S.C. 6295(ff)) Stakeholders provided comment on various aspects of the ceiling fan light kit proposals, which is discussed in the following three sections.

1. *Ceiling Fan Light Kits with Medium Screw Base Sockets.* Section 135(c)(4) of EPACT 2005 amends section 325 of EPCA (42 U.S.C. 6295) to prescribe standards for certain ceiling fan light kits manufactured on or after January 1, 2007. Specifically, new subsection 325(ff)(2) of EPCA (42 U.S.C. 6295(ff)(2)) provides that ceiling fan light kits with medium screw base sockets must be packaged with screw base lamps to fill all of the sockets, and these lamps must either meet the ''ENERGY STAR Program Requirements for Compact Fluorescent Lamps, version 3.0,'' or use light sources other than CFLs that have at least equivalent efficacy. These standards for ceiling fan light kits with medium screw base sockets were adopted by DOE in the October 18, 2005, rulemaking. 70 FR 60413. In accordance with EPACT 2005, DOE proposed to adopt the test methods in version 3.0 of the ENERGY STAR Program Requirements for CFLs in the July 2006 proposed rule. 71 FR 42181. While DOE proposed to adopt the test methods in version 3.0 for ceiling fan light kits with screw base sockets, DOE also sought stakeholder comment on the uniformity of the test procedures for these light kits with medium base compact fluorescent lamps, for which DOE proposed the August 9, 2001 version of the ENERGY STAR test requirements. 71 FR 42202.

Concerning the test method for ceiling fan light kits with medium screw base sockets, the National Electrical Manufacturers Association (NEMA) commented both before and during the public meeting that NEMA recommended DOE adopt its proposed test procedure, the ''ENERGY STAR Program Requirements for [Compact Fluorescent Lamps] CFLs,'' version 3.0. NEMA commented that the ENERGY STAR test procedure version 3.0 is not identical to the August 9, 2001, version, and could yield different results for the same CFL model. (NEMA, No. 9 at p. 1–5; Public Meeting Transcript, No. 18.8 at p. 91) As DOE noted in its July 2006 proposed rule, the August 9, 2001, version of the ENERGY STAR test procedure requires a sample size of five lamps, all tested in the base-up [5] position, while version 3.0 requires a sample of ten lamps, five of which are tested base-up and five of which are tested base-down. 71 FR 42182. In its final comment to DOE following the public meeting, NEMA changed its recommendation, commenting that it now believes DOE should adopt the August 9, 2001 version of ENERGY STAR, as the preponderance of CFL installations in ceiling fan light kits would be base-up to 45 degrees from base-up and virtually no base-down applications. (NEMA, No. 71 at p. 2)

Based, in part, on NEMA's earlier comment, DOE has determined that the August 9, 2001, version of the ENERGY STAR requirements would yield different results than version 3.0, as the test setup for the lamps and sample sizes are different. Moreover, version 3.0 encompasses variability in CFL base orientations, whereas version 2.0 only tests performance in one orientation (base up). Thus, it would be difficult for DOE to conclude that its adoption of the August 9, 2001, version would meet the EPCA requirement that the test procedure for ceiling fans be ''based on'' version 3.0. In addition, DOE is not persuaded that the August 9, 2001, version is the better test method to adopt for lamps packed with ceiling fan light kits with medium screw base sockets. Ceiling fan light kits can have socket configurations that would result in CFLs installed in any range of base orientation configurations, including base-up, base-down, horizontal, and degrees-off-horizontal. Ceiling fan light kits produced today may have a preponderance of base-up to 45 degrees from base-up configurations, but this could change over time, with more horizontal orientations due perhaps to CFL lamp size, which for some CFLs can be longer than incandescent medium screw base lamps. Finally, the referenced industry standards in version 3.0 of the ENERGY STAR specifications are more current than the standards referenced in the August 9, 2001 version. In particular, the industry methods referenced for determining the electrical performance of CFLs are all more current in version 3.0. While the most current version may not always be the most appropriate test standard, in this instance, Congress explicitly cited the latest version. For all these reasons, DOE is adopting version 3.0 of the ENERGY STAR requirements, as it had proposed in the July 2005 notice, rather than the August 9, 2001 version.

2. *Ceiling Fan Light Kits with Pin-Based Sockets for Fluorescent Lamps.* Subsection 325(ff)(3) of EPCA (42 U.S.C. 6295(ff)(3)) requires that ceiling fan light kits that have pin-based sockets for fluorescent lamps manufactured on, or after, January 1, 2007, must be packaged with lamps to fill all of the sockets, and that these lamps must meet the ''ENERGY STAR Program Requirements for Residential Light Fixtures, version 4.0.'' These standards for ceiling fan light kits with pin-based sockets for fluorescent lamps were adopted by DOE in the October 18, 2005 rulemaking. 70 FR 60413.

Concerning the test procedure for ceiling fan light kits with pin-based sockets for fluorescent lamps, DOE proposed to incorporate by reference the test methods in the ''ENERGY STAR Program Requirements for Residential Light Fixtures,'' version 4.0 to measure

[5] The terms ''base-up'' and ''base-down'' used here refer to the physical orientation of the integral CFL during its performance test. ''Base-up'' means that the CFL is tested essentially upside down, with the screw base and the ballast at the top and the fluorescent tube pointed down. ''Base-down'' is the inverse of that orientation, in which the CFL's screw base and ballast are at the bottom, and the fluorescent tube is at the top.

the efficacy of pin-based fluorescent lamps that are packaged with ceiling fan light kits. 71 FR 42181. DOE did not receive any comments on this proposal, and therefore is incorporating the test methods from the ''ENERGY STAR Program Requirements for Residential Light Fixtures,'' version 4.0 in today's final rule.

Philips submitted a comment requiring clarification on the requirement for ceiling fan light kits with pin-based sockets for fluorescent lamps. Philips asked whether an integrally-ballasted CFL with a GU24 pin-base would be subject to the same requirements as a ceiling fan light kit with pin-based socket for fluorescent lamps, if these lamps were packaged with a ceiling fan light kit having GU24 sockets. (Philips, No. 18.8 at p. 93; Philips, No. 19 at p. 1) DOE understands that GU24 is a base type that has large pins that lock into a GU24 socket. The GU24 socket is a line-voltage socket and is capable of accommodating different types of lamps, including incandescent. Since the lamp identified by Philips has pins in its base, and is a fluorescent lamp, Philips sought clarification on whether this lamp would be treated as a pin-based fluorescent lamp, and thus be subject to the requirements of the ''ENERGY STAR Program Requirements for Residential Light Fixtures,'' version 4.0, under the EPCA standards for ceiling fan light kits with pin-based sockets for fluorescent lamps. (42 U.S.C. 6295(ff)(3))

Section 325(ff)(2)–(4) of EPCA classifies ceiling fan light kits by socket type only, not by the lamp-type inserted into those sockets. (42 U.S.C. 6295(ff)(2)–(4)) The socket types fall into three categories: Medium screw base, pin-based for fluorescent lamps, and all other sockets that are not medium screw base or pin-based for fluorescent lamps. *Id.* The socket type classified as pin-based for fluorescent lamps has been uniformly understood to refer to sockets which (1) receive (and operate) fluorescent lamps that lack an integral ballast and (2) transmit voltage, received through a ballast, to such lamps at levels considerably higher than the line voltage. The product Philips identified with GU24-based lamp is a fluorescent lamp that has pins in its base. Due to the fact that this lamp is integrally ballasted, the sockets for this lamp type operate at line voltage and such sockets are not uniquely associated with fluorescent lamps. DOE does not consider them to be ''pin-based sockets for fluorescent lamps.'' (42 U.S.C. 6295(ff)(3)) Rather, DOE considers any ceiling fan light kit with GU24 sockets as the third group of ceiling fan light kits, specifically, those with sockets that are not medium screw base or pin-based for fluorescent lamps. (42 U.S.C. 6295(ff)(4)) Manufacturers could use the GU24 base-type for lamp technologies other than fluorescent technologies. For example, DOE recently learned that a manufacturer is launching a new product that incorporates a ballast and light-emitting diodes (LED) into a reflector lamp that has a GU24 base. While this new LED lamp may indeed be highly efficient and qualify for the standards imposed by EPACT 2005 on pin-based for fluorescent lamps, it clearly is not a fluorescent lamp.

In the July 2006 proposed rule, DOE proposed a definition of pin-based as follows: ''Pin-based means a fluorescent lamp with a plug-in lamp base, including multi-tube, multibend, spiral, and circline types.'' 71 FR 42181, 42203. DOE intended that this definition reflect the well understood meaning of ''pin-based'' as a plug-in base, and not a screw base, for a CFL that was not integrally ballasted. In response to the question from Philips, DOE now recognizes that there could be some ambiguity in this definition, and has therefore inserted the clarifying phrase, ''that is not integrally ballasted,'' to the definition of ''pin-based.'' DOE has also made some clarifying editorial changes to this definition to make clear that it describes the base of a lamp, not the lamp itself, and that it also applies to the sockets that receive pin-based fluorescent lamps. Thus, in today's final rule, the definition, which will appear in 10 CFR 430.2, reads: ''Pin-based means (1) the base of a fluorescent lamp, that is not integrally ballasted and that has a plug-in lamp base, including multi-tube, multibend, spiral, and circline types, or (2) a socket that holds such a lamp.''

3. *Ceiling Fan Light Kits with Sockets Other than Medium Screw Base or Pin-Based.* For this group of products, section 135(c)(4) of EPACT 2005 amends section 325 of EPCA (42 U.S.C. 6295) by adding new subsection (ff)(4), which directs DOE to ''consider and issue requirements'' for any ceiling fan light kits other than those with medium screw base or pin-based sockets, ''including candelabra screw base sockets.'' For these light kits, EPACT 2005 has two default requirements: (1) They shall not be capable of operating with lamps that total more than 190 watts; and (2) they shall include lamps whose total wattage does not exceed 190 watts. (42 U.S.C. 6295(ff)(4)(c)) If the Secretary does not issue a final rule establishing requirements for these ceiling fan light kits by January 1, 2007, the default requirements described above will become law. *Id.* DOE will not be publishing requirements for these light kits by the statutory deadline. Therefore, the statutory requirements, that ceiling fan light kits not be capable of consuming more than 190 watts and that they include such lamps, will become effective for this category of ceiling fan light kits manufactured after January 1, 2009, as specified by EPCA. *Id.*

DOE is not requiring a test procedure for the wattage limitation, but instead is requiring that the total wattage of the lamps packaged with a ceiling fan light kit not exceed 190 watts. A manufacturer would simply ensure that there are sufficient lamps packaged with the ceiling fan light kit to fill any and all sockets in the fixture and the total wattage of those lamps would not exceed 190 watts. In the July 2006 proposed rule, DOE asked for stakeholder comment on whether the ''capable of operating'' requirement should be considered an energy conservation standard (requiring a test procedure) or a design standard (not requiring a test procedure). 71 FR 42181–2. DOE also stated in the July 2006 proposed rule that if DOE considered the 190-watt limitation as a design requirement, manufacturers of these ceiling fan light kits would be required to incorporate some measure such as a fuse, circuit breaker or current-limiting device to ensure the light kit was not capable of operating with a lamp or lamps totaling more than 190 watts. 71 FR 42181.

DOE received comments from several stakeholders as to whether the statutory standard is a design requirement or an energy conservation standard. Hunter and the American Lighting Association (ALA) both commented that DOE should interpret the statutory requirement of ''not [being] capable of operating with lamps [totaling] more than 190 watts'' as a design requirement. (Hunter, No. 3 at p. 1; Hunter, No. 18.8 at pp. 82–83; ALA, No. 97 at p. 5) ALA commented that there are various ways you can control a device to consume not more than 190 watts, including fuses and circuit breakers. These devices have UL and CSA standards already in place for them, which would make it relatively straightforward to meet the 190-watt power limit. (ALA, No. 18.8 at pp. 83–84 and No. 97 at p. 5) ALA provided a detailed cost estimate of the impacts on a typical ALA member should DOE interpret this as an energy conservation standard. (ALA, No. 97 at pp. 6–7) ACEEE commented that it would consider the inclusion of a wattage-limiting device or fuse/circuit breaker as

adequate, provided the device has been tested to show that more than 190 watts cannot be used. (ACEEE, No. 59 at p. 2) Furthermore, ACEEE recommends that the requirements for the 190-watt provision be the same between this category of ceiling fan light kits and torchieres. (ACEEE, No. 59 at p. 2)

DOE considered these comments, and is interpreting the 190-watt limit on power consumption for certain ceiling fan light kits as a design requirement (similar to the features required by section 135(c)(4) of EPACT 2005 for ceiling fans). This approach, consistent with DOE's treatment of a similar provision for torchieres, will require that manufacturers incorporate some measure such as a fuse, circuit breaker or current-limiting device to ensure the light kit is not capable of operating with a lamp or lamps totaling more than 190 watts. Thus, today's final rule does not establish a test procedure, but instead DOE anticipates requiring that manufacturers report to DOE on the feature or features that have been incorporated into the ceiling fan light kit (e.g., circuit breaker, fuse, or other current-limiting device) to ensure they would not draw more than 190 watts of power once certification and enforcement provisions are adopted for these products.

ALA provided six examples of ceiling fans and ceiling fan light kits that it requested DOE's clarification on how the 190-watt limitation should be applied. (ALA, No. 97 at p. 6) These six examples focus on the application of the 190-watt limitation and do not include the mandatory performance requirements for ceiling fan light kits with medium screw base sockets or pin-based sockets for fluorescent lamps. These examples also do not address the mandatory packaging requirements associated with ceiling fan light kits, which are clearly laid out in EPACT 2005. These six examples of ceiling fans and ceiling fan light kits that ALA outlined in their comments and DOE's responses are as follows:

- For ceiling fans with integrated lighting that are incapable of ''attachable'' ceiling fan light kit installation, a 190-watt limiting device will be supplied with the fan to control the integrated lighting.

DOE determined that supplying the 190-watt limiting device with the fan to ensure that the integrated lighting not exceed the 190-watt limitation for ceiling fans with integrated lighting that are incapable of ''attachable'' ceiling fan light kit installation complies with this wattage limitation. This wattage limitation would not apply to ceiling fans with integrated light kits having medium screw base sockets or pin-based sockets for fluorescent lamps.

- For ceiling fans with integrated lighting that are capable of ''attachable'' ceiling fan light kit installation, a 190-watt limiting device will be supplied to control the integrated lighting.

DOE determined that the 190-watt limitation applies to the integrated lighting and/or any other attachable ceiling fan light kit that could be installed on the ceiling fan for ceiling fans with integrated lighting that are capable of ''attachable'' ceiling fan light kit installation. Again, this wattage limitation would not apply to ceiling fans with integrated light kits having medium screw base sockets or pin-based sockets for fluorescent lamps.

- For ceiling fans with pin base fluorescent lamps, a 190-watt limiting device will not be supplied with the fan.

DOE determined that ceiling fans that incorporate an integral light kit with pin-based sockets for fluorescent lamps would not have to include a 190-watt limiting device because the lamps are subject to requirements for ceiling fan light kits with pin-based sockets for fluorescent lamps.

- For ceiling fans without integrated lighting, a 190-watt limiting device will not be supplied with the fan.

DOE determined that the 190-watt limiting device does not need to be supplied with a ceiling fan sold without integrated lighting because there is no light kit packaged with the ceiling fan. However, any ceiling fan light kits sold directly to consumers for installation on a ceiling fan without integrated lighting would be subject to the ceiling fan light kit standards established for medium screw base sockets, pin-based sockets for fluorescent lamps or any other socket type.

- For ''attachable'' ceiling fan light kits with medium screw base sockets or pin-based sockets for fluorescent lamps, a 190-watt limiting device will not be supplied with the light kit. (ENERGY STAR approved medium screw base CFL's and pin-based fluorescent lamps are supplied with the light kit)

DOE determined that a 190-watt limiting device would not be required for ''attachable'' ceiling fan light kits with medium screw base sockets or pin-based sockets for fluorescent lamps because these two types of light kits would be subject to the requirements for ceiling fan light kits with medium screw base sockets and pin-based sockets for fluorescent lamps.

- For ''attachable'' ceiling fan light kits with other than medium base or pin-based sockets for fluorescent lamps, a 190-watt limiting device will be supplied with the light kit.

DOE also determined that ''attachable'' ceiling fan light kits with sockets other than medium screw base or pin-based for fluorescent lamps would be required to be supplied with a 190-watt limiting device. These ''attachable'' ceiling fan light kits are required to meet the mandatory standards, as outlined in EPACT 2005.

Litex Industries submitted a comment recommending that DOE eliminate the requirement to use a circuit breaker or similar limiting mechanisms for these ceiling fan light kits, and instead have a design requirement that manufacturers cannot have more than three candelabra sockets in a ceiling fan light kit. (Litex, No. 103 at pp. 1–2) Litex asserts that it would be impossible for consumers to install wattages in excess of 190 watts, as candelabra lamps are only rated up to 60 watts each. (Litex, No. 103 at p. 2) In addition, Litex recommends that DOE eliminate the need to package candelabra base lamps with the ceiling fan light kit because consumers could obtain the lamps more cheaply from existing suppliers. (Litex, No. 103 at p. 2)

DOE appreciates this comment from Litex, but is not able to accommodate either recommendation. Concerning the design requirement, this category of sockets other than medium screw base and pin base for fluorescent lamps includes ceiling fan light kits with all other socket types, not just candelabra. Thus, EPCA applies to several base types simultaneously, some of which do have lamps rated higher than 60 watts. On the issue of eliminating the requirement to package the ceiling fan light kits with lamps, section 325(ff)(4)(C) of EPCA (42 U.S.C. 6295(ff)(4)(C) states that these ceiling fan light kits manufactured after January 1, 2009, ''(ii) shall include the lamps described in clause (i) in the ceiling fan lighting kits.'' Litex's recommendation is contrary to the requirements of EPCA, and therefore can not be adopted.

Hunter fan asked for clarification as to whether ceiling fan ''up-lighting/accent lighting'' would be included in the 190-watt limitation for these ceiling fan light kits. (Hunter, No. 3 at p. 1) DOE is unclear as to what Hunter means by ''up-lighting'' in the context of ceiling fan light kits. EPCA expressly subjects ceiling fan light kits with sockets other than medium screw base and pin-based

for fluorescent lamps to the wattage limitation requirement. It is conceivable that some ceiling fan light kit designs could provide ''up-lighting'' if the lamps installed in the ceiling fan light kit are directed upward. Thus, these ceiling fan light kits would be subject to the 190-watt limitation. However, DOE does not consider ceiling fan accent lighting that is not a significant light source to be part of the 190-watt limitation.

DOE has made this determination for several reasons. First, pursuant to section 135(a)(3) of EPACT 2005, EPCA defines a ceiling fan light kit, in part, as equipment ''designed to provide light.'' (42 U.S.C. 6291(50)) The purpose of accent lighting is not to provide direct light; instead, it is commonly used for decorative purposes. As such, accent lighting is not covered by EPCA. Second, this application of the standard is clearly consistent with EPCA's treatment of ceiling fan light kits with medium-screw base sockets and those with pin-based sockets for fluorescent lamps. For these two types of ceiling fan light kits, section 325(ff) of EPCA clearly regulates only lamps inserted into screw base or pin-based sockets, and not any accent lights otherwise incorporated into the fan. (42 U.S.C. 6295(ff)(2)–(3)) Third, as with the treatment of torchieres in today's final rule, DOE is concerned with addressing energy consumption by light sources that are aligned with the primary purpose of the ceiling fan light kit. For ceiling fan light kits, the general illumination provided by the light kit is its principal function, and thus should be subject to the 190-watt limitation. Other ancillary lighting, such as accent lighting serves primarily an aesthetic purpose and is therefore not part of the general illumination function of the ceiling fan light kit.

C. Dehumidifiers

Section 135(b)(1) of EPACT 2005 amends section 323(b) of EPCA (42 U.S.C. 6293(b)) to add subsection (b)(13) for dehumidifiers. New subsection 323(b)(13) (42 U.S.C. 6293(b)(13)) directs the Secretary to prescribe test procedures for dehumidifiers based on the test criteria in the ''ENERGY STAR Program Requirements for Dehumidifiers,'' as in effect on August 8, 2005. The July 2006 proposed rule proposed to incorporate by reference into 10 CFR Part 430 the test criteria contained in the ''ENERGY STAR Program Requirements for Dehumidifiers,'' as in effect on August 8, 2005. The ENERGY STAR requirements went into effect on January 1, 2001, and reference the American National Standards Institute (ANSI)/Association of Home Appliance Manufacturers (AHAM) Standard DH–1–2003, ''Dehumidifiers,'' for energy consumption measurements during capacity-rating tests and CAN/CSA Standard C749–1994, ''Performance of Dehumidifiers,'' for energy factor calculations. 71 FR 42182, 42203, and 42206.

DOE received one comment on this issue. AHAM commented that they agreed with the proposal as the test procedure for dehumidifiers. (Public Meeting Transcript, No. 18.8 at p. 23) DOE is incorporating by reference into Appendix X of 10 CFR Part 430, the definitions, tolerances, and testing procedures in the ''ENERGY STAR Program Requirements for Dehumidifiers,'' January 1, 2001 without any modifications. DOE believes this test procedure provides a sound means for determining compliance with the standards in section 325(cc) of EPCA, (42 U.S.C. 6295(cc)), and satisfies the requirements of section 323(b)(3) of EPCA. (42 U.S.C. 6293(b)(3))

D. Medium Base Compact Fluorescent Lamps

Section 135(b)(1) of EPACT 2005 amends section 323(b) of EPCA (42 U.S.C. 6293(b)) to add subsections (b)(12)(A) through (C), for ''medium base'' compact fluorescent lamps (CFLs). (These CFLs are also commonly referred to as ''screw base'' CFLs.) Subsection 323(b)(12)(A) of EPCA requires test procedures for medium base CFLs to be based on the August 9, 2001, version of the ENERGY STAR program requirements for CFLs (version 2.0), which became effective October 1, 2001. (42 U.S.C. 6293(b)(12)(A)) In the July 2006 proposed rule, DOE discussed whether it should adopt the more recent version of the CFL ENERGY STAR program requirements (version 3.0) which became effective January 1, 2004, or the version directed by EPCA, version 2.0. 71 FR 42182. Although DOE proposed to adopt version 2.0, the August 9, 2001 version, in the proposed rule, DOE considered adopting version 3.0 because: (1) It was the current version of the CFL ENERGY STAR test procedure; (2) version 3.0 was required in a different part of the EPACT 2005 that established standards for CFLs packaged with ceiling fan light kits; and (3) DOE believes version 3.0 would result in the same measure of energy efficacy. 71 FR 42205.

DOE received several comments in response to the July 2006 proposal to adopt the August 9, 2001 version of the ''ENERGY STAR Program Requirements for CFLs'' as the test procedure for medium base compact fluorescent lamps. NEMA opposes DOE adopting version 3.0 of the CFL ENERGY STAR program requirements for testing CFLs generally, and recommended that DOE adopt version 2.0, as directed by EPCA. (NEMA, No. 18.8 at pp. 86–91; NEMA No. 9 at pp. 2–6) NEMA provided detailed reasons for its position. NEMA states that these are two separate testing regimens, intended for different products in different applications. The test method itself is different (*e.g.*, version 2.0 tests five lamps base-up while version 3.0 tests ten lamps, five base-up and five base-down), and would therefore yield different lumen per watt and lamp maintenance results. (NEMA, No. 9 at pp. 2–3) NEMA also commented that EPACT 2005 incorporated the August 9, 2001, ENERGY STAR program requirements (version 2.0) to provide a minimum floor for CFLs in the general lighting market, and intentionally adopted the different requirements in version 3.0 for CFLs shipped with ceiling fan light kits. (NEMA No. 9, at pp. 4–5) ALA commented that it agrees with NEMA that the appropriate test procedure for medium base CFLs is version 2.0. (ALA, No. 97 at p. 3) ACEEE disagreed with the viewpoint of NEMA and ALA, commenting that the ENERGY STAR version 3.0 test is more accurate since it includes both base-up and base-down testing. (ACEEE No. 59 at p. 3)

Upon consideration of these comments, DOE agrees that the test method in version 3.0 could result in a different measure of energy efficiency than the method in version 2.0, and DOE recognizes that the standards set by EPACT 2005 for CFLs are based on the August 9, 2001, version of the ENERGY STAR program requirements for CFLs (version 2.0). Therefore, DOE is adopting version 2.0 (August 9, 2001) of the ENERGY STAR program requirements as the test method for CFLs generally. DOE believes this test procedure provides the testing setup and methods for determining compliance with the standards in section 325(cc) of EPCA, as amended (42 U.S.C. 6295(cc)), and it satisfies the requirements of section 323(b)(3) of EPCA. (42 U.S.C. 6293(b)(3))

DOE notes that in section 135(c) of EPACT 2005, which amended section 325 of EPCA to add subsection (bb), the statute established energy conservation standards for medium base CFLs. In that subsection, DOE was directed to adopt the minimum initial efficacy, lumen maintenance, rapid cycle stress test and lamp life requirements prescribed in version 2.0 (August 9, 2001) of the ENERGY STAR program requirement for CFLs. DOE codified these standards in

the October 2005 final rule. 70 FR 60413.

E. Torchieres

Section 135(a) of EPACT 2005 included an amendment to EPCA that defined a ''torchiere'' as ''a portable electric lamp with a reflector bowl that directs light upward to give indirect illumination.'' (42 U.S.C. 6291(42)) DOE codified that definition in the October 2005 final rule. 70 FR 60412. EPACT 2005 also amended section 325 of EPCA to establish an energy conservation standard for torchieres that they (1) consume not more than 190 watts of power and (2) shall not be capable of operating with lamps that total more than 190 watts. (42 U.S.C. 6295(x)) This standard, which took effect for torchieres manufactured on or after January 1, 2006, was also codified in the October 2005 final rule. 70 FR 60413.

In the July 2006 proposed rule, DOE outlined two possible approaches to addressing this energy conservation standard. 71 FR 42183. Since EPACT 2005 neither prescribes nor directs DOE to develop a test procedure for torchieres, DOE's choice of approach will determine whether or not a test procedure is required for torchieres. One approach identified in the July 2006 proposed rule would be for DOE to interpret the statutory requirement of ''not be capable of operating with lamps that total more than 190 watts'' as a design requirement. Under this interpretation, DOE would not require a test procedure. The alternative approach identified in the July 2006 proposed rule would be for DOE to adopt a test procedure that would measure the power consumption of a torchiere. DOE sought stakeholder comment on these two possible approaches to addressing the energy conservation standard. 71 FR 42202.

Three issues were raised by stakeholders in this rulemaking proceeding that pertain to torchieres. First, stakeholders sought clarity on how DOE interprets the definition of a torchiere, as codified at 10 CFR 430.2. Second, stakeholders commented on the two approaches to interpreting EPCA, namely, whether the requirement is a design or energy conservation standard. Associated with this, stakeholders also requested input from DOE on the use of certain types of UL-listed devices (i.e., current-limiting devices) as design options to demonstrate compliance with the standard. And third, stakeholders asked if DOE had any discretion on how and when it might enforce the standard on torchieres, to allow sufficient time for manufacturers to incorporate current-limiting devices into torchiere product lines.

1. *Definition of a Torchiere.* Several stakeholders commented that, for fixtures that provide both indirect lighting through a reflector bowl as well as other lighting, DOE should consider only the reflector bowl portion of the fixture as subject to the 190-watt energy consumption limitation. (ALA, No. 14 at p. 2, No. 18.8 at p. 96, and No. 97 at p. 2; Progress Lighting, No. 96 at p. 1; Holtkotter, No. 92 at p. 1; Pacific Coast Lighting, No. 91 at p. 1; Lite Source, No. 99 at p. 1) In other words, these stakeholders were asserting that any accent lighting, down-lights or other auxiliary energy-using features incorporated into the fixture would not be considered part of the 190-watt energy consumption limitation.

PG&E and ACEEE disagreed with this interpretation. PG&E stated that the 190-watt limitation, which is the California standard for torchieres, applies to any auxiliary lighting features as well the reflector bowl. (PG&E, No. 18.8 at p. 106) ACEEE also disagreed, commenting that a narrower interpretation that excluded task and decorative lighting from the 190-watt limitation would not be appropriate and is beyond DOE's authority. (ACEEE, No. 59 at p. 2)

DOE considered these comments and determined that the EPCA provisions for torchieres mean that the 190-watt limitation applies to the energy consumed to produce light emanating from the reflector bowl, and not to any other direct light or light from other design features. DOE reached this conclusion based on the fact that the EPCA definition for torchiere focuses on its distinctive characteristic of having a reflector bowl directing light upwards. A lighting fixture that includes a torchiere and has one or more task lights that provide direct illumination offers additional consumer utility that is only available in certain consumer product models. Therefore, in today's final rule, DOE interprets the mandatory 190-watt limitation for torchieres as a design standard, which is applicable only to the reflector bowl portion of the torchiere fixture. For those torchieres that do incorporate task lighting or other design features into the torchiere fixture, those task lights or design features are not considered part of the 190-watt limitation.

DOE recognizes that the most common type of torchiere is one that consists solely of a lamp operating in a reflector bowl, directing light upward. Therefore, DOE is interpreting the term ''torchiere'' as including any portable fixture having a reflector bowl that directs light upward, regardless of whether the torchiere may also have any other task lights or other design features incorporated into the fixture.

2. *Design Standard.* ALA commented on the use of certain types of devices (i.e., current-limiting devices) as design options to achieve compliance with the standard. More specifically, ALA asked whether using nominally-rated power and current-limiting devices that are tested and approved by organizations including UL and the CSA is a suitable approach for achieving the 190-watt power limitation. (ALA, No. 14 at p. 2; ALA, No. 18.8 at p. 97) ACEEE commented that it believes a wattage-limiting device would be adequate, provided the device has been tested to show that more than 190 watts cannot be used. (ACEEE, No. 59 at p. 2) DOE indicated in the July 2006 proposed rule that it recognizes manufacturers may choose to follow one of several possible design pathways to comply with the regulations, including, but not limited to, a fuse, circuit breaker or other current-limiting device. 71 FR 42183. Use of a current-limiting device as described by ALA would be one approach to ensuring torchieres do not consume more than 190 watts, and thereby comply with the standard.

DOE notes that EPACT 2005 did not provide explicit authority to DOE for developing a test procedure for torchieres. As noted above, DOE determined to interpret the energy conservation standard for torchieres as a design requirement. In this way, DOE does not require (or adopt) a test procedure in today's final rule, but instead, will require that manufacturers report on the feature or features that have been incorporated into the torchiere (e.g., circuit breaker, fuse, ballast) so they would not draw more than 190 watts of power. These certification requirements as proposed for torchieres in the July 2006 proposed rule will be addressed in a separate final rule as described above in section II. 71 FR 42183. This approach is consistent with the fact that EPCA does not explicitly direct DOE to establish a test procedure.

3. *Enforcement of Design Standard.* ALA, Progress Lighting, Holtkotter, Pacific Coast Lighting, Lite Source, Senator Talent, and Representatives Sessions and Gordon asked whether DOE had any discretion on how and when it might enforce the standard on torchieres, to allow sufficient time for manufacturers to incorporate the current-limiting devices into their product lines. (ALA, No. 14 at p. 4, No. 18.8 at pp. 98–99, and No. 97 at p. 2; Progress Lighting, No. 96 at p. 1; Holtkotter, No. 92 at p. 1; Pacific Coast

Lighting, No. 91 at p. 1; Lite Source, No. 99 at p. 1; Senator Talent, No. 101 at p. 1; Representatives Sessions and Gordon, No. 102 at p. 1) ALA, Progress Lighting, Holtkotter, Pacific Coast Lighting, Senator Talent, and Representatives Sessions and Gordon requested that DOE delay its enforcement of the standard until April 30, 2007. (ALA, No. 14 at p. 4, No. 18.8 at pp. 98–99, and No. 97 at p. 2; Progress Lighting, No. 96 at p. 1; Holtkotter, No. 92 at p. 1; Pacific Coast Lighting, No. 91 at p. 1, Senator Talent, No. 101 at p. 1; Representatives Sessions and Gordon, No. 102 at p. 1) Lite Source requested that DOE delay its enforcement of the standard until July 1, 2007. (Lite Source, No. 99 at p. 1) ACEEE commented that EPCA requires torchiere standards to take effect January 1, 2006, and it does not believe DOE has the authority to delay the effective date to April 2007 as industry requested. (ACEEE, No. 59 at p. 3) DOE notes that EPCA, as amended by section 135(c) of EPACT 2005, specifies that the standard applies to all torchieres manufactured on or after January 1, 2006. (42 U.S.C. 6295(x)) DOE does not have the authority to amend the legislated effective date. All torchieres imported or manufactured after that effective date must be compliant with the national standard, as set by Congress.

F. Unit Heaters

Section 135(c)(4) of EPACT 2005 amends section 325 of EPCA to add subsection (aa) (42 U.S.C. 6295(aa)), which requires that unit heaters manufactured on or after August 8, 2008, be equipped with an intermittent ignition device, and have power venting or an automatic flue damper. DOE incorporated these design standards into 10 CFR 430 in the October 2005 final rule. 70 FR 60407. Since EPACT 2005 promulgated a design standard for unit heaters, DOE is not proposing test procedures for this equipment. Test procedures under EPCA must be designed to measure ''energy efficiency, energy use, * * * or estimated annual operating cost.'' (42 U.S.C. 6314(a)(2))[6] Test procedures are not required for determining compliance with design standards. (42 U.S.C. 6295(s))

In the July 2006 proposed rule, DOE proposed definitions for the terms ''intermittent ignition device,'' ''power venting,'' ''automatic flue damper,'' and ''fan-type heater'' as they relate to unit heaters, since none of these terms are defined in EPCA and DOE believes that the definitions are necessary to clarify the coverage and content of the standards for unit heaters. 71 FR 42184. The term ''fan-type heater'' is part of the EPCA definition of ''unit heater'' (EPACT 2005, section 135(a)(3), and 42 U.S.C. 6291(45)) and the terms ''intermittent ignition device,'' ''power venting,'' and ''automatic flue damper'' are part of the standards established in EPCA (EPACT 2005, section 135(c)(4) and 42 U.S.C. 6295(aa)). DOE based the proposed definitions on those found in industry consensus standards, and modified the definitions to reflect their application to unit heaters. 71 FR 42184.

Today's final rule adopts the proposed definitions with some revisions to provide additional clarity. DOE is also clarifying the regulatory text to indicate that unit heaters with automatic vent dampers comply with the design requirement.

1. *Definitions.* The Gas Appliance Manufacturer Association (GAMA) commented on the proposed definitions for unit heaters, suggesting several modifications to each. (GAMA, No. 7, pg. 1) In particular, GAMA pointed out that the Federal standards for unit heaters are design requirements and stated that it believes Congress's intent when including these standards in EPACT 2005 was to eliminate standing pilots and limit the amount of heat loss during ''off'' cycles. (GAMA, No. 7 at p. 1)

As such, GAMA suggested that the definition for intermittent ignition device be broadened to cover several different types of electronic ignition systems including units that ignite a pilot and those that use a hot surface or a spark to directly ignite the main burner. (GAMA, No. 7 at p. 2) GAMA also stated that the definition of power venting needed to be broadened to provide clarity, and to allow for optional add-on mechanical venting systems that help draw products of combustion from the appliance so as to lower the flue gas temperature, as well as use a non-metallic vent pipe. (GAMA, No. 7 at p. 2) ACEEE commented in support of these suggested modifications to DOE's proposed definitions. (ACEEE, No. 59 at p. 2) DOE agrees with these suggested modifications to its proposed definitions, as well as GAMA's rationale for broadening these definitions to make them applicable to many different configurations of unit heaters, and has incorporated these modifications into today's final rule.

GAMA also asserted that the definition of fan-type heater is not needed to interpret or understand the design standards set forth in EPACT 2005. GAMA stated that this term is not used in any federal requirement except the definition of unit heater and that the proposed definition is incorrect. GAMA states that the July 2006 proposed definition of fan-type heater describes a fan-type heater as providing combustion air, which is not the case for this type of equipment. (GAMA, No. 7 at p. 3) Upon further review, DOE agrees that the proposed definition of fan-type heater is incorrect, and also that a definition of this term is not needed. DOE reached this conclusion because any fan-type heater by nature is designed to move air and that is what the definition of fan-type heater proposed in the July 2006 proposed rule explicitly states. DOE feels that this redundancy is unnecessary; therefore, no such definition is included in today's final rule.

In the July 2006 proposed rule, DOE proposed a definition of automatic flue damper as follows:

> ''Automatic flue damper means a damper, usually electrically operated, which when fitted in the flue of a gas or oil-fired space- or water-heating appliance and connected to the appliance control system opens on firing and shuts after the main burner has been extinguished.''

71 FR 42212–42213. GAMA stated that industry practice distinguishes between flue dampers and vent dampers, and suggested that DOE modify the above definition to clearly recognize this distinction, by adopting the definition of automatic flue dampers from ANSI/the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE)/the Illuminating Engineering Society of North America (IESNA) Standard 90.1, ''Energy Standard for Buildings Except Low-Rise Residential Buildings'' (ANSI/ASHRAE/IESNA Standard 90.1). (GAMA, No. 7 at p. 2) GAMA apparently was concerned that the proposed definition would subsume both flue dampers and vent dampers, and could create confusion because normal industry usage does not include automatic vent dampers within the category of ''automatic flue damper.'' Thus, GAMA suggested incorporating, as part of the definition of automatic flue damper, clarification that the flue damper is located, in relation to the direction of flow of the combustion products, prior to the draft control device. (GAMA, No. 7 at p. 2) Lastly, with regard to unit heaters, GAMA suggested adding a definition of ''automatic vent damper'' to further distinguish between a flue damper and a vent damper, and suggested that for a vent damper, DOE also use the definition contained in ANSI/ASHRAE/

[6] Even though unit heaters are commercial equipment, Congress placed them in the residential section of EPACT 2005.

IESNA Standard 90.1. (GAMA, No. 7 at p. 2) ACEEE also commented in support of these proposals. (ACEEE, No. 59 at p. 2)

In proposing a definition of automatic flue damper, DOE did not explicitly intend to capture automatic vent dampers. DOE recognizes that the proposed definition was broad enough to include a design that has a similar function as automatic flue dampers as defined by industry. However, DOE does not want the definition to conflict with industry-accepted definitions. DOE agrees with GAMA's suggested revisions to the proposed definition of automatic flue damper and with the addition of its suggested definition of automatic vent damper. The revised definition conforms to the scope of equipment DOE intended to include in the proposed July 2006 proposed rule definition of ''automatic flue damper.'' And, addition of the new definition for automatic vent damper will serve two functions. First it will delineate devices excluded from the definition of automatic flue damper. Second, it will provide clarification for manufacturers to distinguish between DOE's treatment of two technologies that perform similar functions, but are placed in different locations within the venting system. These modifications and adoption of these definitions will clarify the coverage and the content of the design standards for unit heaters. Therefore, today's final rule incorporates both the revised definition of automatic flue damper and the new definition of automatic vent damper, incorporating the ASHRAE definitions, into section 431.242 of 10 CFR Part 431.

2. *Automatic Vent Dampers.* As just discussed, DOE's proposed definition of ''automatic flue damper'' was broad enough to include automatic vent dampers. Although DOE did not explicitly address this inclusion in the July 2006 proposed rule that was clearly one possible interpretation of the proposed rule. As proposed, the definition of ''automatic flue damper'' would have permitted the use of automatic vent dampers to comply with the design requirement.

In conjunction with GAMA's comments that DOE modify the definition of automatic flue damper and add the definition of automatic vent damper, GAMA also requested in its written comment and at the public meeting that DOE interpret the EPCA requirements for unit heaters to allow the equipment to use an automatic vent damper instead of, or as an acceptable alternative to, an automatic flue damper for unit heaters that draw combustion air from conditioned space. GAMA asserts that the use of an automatic vent damper on a unit heater meets the intent of the legislation because it saves more energy than a flue damper, by significantly reducing building heat loss through the draft control device and venting system during off cycles. (GAMA, No. 7 at p. 3; Public Meeting Transcript, No. 18.8 at pp. 18 and 54–55) GAMA also explained at the public meeting that ASHRAE is currently considering a proposal that would allow automatic vent dampers as an acceptable alternative to automatic flue dampers. (Public Meeting Transcript, No. 18.8 at pp. 18 and 54) In support of the GAMA proposal, ACEEE commented that ''automatic vent dampers'' should be considered an acceptable alternative to ''automatic flue dampers.'' (ACEEE, No. 59 at p. 2)

Section 135(c)(4) of EPACT 2005 amends section 325 of EPCA to add subsection (aa) (42 U.S.C. 6295(aa)), which requires that unit heaters manufactured on or after August 8, 2008, ''* * * have power venting or an automatic flue damper.'' DOE has determined that an established way for manufacturers to reduce or minimize energy losses through the vent system of certain unit heaters, namely those that draw combustion air from the conditioned space, is to include an automatic vent damper in lieu of an automatic flue damper. In addition, DOE believes the intent of the EPCA requirement that unit heaters have power venting or an automatic flue damper, is to reduce the heat loss through the vent system during ''off'' cycles, as that is the purpose of power venting and of automatic flue dampers. An ''automatic vent damper'' in a unit heater performs this function of reducing energy losses, by restricting the flow of heated air out of the venting system during off cycles, and the automatic vent damper performs this function in a manner superior to the automatic flue damper. (GAMA, No. 7 at p. 2) In consideration of the above, DOE is adopting the term ''automatic vent damper,'' and today's final rule will explicitly permit the use of an automatic vent dampers to comply with the standard for unit heaters that draw combustion air from the conditioned space. These provisions will be placed in sections 431.242 and 431.246 of 10 CFR Part 431.

G. Automatic Commercial Ice Makers

Section 136(f)(1)(B) of EPACT 2005 amends section 343 of EPCA to add subsection (a)(7)(A) (42 U.S.C. 6314(a)(7)(A)), which states that the test procedures for automatic commercial ice makers ''shall be the test procedures specified in the Air-Conditioning and Refrigeration Institute Standard 810–2003, as in effect on January 1, 2005.'' The title of this Standard is ''Performance Rating of Automatic Commercial Ice Makers.''

1. *Test Procedure.* In the July 2006 proposed rule, DOE stated its intention to adopt Air-Conditioning and Refrigeration Institute (ARI) Standard 810–2003 as the test procedure for automatic commercial ice makers of cube-type, which references ASHRAE Standard 29–1988 (RA 2005), with one modification. 71 FR 42184–85. Section 4, ''Test Requirements,'' of ARI Standard 810–2003 references the performance tests in ASHRAE Standard 29, ''Methods of Testing Automatic Ice Makers.'' DOE stated in the July 2006 proposed rule that it believes ARI Standard 810–2003 provided for use of the most current version of ASHRAE Standard 29, which at present is ANSI/ASHRAE Standard 29–1988 (Reaffirmed 2005). 71 FR 42184–42185. DOE also proposed to require explicitly that the energy consumption rate calculated using ANSI/ASHRAE Standard 29–1988 (RA 2005) be determined using the total amount of ice produced during the cycles in which energy consumption is measured in the calculation of the energy consumption rate. 71 FR 42185. The July 2006 proposed rule included the requirement that the energy consumption rate normalized to 100 pounds (100 lbs) of ice be determined as follows:

$$\text{Energy Consumption Rate (per 100 lbs ice)} = \frac{\text{Energy Consumed During Testing (kWh)}}{\text{Mass of Ice Collected During Testing (lbs)}} \times 100\%$$

At the September 2006 public meeting, ARI commented in support of DOE's proposal to adopt ARI Standard 810–2003 as the test procedure for automatic commercial ice makers with the revised energy use rate equation.

ARI further elaborated on the modified energy use rate equation by stating that ARI believes that this method has been used without the clarification. ARI suggested that DOE submit any revisions and clarifications to the ASHRAE Standard 29 committee, which would ensure that ASHRAE Standard 29 be amended to reflect and clarify this energy use rate situation. ARI Standard 810–2003 references ASHRAE Standard 29–1988 (RA 2005) for the methods of tests and energy consumption rate calculations. (Public Meeting Transcript, No. 18.8 at pp. 45–46)

DOE is incorporating by reference the definitions, testing methods, and rating requirements of ARI Standard 810–2003, which references the testing provisions from ASHRAE Standard 29–1988 (RA 2005), and the revised method of calculating the energy consumption rate as proposed in the July 2006 proposed rule. The adopted test procedure provides a method for measuring the energy use and water use at the harvest rate levels specified in section 342(d) of EPCA (42 U.S.C. 6313(d)), and for determining compliance with the standard levels in that section. Furthermore for the reasons stated in the July 2006 proposed rule, 71 FR 42184–85, the adoption of these provisions satisfies both the requirement that the test procedures for automatic commercial ice makers ''shall be'' the test procedures in ARI Standard 810–2003 (42 U.S.C. 6314(a)(7)(A)) and the general requirements for test procedures in 42 U.S.C. 6314(a)(2).

Finally, section 136(h)(3) of EPACT 2005 amends section 345 of EPCA (42 U.S.C. 6316) to add subsection (f)(4) directing the Secretary to ''monitor whether manufacturers are reducing harvest rates below tested values for the purpose of bringing non-complying equipment into compliance,'' and authorizing the Secretary to take steps to minimize manipulation if the Secretary determines ''that there has been a substantial amount of manipulation with respect to harvest rates'' of commercial ice makers. (42 U.S.C. 6316(f)(4)) As stated in the July 2006 proposed rule, DOE will monitor commercial ice maker harvest rates to determine if such manipulation occurs.

2. *Additional Product Classes.* The Howe Corporation (Howe) requested that DOE extend the ice maker standard to cover other types of automatic commercial ice makers beyond those that produce cube-type ice. (Howe, No. 6 at p. 1) Howe stated that a significant disparity has existed in the way manufacturers rate the productive capacities and energy consumption of their equipment for all types of automatic ice makers. Howe also noted that DOE's efforts to regulate automatic commercial ice makers will only apply to cube-type ice makers, which apply only to a portion of all automatic commercial ice makers that are manufactured and sold. (Howe, No. 6 at pp. 3–4) Howe concluded by requesting that DOE test procedures and requirements be amended and expanded to apply a revised ARI Standard 810 to all automatic ice makers regardless of ice-cube type. (Howe, No. 6 at pp. 3–4)

EPCA, as amended by section 136(d) of EPACT 2005, establishes energy and water conservation standards for automatic commercial ice makers that produce cube-type ice. (42 U.S.C. 6313(d)(1)) EPCA does not set energy conservation standards for other types of automatic commercial ice makers, including those that make flake-type ice. The purpose of adopting a test procedure for commercial ice makers in this rulemaking is to adopt methods for testing equipment for which EPACT 2005 set energy conservation standards, and to comply with the requirement that the test procedure for such ice makers be ARI Standard 810–2003, which applies only to the equipment that produces cube-type ice. Therefore, the test methods proposed in the July 2006 proposed rule provides for measuring the condenser water rate, harvest rate, and energy use of automatic commercial cube-type ice makers. 71 FR 42184, 85. DOE's adoption of these provisions satisfies the general requirements for test procedures in 42 U.S.C. 6314(a)(2).

Consideration for expanding the standard for automatic commercial ice makers to include equipment that produces ice other than cube-type ice is outside the scope of this rulemaking proceeding. DOE acknowledged at the public meeting, however, that it is authorized to adopt standards for such other commercial ice makers (42 U.S.C. 6313(d)(2)), and if and when it seeks to adopt such standards, it intends to consider ice makers that produce flake-type ice. (Public Meeting Transcript, No. 18.8 at pp. 46, 48)

H. Commercial Prerinse Spray Valves

Section 135(b)(1) of EPACT 2005 amends section 323(b) of EPCA (42 U.S.C. 6293(b)) to add subsection (14), which states that test procedures for measuring the flow rate for commercial prerinse spray valves ''shall be based on [the] American Society for Testing and Materials [ASTM] Standard F2324, entitled 'Standard Test Method for Pre-Rinse Spray Valves.' '' Section 135(c)(4) amends EPCA to require that commercial prerinse spray valves manufactured on or after January 1, 2006, have a flow rate of 1.6 gallons per minute or less. (42 U.S.C. 6295(dd))

1. *Performance Test.* PG&E commented that DOE should adopt a cleanability test procedure as cleanability is a function of the prerinse spray nozzle. (Public Meeting Transcript, No. 18.8 at pp. 56–57) PG&E further suggested that DOE examine the characteristic of the prerinse spray valve because they do not want to see a problem with people having to use more hot water because of the inadequate capability of the nozzle. Overall, PG&E stated that various experts in the field have generated standards which are available for cleanability and they believe that cleanability does have energy-related consequences for the commercial prerinse spray valve.

While ASTM Standard F2324–03 covers water consumption flow rate and cleanability of prerinse spray valves, EPCA gives DOE the authority for establishing a standard that addresses flow rate only. It does not give DOE the authority to regulate other performance features of commercial prerinse spray valves, such as cleaning performance. Therefore, DOE has not considered adoption of the cleanability provisions of ASTM Standard F2324–03 and is adopting the test procedure as proposed in the July 2006 proposed rule. 71 FR 42185, 42213. ASTM Standard F2324–03 provides a sound basis for determining the flow rate and compliance with the standards for prerinse spray valves, which thereby complies with the requirements of section 343(b)(3) of EPCA. (42 U.S.C. 6314(a)(2))

I. Illuminated Exit Signs

Section 135(b)(1) of EPACT 2005 amends section 323(b) of EPCA (42 U.S.C. 6293(b)) to add subsection (9), which provides that test procedures for illuminated exit signs ''shall be based on the test method contained in version 2.0 of the EPA's 'ENERGY STAR Program Requirements for Exit Signs.' '' Furthermore, section 135(c)(4) of EPACT 2005 added a new subsection (w) to 325 of EPCA, requiring illuminated exit signs manufactured on, or after January 1, 2006, to meet version 2.0's performance requirements. Under version 2.0 such signs must have an input power demand of five watts or less per face. See 70 FR 60417; 10 CFR 431.206. EPA updated the ''ENERGY STAR Program Requirements for Exit Signs'' and published version 3.0, effective August 1, 2004.

Although subsection 323(b)(9) of EPCA (42 U.S.C. 6293(b)(9)), specifically identifies the test method in version 2.0 as the version on which the test

procedure for illuminated exits signs ''shall be based,'' DOE proposed to incorporate by reference, the ''ENERGY STAR Program Requirements for Exit Signs,'' version 3.0, effective August 1, 2004, because: (1) Version 3.0 is the most recent version of the ENERGY STAR test procedure; and (2) DOE believed the test methods in versions 2.0 and 3.0 are the same with regard to energy consumption and would result in the same measure of energy consumption. 71 FR 42186. DOE also proposed to include a requirement in the test procedure that the time duration of the test shall be sufficient to measure power consumption with a tolerance of ±1 percent in order to provide a basis for comparable measurements and to clarify the test procedure. 71 FR 42185, 42211. These requirements were proposed in section 431.204 of 10 CFR Part 430. *Id.*

NEMA, Acuity Lighting Group (Acuity), and Osram Sylvania commented that the two versions of the ENERGY STAR are not the same. They commented that version 2.0 includes safety requirements such as brightness and visibility for illuminated exit signs that are not included in version 3.0. (NEMA, No. 71 at p. 2; Acuity Lighting Group, No. 5 at p. 1; Osram Sylvania, No. 16 at p. 1) NEMA also stated that the safety requirements included in version 2.0 for brightness and visibility are equally important as the input power demand test for energy consumption. (NEMA, No. 71 at p. 2) Furthermore, ACEEE stated that it worked with NEMA on the development of the EPCA provisions for illuminated exit signs and asserted that Congress made a conscious choice to reference version 2.0 of the ENERGY STAR program requirements for illuminated exit signs, even though version 3.0 was available. (ACEEE, No. 59 at p. 3)

Although inclusion of safety requirements in the ''ENERGY STAR Program Requirements for Exit Signs'' is laudable, EPCA provides DOE with the authority to set only energy conservation requirements for illuminated exit signs. As to test procedures in particular, DOE's authority under EPCA is limited to adoption of test methods and related provisions that concern energy consumption. (See 42 U.S.C. 6214) Thus, even though, as discussed below, DOE is adopting version 2.0 of the ''ENERGY STAR Program Requirements for Exit Signs,'' as the DOE test procedure for this equipment under EPCA, DOE will require use only of those elements of version 2.0 that concern testing for energy consumption.

While DOE continues to believe that the two versions of the ENERGY STAR criteria for illuminated exit signs provide the same measure of energy consumption, DOE is adopting the earlier version, the ''ENERGY STAR Program Requirements for Exit Signs,'' version 2.0, since it was explicitly specified in EPACT 2005. DOE recognizes that several states have adopted the safety standards in version 2.0 of the ''ENERGY STAR Program Requirements for Exit Signs.'' DOE believes that the concern for having two different specifications for testing the same product outweigh the consideration for using the most recent version of the specification. In addition, DOE realizes that both version 2.0 and version 3.0 of the ''ENERGY STAR Program Requirements for Exit Signs'' are equally available from the EPA. DOE is adopting version 2.0, which complies with the requirement in EPCA that the test procedures for such signs ''be based on'' that version. (42 U.S.C. 6293(b)(9))

In addition, NEMA also commented that the adoption of version 3.0 would allow the introduction of photo luminescent products, and would lessen the value of life safety requirements, which allow dim, photo luminescent signs to meet the requirements. (NEMA, No. 71 at p. 3) EPCA defines an ''illuminated exit sign'' as a ''sign that * * * is designed to be permanently fixed in place to identify an exit; and * * * consists of an electrically powered integral light source * * *.'' (Section 321(37) of EPCA (42 U.S.C. 6291(37) Photo luminescent light products do not include ''electrically powered integral light sources.''

Photo luminescent products are not covered equipment, and DOE test procedures and energy conservation standards do not apply to or affect these products. DOE's adoption of version 3.0 would not have allowed introduction of these products, and adoption of version 2.0 would not preclude their introduction.

NEMA has also stated that a requirement for time duration for the test is unnecessary because wattage is not dependent upon time, measurements change very little over time, and measurement instruments may not be capable of measuring within a ±1 percent tolerance range. (NEMA, No. 71 at p. 4) Based on these comments, DOE reconsidered its proposed requirement that the time duration of the test be sufficient to measure power consumption with a tolerance of ±1 percent. DOE agrees wattage is not dependent upon time and that measurements using different durations would not lack comparability because the input power is not a function of time. Therefore, DOE is not adopting a time duration requirement in today's final rule.

J. Traffic Signal Modules and Pedestrian Modules

Section 135(b)(1) of EPACT 2005 amends section 323(b) of EPCA (42 U.S.C. 6293(b)) to add subsection (11), which states that test procedures for traffic signal modules and pedestrian modules shall be based on the test method used under the ENERGY STAR program for traffic signal modules, as in effect on August 8, 2005. Section 4 of the ENERGY STAR specification in effect at that time, the ''ENERGY STAR Program Requirements for Traffic Signals,'' version 1.1, prescribes use of the test methods from the Institute for Transportation Engineers (ITE), ''Vehicle Traffic Control Signal Heads (VTCSH),'' Part 2, 1985, section 6.4.2, ''Maintained Minimum Luminous Intensity.'' In addition, pursuant to Section 135(c)(4) of EPACT 2005, new subsection 325(z) of EPCA (42 U.S.C. 6295(z)) requires that traffic signal modules and pedestrian modules manufactured on or after January 1, 2006, meet the performance requirements specified in the ENERGY STAR program requirements for traffic signals, version 1.1, which preclude the maximum wattage and nominal wattage of these modules from exceeding certain specified levels. These requirements were codified in 10 CFR 431.226(a). 70 FR 60417.

1. *Definitions of Nominal and Maximum Wattage.* In the July 2006 proposed rule, DOE proposed to clarify both the standards and test conditions for these products by adopting the following definitions of nominal wattage and maximum wattage into section 431.222:

- Nominal wattage means the power consumed by the module when it is operated within a chamber at a temperature of 25 °C after the signal has been operated for 60 minutes.
- Maximum wattage means the power consumed by the module after being operated for 60 minutes while mounted in a temperature testing chamber so that the lensed portion of the module is outside the chamber, all portions of the module behind the lens are within the chamber at a temperature of 74 °C, and the air temperature in front of the lens is maintained at a minimum of 49 °C.

71 FR 41286, 42212. DOE developed these definitions by drawing on language in the VTCSH test procedure and from consultations with ITE and proposed to place these definitions into § 431.222 of 10 CFR Part 430. *Id.*

ITE commented that it supported the definitions for ''nominal wattage'' and

''maximum wattage'' of the traffic signal or pedestrian module. (Public Meeting Transcript, No. 18.8 at p. 124) GELcore commented that it fully supports DOE's desire to add definitions for wattage as set forth in the July 2006 proposed rule to reflect equal test conditions for either 25 °C or 74 °C of green and red signal modules as well as for pedestrian white/Portland orange signal modules. (GELcore, No. 60 at p. 1) However, GELcore also suggested modifying the proposed definitions under § 431.222 to include a duty cycle, specify a calibrated instrument, and specify ''Design Qualification Testing'' for the set-up of the testing chamber. (GELcore, No. 60 at p. 2)

DOE has determined that the clarifications suggested by GELcore are not necessary to define a traffic signal module or pedestrian module. The three clarifications suggested by GELcore are specifications for testing and are included in and accounted for in the VTCSH 2005 test procedure, which is being adopted in today's final rule. VTCSH 2005 specifies the duty cycle, the testing-chamber set-up, the instrumentation to be used for testing, and further test criterion needed to determine the nominal and maximum wattages. Furthermore, DOE did not receive any comments objecting to the proposed definitions and believes all of the clarifications proposed by GELcore are subsumed in the methods of test in VTCSH 2005. DOE is therefore incorporating the definitions as proposed in the July 2006 proposed rule into § 431.222 of 10 CFR Part 431. 71 FR 41286, 42212.

2. *ITE VTCSH Test Procedure Version.* In the July 2006 proposed rule, DOE proposed to incorporate by reference the test methods for measuring the maximum and nominal wattages as contained in the test specifications in section 4 of the ''ENERGY STAR Program Requirements for Traffic Signals,'' version 1.1, and section 6.4.2 of VTCSH Part 2 (1985). However, in the July 2006 proposed rule, DOE pointed out that ITE recently updated the VTCSH to the June 27, 2005, version, referred to as VTCSH 2005. DOE did not propose to adopt the later VTCSH standard (VTSCH 2005) because (1) it would give stakeholders the perception that DOE extended coverage to products not covered by EPACT 2005; (2) it added a number of testing requirements DOE does not find necessary to meet the requirements of EPACT 2005; and (3) it wasn't clear if the new VTCSH standard would give the same measure of energy consumption as the older version. 71 FR 42186–42187. DOE requested comments on whether DOE should adopt the later VTCSH standard. *Id.*

DOE received numerous comments concerning the proposed test procedure for traffic signal modules and pedestrian modules in the July 2006 proposed rule. Johnson City, Tennessee (Johnson City) stated that the VTCSH Part 2 (1985) is an outdated specification that has been superseded by VTCSH 2005 and should not be adopted; instead, DOE should adopt the later version of the VTCSH test procedure. Johnson City further stated that State and Federal agencies will move away from using the old specification and will begin using the VTCSH 2005 for traffic signal modules and that adopting the outdated specification would cause confusion and could be less comprehensive. Consequently, Johnson City urged the use of the specifications that are currently active, VTCSH 2005, for traffic signal modules and pedestrian modules available from ITE. (Johnson City, No. 2 at p. 1) DOE received similar comments from over 106 States, cities, municipalities and ITE members echoing ITE's comments and position for traffic signal modules and pedestrian modules.

ITE urged DOE to adopt the 2005 version of the VTCSH. ITE stated that the older version of the LED specification is no longer available through ITE and it will no longer publish the older version. (Public Meeting Transcript, No. 18.8 at p. 124) In addition, ITE stated that approximately 80 percent of public agencies use the 2005 LED specification to procure signal systems. (ITE, No. 4 and No. 8 at pp. 1–3) In addition, ITE believes that there exist technical difficulties in the design of LED signal modules that inhibit them from meeting two separate ITE specifications, namely, the 2005 version and the older version. (Public Meeting Transcript, No. 18.8 at p. 125) ITE stated that LED traffic signal modules would have to qualify for overall design and manufacturing to the 2005 specification to meet the need of the purchasing agencies and using an older version of the specification for DOE testing could require design and manufacturing changes. ITE urged DOE to use VTCSH 2005 for testing traffic signal modules to eliminate non-trivial cost increases associated with dual testing to two separate specifications and confusion within the industry. (ITE, No. 4 and No. 8 at pp. 1–3)

NEMA commented in support of the ITE position to use the current 2005 version of the LED circular specification (VTCSH 2005) because using an older version could cause confusion in the industry as agencies are beginning to require compliance with the new ITE specification. NEMA stated that the VTCSH 2005 has different testing requirements than the VTCSH Part 2 (1985) and could conceivably require LED module manufacturers to provide additional testing to meet both the ITE specification (VTCSH 2005) and the ENERGY STAR Version 1.1 requirements (VTCSH 1985). (NEMA, No. 9 at p. 3)

Transportation and Energy Solutions, Inc., commented that the standards are ENERGY STAR specifications for LED traffic signals are obsolete and need to be updated. (Transportation and Energy Solutions, Inc, No. 100 at p. 1) Transportation and Energy Solutions also stated that the VTCSH specifications for traffic signal modules and pedestrian modules, regardless of the version, do not have any specific test methods for measuring wattage.

The Federal Highway Administration (FHWA) commented that test requirements in VTCSH do not have any requirements for measuring wattage. (Public Meeting Transcript, No. 18.8 at pp. 128–129) FHWA commented that the VTCSH test procedure only measures photometric and colormetric output (*i.e.*, photometric and colormetric performance) and that these performance requirements differ in the VTCSH 1985, 1998, and 2005 specifications. However, FHWA stated that if a product that is designed to the VTCSH 2005 performance specifications is tested under the 1998 testing requirements then the energy consumption results would be the same for red and green traffic signal modules and pedestrian modules covered by the EPACT 2005 standards. FHWA also stated that DOE would have to specify the watt meter or the type of tests that DOE requires to be conducted. FHWA suggests that DOE simply specify that during the qualification testing, the manufacturers conduct an RMS wattage measurement or do a measurement of the current consumption and voltage simultaneous to the measurement of the luminescence intensity. FHWA expressed the necessity to add the wattage requirements using the most straightforward methodology and concluded that the current and previous VTCSH specifications yield the same energy consumption results. (Public Meeting Transcript, No. 18.8 at p. 132)

In light of the comments received, DOE has reexamined the ENERGY STAR specifications for traffic signals in effect on August 8, 2005, and the VTCSH 2005 testing procedures it references. As DOE stated in the July 2006 proposed rule, DOE did not propose to adopt VTCSH 2005 because

DOE believed the specification extended coverage to products not covered by EPACT 2005, used a format that is not conducive to incorporation in the DOE test procedure, and added a number of testing requirements DOE does not find necessary to meet the requirements of EPACT 2005. 71 FR 42186–42187. While DOE recognizes that the VTCSH 2005 incorporates specifications for amber-colored modules, DOE points out that the energy conservation standards for nominal and maximum wattage specified by EPACT 2005 and codified in the October 2005 final rule are only applicable to red and green traffic signal modules and pedestrian modules, and thus, only the testing method for red and green traffic signal modules and pedestrian modules is applicable.

DOE recognizes the concerns of ITE, FHWA, and the numerous State and local municipalities about using two different specifications for testing the same product, and believes these concerns for using two different specifications for testing the same product outweigh the considerations for the additional tests included in VTCSH 2005. DOE has determined the testing requirements in VTCSH 2005, while more detailed, are a better reflection of current technologies used by traffic signal modules and pedestrian modules. While DOE stated in the July 2006 proposed rule that VTCSH 2005 added a number of testing requirements, DOE has determined that these provisions are mostly applicable to amber traffic signals and pedestrian modules, which are not covered by EPCA. Therefore, DOE has since determined that the testing requirements in the VTCSH 2005 will produce the same results as the VTCSH (1985) specification when testing red and green traffic signal modules or pedestrian modules and DOE is therefore adopting the 2005 version of the VTCSH standard. In addition, DOE is adding a provision, as suggested by FHWA, to specify the use of a wattmeter when testing a product for energy consumption, as follows:

> Use a wattmeter having an accuracy of ±1% to measure the nominal wattage and maximum wattage of a red or green traffic signal module or pedestrian module when conducting the photometric and colormetric tests as specified by the testing procedures in VTCSH 2005.

The addition of the definitions of ''maximum wattage'' and ''nominal wattage,'' in conjunction with the adoption of the test conditions in VTCSH 2005, and the test method clarification above that is specified in § 431.224(b) provide a sound basis for measuring the maximum and nominal wattages for traffic signal and pedestrian modules. DOE's adoption of these test methods satisfy the requirements of section 323(b)(3) of EPCA (42 U.S.C. 6293(b)(3)). Adoption of these test methods also complies with EPCA's requirement that the test procedures for traffic signal modules and pedestrian modules be based on the ENERGY STAR specification in effect on August 8, 2005. (42 U.S.C. 6293(b)) For these reasons, DOE is incorporating by reference the test methods for measuring the maximum and nominal wattages as contained in the test specifications in section 4 of the ''ENERGY STAR Program Requirements for Traffic Signals,'' version 1.1, and VTCSH 2005.

Finally, DOE also received several inquiries at the public meeting about generically referencing the current version of the ITE specifications, which would result in the test procedure being automatically updated when amended versions of the ITE are released. Section 553 of the Administrative Procedure Act (APA) describes the rulemaking process that an agency must follow in order to adopt a rule. (5 U.S.C. 553) If an agency were to adopt a rule that required compliance with the latest version of an industry standard, the agency rule would be amended without the agency having to follow the notice and comment process set forth by the APA. A rule requiring a manufacturer to test in accordance with the ''latest version'' of an industry test standard would be delegating DOE's rulemaking authority to that entity, which DOE does not have the authority to do. In addition, all incorporations by reference in rules must be approved by the Office of the Federal Register, and the regulations of that Office limit incorporation to the edition of a document that is approved by the Director of the Federal Register (10 CFR 51.1(f)). DOE, therefore, is adopting a specific version of the industry test standard. Future amendments to the industry test standard would have to be considered by DOE in a separate rulemaking. This is the approach DOE has consistently taken when it has incorporated industry or consensus test procedures by reference into its regulations. See 10 CFR 430.22(a)(1).

3. *Pedestrian Modules.* As detailed by the July 2006 proposed rule, EPCA provides that the test procedures for both traffic signal and pedestrian modules must be based on the ENERGY STAR specification for traffic signal modules, (*i.e.*, 6.4.2 of VTCSH Part 2). 71 FR 42186. DOE stated in the proposed rule that VTCSH Part 2 does not mention or, by its terms, apply to pedestrian modules. However, DOE determined upon careful consideration and review of VTCSH Part 2 that its test procedures for determining maximum and nominal wattages of traffic signal modules are equally applicable to testing pedestrian modules. DOE sought stakeholder comment on whether there were any technical reasons for developing testing requirements for maximum and nominal wattage for pedestrian modules that differ from the requirements for traffic signal modules. *Id.*

ITE commented at the public meeting that pedestrian modules are fundamentally different than traffic signal modules. ITE also mentioned that it is about to update the specification for pedestrian LED modules and will have specific test criteria in the specification that are pertinent to pedestrian modules. (Public Meeting Transcript, No. 18.8 at pp. 126–127. ITE submitted written comments urging DOE to use the most current ITE specification because manufacturers and public agencies will be confused if DOE prescribes an outdated version of the specification. (ITE, No. 18, p. 3)

DOE has considered all of the comments received and continues to believe that the test procedures in VTCSH 2005 provide a sound means of testing pedestrian modules as described in the July 2006 proposed rule. 71 FR 42186–87. ITE did not provide any additional data that would lead DOE to alter this conclusion. Further, as stated above, EPCA requires DOE to adopt a test procedure for pedestrian modules that is ''based on'' the ENERGY STAR program's test method for traffic signal modules.

DOE has not had a chance to review ITE's new test procedure for pedestrian modules and is unable to determine if this test procedure is ''based on'' the ''ENERGY STAR Program Requirements for Traffic Signals,'' Version 1.1. When appropriate, DOE prefers to adopt the most up-to-date industry test procedure that is available, but as previously stated, the updated test procedure referenced by ITE has not been published and DOE would be reluctant to adopt a draft that is still under consideration by industry. Furthermore, DOE is unwilling to delay action on adoption of a test procedure, to await ITE's adoption of a new test procedure specification for pedestrian modules, because Federal standards for pedestrian modules are already in place under EPCA (42 U.S.C. 6295(z)) and DOE needs to put a test procedure in place so that manufacturers have a uniform means of testing this equipment. For these reasons, DOE is adopting ''ENERGY STAR Program

Requirements for Traffic Signals,'' version 1.1, and VTCSH 2005, for both traffic signal modules and pedestrian modules.

K. Refrigerated Bottled or Canned Beverage Vending Machines

Section 135(c)(4) of EPACT 2005 amends section 325 of EPCA by adding, in part, new subsection 325(v)(2) (42 U.S.C. 6295(v)(2)), which directs the Secretary to prescribe, by rule, energy conservation standards for refrigerated bottled or canned beverage vending machines. Further, section 135(b)(1) of EPACT 2005 amends section 323(b) of EPCA by adding, in part, new subsection 323(b)(15) (42 U.S.C. 6293(b)(15)), which states that test procedures for this equipment ''shall be based on ANSI/ASHRAE Standard 32.1–2004, entitled ''Methods of Testing for Rating Vending Machines for Bottled, Canned or Other Sealed Beverages.'' Also, pursuant to section 135(b)(2) of EPACT 2005, new subsection 323(f) of EPCA, 42 U.S.C. 6293(f)(1), directs the Secretary to prescribe testing requirements for refrigerated bottled or canned beverage vending machines no later than two years after the enactment of EPACT 2005, that is, August 8, 2007. (42 U.S.C. 6293(f)(1)) This section also directs DOE to base such testing requirements on existing industry test procedures to the maximum extent practicable. (42 U.S.C. 6292(f)(2))

Pursuant to section 325(v)(2) of EPCA (42 U.S.C. 6295(v)(2)), DOE initiated the energy conservation standards rulemaking for refrigerated bottled or canned beverage vending machines on June 28, 2006, by publishing a **Federal Register** notice announcing the availability of the Framework Document, ''Energy Conservation Standards for Refrigerated Bottled or Canned Beverage Vending Machines.'' 71 FR 36715. The Framework Document describes the procedural and analytical approaches DOE anticipates using, and encourages and facilitates stakeholder input during the rulemaking.

DOE examined ANSI/ASHRAE Standard 32.1–2004 and concluded that it provides sound methods for testing the energy efficiency of a refrigerated bottled or canned beverage vending machine, and that it complies with the requirements of section 323(b)(3) of EPCA. (42 U.S.C. 6293(b)(3)) As further explained in the July 2006 proposed rule, DOE understands that the method has been widely used in the industry, which indicates that it is not unduly burdensome to conduct. 71 FR 42187. Therefore, DOE proposed to incorporate this test procedure by reference into 10 CFR Part 431 for the measurement of energy consumption and determination of capacity of this equipment. *Id.*

In the July 2006 proposed rule, DOE also proposed that dual-voltage refrigerated bottled or canned beverage vending machines be tested at the lower nameplate voltage, to characterize the energy consumption. 71 FR 42187; 42214. Testing at the lower voltage is consistent with ASHRAE Standard 32.1–2004. DOE's understanding is that test results for a given piece of dual-voltage equipment would not be affected by the voltage during testing.

1. *ANSI/AHAM HRF–1–2004 Refrigerated Volume Calculation.* ANSI/ASHRAE Standard 32.1–2004 includes a method for determining the capacity of vending machines, referred to in ANSI/ASHRAE Standard 32.1–2004 as ''vendible capacity.'' Vendible capacity consists essentially of the maximum number of units of product a vending machine can hold for sale. DOE updated the proposed test procedures for refrigerated bottled or canned beverage vending machines on October 3, 2006 by publishing a Supplemental Notice of Proposed Rulemaking (SNOPR), 71 FR 58308, and discussing the proposals at the September 26, 2006 public meeting. (Public Meeting Transcript, No. 18.8 at pp. 175–176) DOE proposed to add to its test procedure an additional, alternative means for measuring the capacity of refrigerated bottled or canned beverage vending machines, namely the method to measure ''refrigerated volume'' that is set forth in ANSI/AHAM HRF–1–2004, ''Energy, Performance and Capacity of Household Refrigerators, Refrigerator-Freezers and Freezers.''

DOE stated that refrigerated volume may be a better alternative to vendible capacity because, among machines that are designed and intended for vending 12-ounce cans, there are a variety of dispensing mechanisms and storage arrangements that lead to potentially different refrigerated volumes for different machines with the same vendible capacity. In addition, EPCA has historically used upper limits on energy consumption as a function of volume for the purposes of establishing energy conservation standards for refrigeration equipment. 71 FR 58310.

Royal Vendors commented that it agrees with DOE's proposal to use ASHRAE Standard 32.1–2004 as the test procedure for refrigerated bottled or canned beverage vending machines. (Public Meeting Transcript, No. 18.8 at p. 49) Royal Vendors further commented in support of using refrigerated volume for measuring the capacity of refrigerated bottled or canned beverage vending machines. (Public Meeting Transcript, No. 18.8 at p. 50) There were no negative comments regarding either DOE's proposal to adopt ASHRAE Standard 32.1–2004 or to add refrigerated volume to its test procedure as an additional metric for measuring capacity.

DOE is adopting the updated test procedure, ANSI/ASHRAE Standard 32.1–2004, for measuring equipment energy consumption and for determining the ''vendible capacity'' of refrigerated bottled or canned beverage vending machines, as well as the method in ANSI/AHAM HRF–1–2004 for measuring the ''refrigerated volume'' of such machines. As to the latter, DOE is incorporating by reference in section 431.294 of Subpart Q to 10 CFR Part 431, section 5.2 of ANSI/AHAM HRF–1–2004, excluding subsections 5.2.2.2 through 5.2.2.4, which are not relevant to measuring refrigerated volume for refrigerated bottled or canned beverage vending machines.

In the SNOPR, DOE recognized that sections 4.2 and 5.2 of ANSI/AHAM HRF–1–2004 address the measurement of refrigerated volume in household refrigerators and freezers, respectively, and do not directly address refrigerated bottled or canned beverage vending machines for which no commercial standards exist. Nevertheless, DOE has determined that the methodology described in section 5.2 includes methods for the measurement of refrigerated volumes that are applicable to refrigerated bottled or canned beverage vending machines, namely the gross interior volume contained within the refrigerated space. Although EPCA defines such equipment as a type of commercial refrigerator, the language in section 5.2 for household freezers is more appropriate than the language in section 4.2 for household refrigerators. The methodology in section 5.2 is more relevant to the type of compartment(s) being measured in a refrigerated bottled or canned beverage vending machine. For example, section 5.2 includes the measurement of special features of a freezer such as can or package racks and dividers or dispensers, which are also found in refrigerated bottled or canned beverage vending machines.

2. *Voltage.* No comments were received regarding DOE's proposal to test dual-voltage equipment at the lower voltage. DOE is adopting ANSI/ASHRAE Standard 32.1–2004 with a modification in Section 6.2, ''Voltage and Frequency,'' to test equipment with dual nameplate voltages at the lower of the two voltages only, as proposed into § 431.294 of 10 CFR Part 431. 71 FR 42214.

L. Commercial Package Air-Conditioning and Heating Equipment

Section 136(f)(1)(A) of EPACT 2005 amends section 343(a)(4)(A) and (B) of EPCA (42 U.S.C. 6314(a)(4)(A) and (B)) to require test procedures for air-cooled package air-conditioning and heating equipment rated at or above 240,000 and below 760,000 British thermal units per hour (Btu/h) cooling capacity (defined as ''very large'' equipment under section 136(a)(3) of EPACT 2005, 42 U.S.C. 6311(8)(D)). This provision provides that the test procedure for such equipment shall be the ''generally accepted industry testing procedures or rating procedures developed or recognized by the Air-Conditioning and Refrigeration Institute or by the American Society of Heating, Refrigerating and Air-Conditioning Engineers, as referenced in ASHRAE/IES Standard 90.1 and in effect on June 30, 1992.'' (42 U.S.C. 6314(a)(4)(A)) The provisions also provides that DOE must adopt any amendment to such test procedure, unless it determines that the amended test procedure would fail to meet EPCA's general requirements for test procedures for commercial equipment. (42 U.S.C. 6314(a)(4)(B))

As explained in the July 2006 proposed rule, the test procedures in effect on June 30, 1992, for very large commercial package air-conditioning and heating equipment were ARI Standard 340–1986, ''Commercial and Industrial Unitary Heat Pump Equipment,'' and ARI Standard 360–1986, ''Commercial and Industrial Unitary Air-Conditioning Equipment.'' 71 FR 42187. In 2000, ARI replaced these standards with ARI Standard 340/360–2000, ''Commercial and Industrial Unitary Air-Conditioning and Heat Pump Equipment,'' but this new version did not alter the efficiency test methods or the calculation procedures that were in ARI Standards 340 and 360 as in effect on June 30, 1992, nor the measured efficiencies for the equipment being tested. *Id.* Subsequently, in an October 21, 2004, direct final rule, ''Test Procedures and Efficiency Standards for Commercial Air Conditioners and Heat Pumps,'' DOE adopted test procedures for small commercial package air-conditioning and heating equipment (cooling capacities less than 135,000 Btu/h), and for large commercial package air-conditioning and heating equipment (cooling capacities at or above 135,000 Btu/h and less than 240,000 Btu/h) into section 431.96 of 10 CFR Part 431. 69 FR 61962. Under that rule, DOE adopted ARI Standard 340/360–2000, the most recent ARI test procedure at the time, for commercial package air-conditioning and heating equipment with cooling capacities at or above 135,000 Btu/h and less than 240,000 Btu/h. 69 FR 61971; 10 CFR 431.96. For equipment with cooling capacities at or above 65,000 Btu/h and less than 135,000 Btu/h, other than water-source equipment, DOE adopted ARI Standard 340/360–2000 with four modifications (taken from ARI Standard 210/240–2003) as the applicable test procedure. 69 FR 61971–72; 10 CFR 431.96. These four modifications as shown in Table 2 of section 431.96 of 10 CFR Part 431, were necessary to ensure the proper testing of certain types, or configurations, of equipment. 69 FR 61965–66.

ARI has since published ARI Standard 340/360–2004, which revised ARI Standard 340/360–2000, by adding the four modifications DOE had adopted in the October 2004 direct final rule for equipment with cooling capacities at or above 65,000 Btu/h and less than 135,000 Btu/h. As DOE pointed out in the July 2006 proposed rule, ARI Standard 340/360–2004, ''Performance Rating of Commercial and Industrial Unitary Air-Conditioning and Heat Pump Equipment,'' is now the most current industry test procedure for all types of this equipment, including very large commercial package air-conditioning and heating equipment. 71 FR 42187–88.

In response to the publication of the July 2006 proposed rule, ARI commented in support of DOE's proposal to adopt ARI Standard 340/360–2004, for commercial package unitary air conditioners and heat pumps of all three size categories. (Public Meeting Transcript, No. 18.8 at p. 52)

For the reasons stated in the July 2006 proposed rule, 71 FR 42188, in accordance with 42 U.S.C. 6314(a)(4)(B), DOE is incorporating ARI Standard 340/360–2004 by reference into 10 CFR Part 431 as the test procedure for very large air-cooled commercial package air-conditioning and heating equipment. In addition, DOE is also replacing the references to ARI Standard 340/360–2000, as well as the modifications to the standard, with references to ARI Standard 340/360–2004 in the test procedures in § 431.96 of 10 CFR Part 431 for all small and large commercial package air-conditioning and heating equipment (cooling capacities equal to, and greater than, 65,000 Btu/h, but less than 240,000 Btu/h), except for water-source heat pumps with cooling capacities of less than 135,000 Btu/h. For the latter, the applicable test procedure is ISO Standard 13256–1 1998. As indicated above, ARI Standard 340/360–2004 changes the previous version of ARI Standard 340/360 only by incorporating the four provisions in Table 2 of § 431.96 of 10 CFR Part 431, which were already a part of DOE's current test procedures. Thus, incorporation of ARI Standard 340/360–2004 will not alter DOE's test procedure for small and large equipment as explained in the July 2006 proposed rule. 71 FR 42187.

M. Commercial Refrigerators, Freezers, Refrigerator-Freezers, and Ice-Cream Freezers

1. *Use of ARI Standard 1200–2006 Test Procedure for Equipment for Which EPCA Prescribes Standards.* Section 136(f)(1)(B) of EPACT 2005 amends section 343 of EPCA by adding subsection (a)(6)(A)(i), (42 U.S.C. 6314(a)(6)(A)(i)), which prescribes test procedures for commercial refrigerators, freezers, and refrigerator-freezers, generally. New subsection 343(a)(6)(A)(ii) requires that ASHRAE Standard 117, as in effect on January 1, 2005, shall be the initial test procedure for the types of equipment to which standards are applicable under section 342(c)(2)–(3) of EPCA, (Section 136(c) of EPACT 2005: 42 U.S.C. 6313(c)(2)–(3)) including: (1) Commercial refrigerators, freezers, and refrigerator-freezers with a self-contained condensing unit and designed for holding temperature applications; and (2) commercial refrigerators with a self-contained condensing unit, designed for pull-down temperature applications, and with transparent doors. (42 U.S.C. 6314(a)(6)(A)(ii)) Also new subsection 343(a)(6)(E) provides that, if ASHRAE Standard 117 is amended, the Secretary must address whether to amend the test procedures for this equipment. (42 U.S.C. 6314(a)(6)(E)) ASHRAE Standard 117–2002, ''Method of Testing Closed Refrigerators,'' was in effect on January 1, 2005.

ASHRAE Standard 117–2002 was the initial test procedure mandated by subsection 343(a)(6)(A)(ii) of EPCA, (42 U.S.C. 6314(a)(6)(A)(ii)), that is, it was the standard in effect on January 1, 2005. Subsequently, ASHRAE amended this test procedure and adopted ASHRAE Standard 72–2005, ''Method of Testing Commercial Refrigerators and Freezers,'' which was approved by ANSI on July 29, 2005. Consistent with the statutory mandate, DOE reviewed ASHRAE Standard 72–2005 in the July 2006 proposed rule, pursuant to subsection 343(a)(6)(E), (42 U.S.C. 6314(a)(6)(E)). ASHRAE Standard 72–2005 clarifies or modifies certain door opening requirements, definitions, and the reporting of results, as well as provides improved precision by

delineating the exact specifications for testing conditions. 71 FR 42188. Based on the review, DOE determined in the July 2006 proposed rule that no basis exists for concluding that the latest ASHRAE Standard 72–2005 fails to meet the general requirements for test procedures in 42 U.S.C. 6314(a)(2) and (3). *Id.*

During the September 26, 2006, public meeting, ARI (Public Meeting Transcript, No. 18.8 at p. 39) and Hill Phoenix (Public Meeting Transcript, No. 18.8 at p. 42) stated that EPACT 2005 includes language that directs DOE to review rating procedures approved by ANSI, that ARI Standard 1200–2006 was approved by ANSI as of August 28, 2006 (Section 136(c) of EPACT 2005: 42 U.S.C. 6314(a)(6)(A)(i)(II)), and that ARI Standard 1200–2006 includes the test procedures in ASHRAE Standard 72–2005 as well as the rating temperatures prescribed in the EPACT 2005 amendments to EPCA. (Public Meeting Transcript, No. 18.8 at p. 39) ARI and Hill Phoenix urged DOE to consider adoption of ARI 1200–2006 in lieu of ASHRAE Standard 72–2005. *Id.*

DOE has reviewed ARI Standard 1200–2006 and has found that it specifically references ASHRAE Standard 72–2005 as the method of testing commercial refrigeration equipment and would therefore give identical test results for the measurement of energy consumption. As stated above, DOE determined that ASHRAE Standard 72–2005 meets EPCA requirements for the DOE test procedure for the equipment covered by the standards under section 342(c)(2)–(3) of EPCA. Thus, ARI Standard 1200–2006 also meets these requirements. Additionally, ARI Standard 1200–2006 is ANSI approved and includes the applicable rating temperatures for this equipment prescribed under subsection 343(a)(6)(B) of EPCA (42 U.S.C. 6314(a)(6)(B)). DOE is therefore adopting in this final rule ARI Standard 1200–2006 as the test procedure for equipment to which standards are applicable under section 342(c)(2)–(3) of EPCA.

2. *Use of ARI Standard 1200–2006 Test Procedure for Which EPACT 2005 Directs DOE To Develop Test Procedures.* New section 343(a)(6)(C) of EPCA (Section 136(f)(1)(B) of EPACT 2005, 42 U.S.C. 6314(a)(6)(C)), in effect, directs DOE to develop test procedures for ''products for which standards will be established under section 342(c)(4),'' *i.e.*, (1) ice-cream freezers; (2) commercial refrigerators, freezers, and refrigerator-freezers with a self-contained condensing unit without doors; and (3) commercial refrigerators, freezers, and refrigerator-freezers with a remote condensing unit. ARI recently developed methods for testing such commercial refrigeration equipment in ARI Standard 1200–2006, ''Performance Rating of Commercial Refrigerated Display Merchandisers and Storage Cabinets.'' DOE reviewed ARI Standard 1200–2006 in the July 2006 proposed rule and found that it includes product temperature rating specifications that require maintaining test package temperatures during the tests, which is important for a valid comparative evaluation of energy consumption among products. These rating temperature provisions provide a basis for accurate efficiency determinations, as required under EPCA. (Section 136(f)(1)(B) of EPACT 2005; 42 U.S.C. 6314(a)(6)(C)). 71 FR 42188.

In addition, ARI Standard 1200–2006 requires performance tests to be conducted according to the ASHRAE Standard 72 test method, which DOE believes, as mentioned above, to be a sound method that will produce results that accurately reflect the efficiency of the products tested. DOE also stated in the July 2006 proposed rule that it understands that the method has been widely used in the industry, thus indicating that it is not unduly burdensome to conduct. 71 FR 42188. Finally, DOE reviewed the calculation methods as well as the definitions of terms used in the test procedure, and determined that they help to produce accurate results as to the efficiency of the products being tested.

DOE proposed in the July 2006 proposed rule to incorporate ARI Standard 1200–2006 by reference into § 431.64 of 10 CFR Part 431 for ice-cream freezers; commercial refrigerators, freezers, and refrigerator-freezers with a self-contained condensing unit and without doors; and for commercial refrigerators, freezers, and refrigerator-freezers with a remote condensing unit. 71 FR 42188.

ARI commented that it supports DOE's proposal to adopt ARI Standard 1200–2006 as the Federal test procedure for ice-cream freezers; commercial refrigerators, freezers, and refrigerator-freezers with a self-contained condensing unit without doors; and commercial refrigerators, freezers, and refrigerator-freezers with a remote condensing unit. (ARI, No. 63 at p. 2) No other comments were received regarding this proposal. DOE is adopting ARI Standard 1200–2006 in today's final rule into § 431.64 of 10 CFR Part 431.

3. *Ice-Cream Freezer Rating Temperature.* As mentioned above, new section 343(a)(6) of EPCA (Section 136(f)(1)(B) of EPACT 2005, 42 U.S.C. 6314(a)(6)), in effect directs DOE to develop test procedures for ice-cream freezers. DOE proposed to incorporate ARI Standard 1200–2006 by reference into 10 CFR Part 431 for ice-cream freezers in the July 2006 proposed rule. 71 FR 42188, 42209.

ARI commented that it generally supports DOE's proposal to adopt ARI Standard 1200–2006 as the federal test procedure for ice-cream freezers. (ARI, No. 63 at p. 2) ARI Standard 1200–2006 specifies a rating temperature for ice-cream freezers of −5 °F. ARI and Hill Phoenix stated that they believe a −15 °F rating temperature is more appropriate for ice-cream freezers than −5 °F because there is not much difference between rating freezers at the −5 °F ice-cream freezer rating temperature and 0 °F freezer rating temperature (the rating temperature used for conventional, general application freezers), and that the bulk of the equipment that is specifically used for the dispensing and display of ice-cream operates at −15 °F. (Public Meeting Transcript, No. 18.8 at pp. 40, 42) ARI believes that the −15 °F rating temperature would be a much better representation of ice-cream freezer operation than the 0 °F rating temperature. *Id.* Zero Zone stated that a survey of the industry found that freezers specifically designed for ice-cream products utilized components and are designed for an integrated average product temperature of −15 °F. (Zero Zone, No. 81 at p. 1) ACEEE, on the other hand, endorsed the −5 °F ice-cream freezer rating temperature because that is the temperature the ENERGY STAR criteria are based on. (ACEEE, No. 59 at p. 1)

While DOE recognizes that ENERGY STAR criteria and claims are based on testing at −5 °F, the ENERGY STAR program is specific to self-contained commercial freezers with solid doors. ENERGY STAR does not include most ice-cream freezers, while DOE's coverage of ice-cream freezers is much broader. In light of the new information presented above, DOE now believes testing at −5 °F would lead to results that are not representative of the true energy consumption of freezers specifically designed for ice-cream products. In consideration of the above, DOE has determined that a rating temperature of −15 °F is more appropriate for ice-cream freezers and is therefore adopting in this final rule −15.0 °F (±2 °F) as the rating temperature for ice-cream freezers, as a modification to the referenced ARI Standard 1200–2006.

Since ice-cream freezers generally operate at −15.0 °F, DOE believes

adoption of this rating temperature is warranted by the requirement that DOE test procedures ''shall be reasonably designed to produce test results which reflect [the] energy efficiency'' of the equipment being tested (42 U.S.C. 6314(a)(2)). This is essentially the same reasoning that supported the NOPR proposal of a rating temperature of −5.0 °F. *Id.*

4. *ANSI/AHAM Standard HRF–1.* EPCA defines refrigeration equipment compartment volumes, for purposes of standards for all covered commercial refrigerators, freezers, and refrigerator-freezers, in terms of ANSI/AHAM Standard HRF–1–1979, ''Association of Home Appliance Manufacturers Standard for Household Refrigerators, Combination Refrigerator-Freezers, and Household Freezers'' (Section 136(c) of EPACT 2005; 42 U.S.C. 6313(c)(1)((A) and (B)) DOE proposed to incorporate ANSI/AHAM Standard HRF–1–1979 by reference into section 431.63 of 10 CFR Part 431 in the July 2006 proposed rule. 71 FR 42208. DOE included in proposed § 431.64(b)(3) of the July 2006 proposed rule the applicable rating temperatures for this equipment prescribed under subsection 343(a)(6)(B) of EPCA. (42 U.S.C. 6314(a)(6)(B)) In the October 3, 2006, SNOPR (71 FR 58308, 58311), DOE proposed to replace references to ANSI/AHAM HRF–1–1979, with references to ANSI/AHAM HRF–1–2004, at 10 CFR 431.63(b)(2) of the July 2006 proposed rule for commercial refrigerators, freezers, and refrigerator-freezers, 71 FR 42208, and in the existing rule for such equipment under 10 CFR 431.66(a).

ARI commented that it agrees with the suggestion by AHAM that the referenced version of the ANSI/AHAM Standard HRF–1 should be updated to the latest 2004 version. (Public Meeting Transcript, No. 18.8 at p. 41) DOE has reviewed both versions and found that the methodologies for measuring refrigerated compartment volumes are identical. Aside from purely editorial changes, the only language changes in the 2004 version serve to clarify the testing methodology. 71 FR 58310. The 2004 version is also more readily available than the 1979 version. For these reasons, DOE is adopting in this final rule ANSI/AHAM Standard HRF–1–2004 for determining compartment volumes for this equipment.

N. Battery Chargers

In the July 2006 proposed rule, to address Subsection 325(u)(1)(A) of EPCA (42 U.S.C. 6295(u)(1)(A)), which requires DOE to prescribe test procedures for battery chargers, DOE proposed to incorporate by reference into 10 CFR Part 430, with limited modifications, the test procedure presented in sections 4 and 5 of EPA's ENERGY STAR ''Test Methodology for Determining the Energy Performance of Battery Charging Systems, December 2005'' (the ENERGY STAR test method). Subsection 325(u)(1)(B) of EPCA directs the Secretary to consider existing definitions and test procedures for measuring the energy consumption of battery chargers in standby mode and other modes. DOE stated in the July 2006 proposed rule that it believes its proposal fulfills the statutory requirements. 71 FR 42190. DOE received several comments on this proposal, spanning a range of issues from the scope of coverage to the test method itself. In today's final rule, DOE is finalizing its incorporation by reference of sections 4 and 5 of the ENERGY STAR test method, with the modifications discussed in the proposed rule. 71 FR 42190–1.

1. *Scope of Coverage.* In the July 2006 proposed rule, DOE proposed to adopt the statutory definition of a battery charger without modification. In that notice, DOE also proposed to refine the scope of the test procedure, so that it would have the same scope of applicability as the test method used by the ENERGY STAR program. 71 FR 42206. DOE proposed that the new scope of coverage be part of section 1 of Appendix Y to Subpart B of CFR Part 430. 71 FR 42206.

On the issue of scope of coverage for the battery charger test procedure, PG&E expressed concern about the limitations being placed by DOE on the applicability of the test procedure so early in the process. (PG&E, No. 12 at p. 3, No. 18.8 at p. 149, and No. 77 at p. 4) AHAM and PTI indicated that they believed the scope of coverage proposed by DOE represented the appropriate range of products on the market, which they feel should be included in DOE's rulemaking for battery chargers, limiting the scope of coverage to the residential sector. (AHAM, No. 18.8 at p. 157 and No. 84 at pp. 2–3; PTI No. 73 at p. 2) AHAM and PTI also commented that the range of wattages considered under DOE's scope should include battery chargers between 0 and 2 watts, so the complete range of power ratings would span from 0 to 300 watts. (AHAM, No. 18.8 at pp. 156–157 and No. 84 at p. 3; PTI No. 73 at p. 2). AHAM and Philips commented that inductively coupled devices should be included in the scope of the test procedure, even though these products were exempt from the ENERGY STAR battery charger program. (AHAM, No. 18.8 at p. 156 and No. 84 at p. 3; Philips, No. 68 at p. 2) Finally, AHAM commented that the scope of coverage should include consumer products and those commercial products that are virtually identical to the consumer products, such as cordless rechargeable hair trimmers. (AHAM, No. 84 at p. 3)

DOE's proposed scope of coverage, proposed in Appendix Y to Subpart B of Part 430, Uniform Test Method for Measuring the Energy Consumption of Battery Chargers, attempted to refine the applicability of the test procedure to the same subset of battery chargers covered under the ENERGY STAR program. After careful consideration of stakeholder concerns and further review of the statute, DOE decided to remove the scope of coverage in Appendix Y from today's final rule. DOE now recognizes that the test procedure itself is relatively simple and can apply to a broad range of battery chargers, not only those units included in the scope of the ENERGY STAR program. Thus, the test procedure will be applicable generally to battery chargers for consumer products (i.e., without limitation to specific wattage ranges or application types).

EPCA defines ''battery charger'' as ''a device that charges batteries for consumer products, including battery chargers embedded in other consumer products.'' (42 U.S.C. 6291(32)) DOE is adopting this definition verbatim in today's final rule, and is modifying the scope of the test procedure to apply simply to battery chargers, as just defined.

In parallel with this rulemaking, DOE is conducting a determination analysis to ascertain whether energy conservation standards are technologically feasible and economically justified, and would result in significant energy savings, for battery chargers (and external power supplies). In that proceeding, DOE will initially decide which products are within the EPCA definition of ''battery charger,'' and will address all such products in conducting its analysis. To the extent DOE decides that products considered to be external power supplies are actually battery chargers and should be regulated as such, DOE will include such products in its analysis for battery chargers. If the determination as to battery chargers is positive, DOE will refine its scope of coverage as appropriate, through its public regulatory process, so that standards will cover only products for which they are warranted. DOE will also work to ensure that any resulting energy conservation standards will be appropriate for the various classes of

battery chargers operating consumer products.

PG&E and NRCan both submitted comments in which they appear to advocate that DOE adopt a single, inclusive test procedure that would apply to both external power supplies and battery chargers, and that DOE make a determination later about which products should be classified as an external power supply or a battery charger. (PG&E, No. 12 at pp. 1–2 and No. 77 at p. 2; NRCan, No. 86 at p. 1) DOE appreciates these comments, but disagrees with this approach. First, the statute separately defines external power supplies and battery chargers. (42 U.S.C. 6291(32) and (36)) Although EPCA sets forth in a single section the same process and criteria for DOE to develop test procedures and standards for these products, 42 U.S.C. 6295(u), the statute provides no indication that they should be treated as a single product. Second, DOE believes that to do so, even as a temporary measure, would be technically inappropriate. DOE's preliminary technical analysis of battery chargers and external power supplies has shown that these two devices have fundamentally different designs because they provide completely different utility to consumers. Generally, battery chargers are designed to be constant current devices while external power supplies are designed to be constant voltage devices. Moreover, the same test method cannot be employed to accurately determine the energy use and efficiency of both products under normal use by consumers. Therefore, DOE proposed and is adopting today one test procedure for battery chargers, and a different one for external power supplies. DOE is not classifying battery chargers as external power supplies, or otherwise treating them as a single product, even as a temporary measure. This interpretation was supported by a comment from AHAM, which asserted that DOE should require that a battery charger, including components of a battery charging system that together constitute a battery charger, be tested by the test procedure DOE adopts for battery chargers, and not by a test procedure for external power supplies or some other test procedure. (AHAM, No. 84 at p. 2)

DOE recognizes that in limited instances the distinction between a battery charger and an external power supply may not always be clear. For some power converting devices, such as those powering laptop computers or hand-held video cameras, the power converter can both charge a battery and operate the consumer product, even if the battery is completely discharged or removed. For these devices, which could understandably be classified either battery chargers or external power supplies, DOE will work cooperatively with stakeholders to develop clear guidelines that remove any ambiguity as to which of the two test procedures adopted today would apply.

DOE is planning to hold a ''Scoping Workshop'' to receive public comment on the respective scope of coverage and applicability for battery chargers and external power supplies, which is a requirement of EPCA under subsection 325(u)(1)(D). (42 U.S.C 6295(u)(1)(D)) DOE's initial understanding of the principal difference between a battery charger and an external power supply concerns whether the power-converting device is able to operate the consumer product, independent of the battery. In other words, if the power converter can operate a consumer product which has the batteries removed (or has completely discharged batteries installed), then that power converter is considered to be an external power supply. If, on the other hand, a consumer product is not fully operational when the battery is removed or is completely discharged, even when the power converter is connected to the device and plugged into the wall outlet, then the device is considered to be a battery charger. DOE will be discussing this initial understanding, as well as other comments and clarifications stakeholders have about the scope of coverage and applicability for battery chargers and external power supplies, in the Scoping Workshop.

2. *Modes of Test, including Active Mode.* With regard to the test method itself, there were dissenting viewpoints as to whether DOE should include active mode testing in its procedure. Under the DOE proposal, battery chargers would only be tested during standby and maintenance mode. 71 FR 42190–42191. Several stakeholders commented that DOE should consider the measurement of active mode in its battery charger test procedure. (PG&E, No. 12 at p. 2, No. 18.8 at pp. 168 and 173, and No. 77 at p. 3; NRCan, No. 18.8 at pp. 164–165, CEC No. 18.8 at p. 165; ACEEE No. 59 at p. 3) PG&E stated that active mode is the second most energy consuming mode of operation for these products, and is therefore deserving of consideration (PG&E, No. 18.8 at pp. 150–151; No. 77 at p. 3) PG&E informed DOE that the California Energy Commission (CEC) is working to develop an active mode test procedure for battery chargers, and provided DOE with copies of draft versions of the test method and stakeholder comments on those drafts. (PG&E, No. 18.8 at p. 166 and No. 77 at pp. 3–4) PG&E asked that DOE acknowledge the draft CEC test method as a viable alternative to the ENERGY STAR test procedure for battery chargers. (PG&E, No. 77 at p. 4)

PG&E and ACEEE also commented that EPCA requires DOE to evaluate energy consumed by battery chargers considering standby mode and other operating modes. PG&E and ACEEE stated that they found it problematic that DOE's proposal only considers standby mode and maintenance mode, as EPCA calls for ''other modes'' and maintenance mode represents only one additional mode. (PG&E, No. 12 at p. 2, No. 18.8 at p. 150, No. 77 at p. 3; ACEEE No. 59 at p. 3) Finally, PG&E commented that the incremental testing burden of including the measurement of power consumption during active mode was small, given that the existing ENERGY STAR test procedure DOE proposed to adopt requires charging a battery as the first step. (PG&E, No. 18.8 at pp. 167–168 and No. 77 at p. 4)

AHAM, CEA, Wahl, Philips, and PTI commented that DOE should not include testing for active mode in its test procedure. (AHAM No. 18.8 at pp. 159–161 and No. 84 at pp. 2, 4–5; CEA No. 18.8 at p. 172, Wahl, No. 67 at p. 1; Philips No. 68 at p. 1; PTI No. 73 at p. 3) AHAM stated that testing active mode is not in keeping with the overall mission of reducing standby energy consumption. (AHAM, No. 18.8 at p. 160) AHAM is concerned that active mode testing will create considerable complexities, stating that in order to have accurate tracking of active mode, a test procedure would need to bring in elements of the usage patterns of the products. (AHAM, No. 18.8 at p. 160 and No. 84 at pp. 2 and 4) AHAM further commented that EPA considered active mode in its development of the ENERGY STAR program for battery chargers, and a study it completed found that the inclusion of active mode did not reveal additional energy savings opportunities. (AHAM, No. 18.8 at pp. 161 and 170 and No. 84 at pp. 2 and 4) PTI also commented that it was involved in the development of the ENERGY STAR program for battery chargers, and active mode had been part of the scope of investigation. According to PTI, the ENERGY STAR development team came to the conclusion that active mode offered no benefit with respect to measuring that mode, so it was excluded from the final standard. (PTI, No. 18.8 at p. 163 and No. 73 at p. 3) Wahl and CEA commented that if DOE were to include active mode in its test procedure, it must incorporate it with variable timeframes for different types of products. (Wahl, No. 18.8 at p. 171,

CEA, No. 18.8 at p. 172) In particular, Wahl is concerned that the duty cycle of a rechargeable shaver is significantly different from that of a vacuum cleaner or cordless drill. (Wahl, No. 18.8 at p. 171)

DOE considered all the comments concerning the inclusion of active mode in its test procedure, and decided to finalize its test procedure as proposed, based on the ENERGY STAR test procedure for battery chargers, which measures stand-by mode and maintenance mode.

DOE recognizes that analytical efforts are underway to develop and finalize active mode test methods for battery chargers; however, the statutory deadline for codifying a test procedure for this product does not allow DOE to postpone publication. (42 U.S.C. 6295(u)) DOE recognizes that at least one draft battery charger test procedure including active mode does exist, but it is still being developed, and DOE has therefore not been able to review a final test method and determine its accuracy and repeatability for measuring active mode energy consumption by battery chargers. That said, DOE does recognize the potential importance and potential energy savings of regulating active mode, and therefore is reserving a section in Appendix Y to Subpart B of Part 430 for Active Mode measurement and incorporating the ENERGY STAR definition for Active Mode in that same appendix. DOE intends to continue to study the issue of active mode for battery chargers while observing the test procedure development processes in California, Canada and elsewhere. If DOE finds the active mode to be a necessary part of determining and capturing energy savings for battery chargers, DOE will work through its public regulatory process to explore development of an active mode test procedure that takes into consideration concerns from all stakeholders.

3. *Definitions.* With respect to the test method, AHAM and PTI recommended that DOE include in its final rule several definitions contained in the ENERGY STAR requirements for battery chargers that would further clarify the application of DOE's test procedure for battery chargers. (AHAM, No. 18.8 at p. 159; PTI, No. 73 at p. 3) These terms include: ''active-mode,'' ''battery,'' ''multi-port chargers'' and ''multi-voltage a la carte chargers.'' DOE provided an explanation of these terms in the July 2006 proposed rule, which will be placed into Appendix Y of 10 CFR Part 430. 71 FR 42206. However, DOE recognizes that moving this material into the definitions section of the test procedure would clarify the test procedure methodology stakeholders need to follow. Thus, in today's final rule, DOE is including the definitions from the ENERGY STAR test method referenced for ''active-mode,'' ''battery,'' ''multi-port chargers'' and ''multi-voltage a la carte chargers.'' DOE will also clarify that the ''standby mode'' term defined in section 2(e) of proposed Appendix Y to Subpart B of Part 430 is also sometimes referred to as 'no-load mode'.

Wahl, Philips, and AHAM commented concerning definitions that DOE did not propose, but are part of the ENERGY STAR program. These stakeholders are seeking adoption of the ENERGY STAR definitions for cord/cordless products and nameplate nominal charging input power, with revisions. (Wahl, No. 67 at pp. 1–2; Philips, No. 68 at p. 1; AHAM No. 84 at p. 3) AHAM and Wahl commented that a cord/cordless product should be defined as a ''product or appliance that is designed to operate on battery power, but also is designed such that the product or appliance can operate with a discharged battery when connected to charger or mains.'' *Id.* Stakeholders then request a revision to the definition of nominal power, such that companies making cord/cordless products focus on the energy consumed in battery maintenance mode rather than the wattage rating on the nameplate. (Philips, No. 68 at p. 1) AHAM and Wahl proposed language to be added to the definition of Nameplate Nominal Charging Input Power as follows: ''or 3) for cord/cordless products where the nameplate power may reflect power consumed by the product in modes other than charging/maintaining batteries, the nominal charging input power shall be the highest measured power consumed during battery charging alone.'' (Wahl, No. 67 at p. 2; AHAM, No. 84 at p. 3)

DOE appreciates these comments, but recognizes that both are directed to whether products could be classified as battery chargers. DOE will take them into consideration in the determination analysis, in which DOE will establish the scope of applicability for the analysis, and will address and clarify issues pertaining to product classes and nameplate wattages.

4. *Test Method.* In the July 2006 proposed rule, DOE stated that some battery charger designs draw current in short pulses and, therefore, the instrumentation requirements for testing such designs should be capable of fully measuring the energy consumed by these pulses. 71 FR 42191. DOE proposed adding a requirement in section 3 of proposed Appendix Y to Subpart B of Part 430 that addresses the capability of testing equipment to account for crest factor and frequency spectrum in the measurement. *Id.*

Finally, with respect to the test method, AHAM and PTI both provided comments that they agreed DOE should include provisions in the test procedure for evaluating pulsing and non-sinusoidal wave form battery chargers, as this will enhance the technical accuracy of the test procedure and will not cause any undue burden. (AHAM, No. 18.8 at p. 157 and No. 84 at p. 3; PTI, No. 73 at p. 3) Several stakeholders agreed with DOE that the testing need only be conducted at 115 volts at 60 hertz input power. (AHAM, No. 18.8 at p. 157 and No. 84 at p. 3; PSMA No. 72 at p. 2; PTI No. 73 at p. 3) DOE appreciates these comments, and has incorporated in today's test procedure final rule the requirements for evaluating pulsing and non-sinusoidal wave form battery chargers into Appendix Y to Subpart B of Part 430 as proposed in the July 2006 proposed rule. 71 FR 42206.

AHAM also commented that they supported DOE's proposal to use the 48-hour testing period for the test procedure. (AHAM, No. 18.8 at p. 158 and No. 84 at p. 3) PSMA recommended that DOE adopt an alternative (shorter) testing time period that takes only 7 hours to complete instead of 48 hours. (PSMA, No. 72 at p. 2) PSMA comments that this shorter time period would reduce testing time and cost. DOE recognizes that the ENERGY STAR test method allows manufacturers to choose either the 7-hour or the 48-hour approach when rating their products. However, DOE believes that allowing two different testing time periods for the same battery charger, in a test method that would be used to determine compliance with a mandatory standard, would pose a potential problem in that it would diminish the repeatability of the procedure. Furthermore, DOE believes the shorter testing time period (7-hour) does not allow ample time for the circuit to stabilize, which also diminishes the repeatability of the test procedure. In the July 2006 proposed rule, DOE proposed to adopt the longer (48-hour) testing time period, which is supported by AHAM. 71 FR 42190, 42206. DOE is not persuaded by PSMA's arguments to change the time period to 7 hours. Therefore, DOE is adopting this test procedure for battery chargers with the 48-hour testing time period.

O. External Power Supplies

In the July 2006 proposed rule, to address Subsection 325(u)(1)(A) of EPCA (42 U.S.C. 6295(u)(1)(A)), DOE

proposed to incorporate by reference certain sections of the EPA's ENERGY STAR ''Test Method for Calculating the Energy Efficiency of Single-Voltage External AC-DC and AC-AC Power Supplies (August 11, 2004)'' (the ENERGY STAR test method). 71 FR 42191. DOE received comments expressing concern over the scope of coverage and certain aspects of the proposed test method.

1. *Scope of Test Procedure.* DOE also proposed to adopt the EPACT 2005 definition of an external power supply without modification in the July 2006 proposed rule. 71 FR 42191, 42206. Additionally, DOE proposed to make the scope of applicability for the test method consistent with that of the ENERGY STAR program, which was designed to address external power supplies used with consumer electronics. DOE stated that it believes that the proposed scope of coverage for the external power supply test method did not deviate substantively from the statutory definition, since it was drafted to be applicable to these devices when powering consumer products. DOE requested comment on the proposed scope of applicability for the test procedure, which was proposed to be incorporated into section 1 of Appendix Z to Subpart B of CFR Part 430. 71 FR 42191.

On the issue of scope of coverage, some stakeholders were concerned about some of the limitations being imposed by DOE in the test procedure. (PG&E, No. 12 at p. 4, No. 18.8 at p.174 and No. 77 at p. 2; ACEEE, No. 59 at p. 3; CEC, No. 75, at p. 1; NRCan No. 86 at p. 1) ACEEE commented that at the test procedure stage, DOE should cover all products, and stated that it would be better for DOE to decide whether standards are appropriate for certain products in an energy conservation standards rulemaking. (ACEEE, No. 59 at p. 3) CEA commented that they supported DOE's proposal to make the scope of applicability for the external power supply test method consistent with that of the EPA's ENERGY STAR program. (CEA, No. 79 at p. 2) CEA stated that it is important for DOE to clearly define the scope of products subject to the test procedure for external power supplies and the scope of products subject to the test procedure for battery chargers. (CEA, No. 79 at p. 2)

The scope of coverage, contained in section 1 of proposed Appendix Z to Subpart B of Part 430, Uniform Test Method for Measuring the Energy Consumption of External Power Supplies attempted to refine the applicability of the test procedure to the same subset of external power supplies covered under the ENERGY STAR program. 71 FR 42206. After careful consideration of stakeholder concerns and further review of the statute, DOE has decided to remove the scope of coverage from Appendix Z in today's final rule. DOE now recognizes that the test procedure itself can be applied to a broad range of external power supplies for consumer products, which may be more expansive than those included in the scope of the ENERGY STAR program. Thus, the test procedure will be applicable generally to external power supplies for consumer products (i.e., without limitation to specific wattage ranges or application types).

EPCA defines external power supply as ''[a] circuit that is used to convert household electric current into DC current or lower-voltage AC current to operate a consumer product.'' (42 U.S.C. 6291(36)) DOE is adopting this definition verbatim in today's final rule into section 430.2 of 10 CFR Part 430, and is modifying the scope of the test procedure to apply simply to external power supplies, as just defined.

In parallel with this rulemaking, DOE is conducting a determination analysis to ascertain whether energy conservation standards are technologically feasible and economically justified, and would result in significant energy savings, for external power supplies (and battery chargers). In that proceeding, DOE will initially decide which products are within the EPCA definition of ''external power supply,'' and will address all such products in conducting its analysis. To the extent DOE decides that products considered to be external power supplies are actually battery chargers and should be regulated as such, DOE will exclude such products from this analysis and consider them in the similar analysis it is conducting for battery chargers. If the determination as to external power supplies demonstrates compelling evidence that DOE should further investigate energy conservation standards for external power supplies, DOE will refine its scope of coverage as appropriate, through its public regulatory process, so that standards will cover only products for which they are warranted. DOE will also work to ensure that any resulting energy conservation standards would be appropriate for the various classes of external power supplies operating consumer products.

PG&E's and NRCan's both submitted comments in which they appear to advocate that DOE adopt a single, inclusive test procedure that would apply to both external power supplies and battery chargers. These commenters also urged DOE to make a determination about which products should be classified as an external power supply or a battery charger in a separate rulemaking. (PG&E, No. 12 at pp. 1–2 and No. 77 at p. 2; NRCan, No. 86 at p. 1)

As indicated above for battery chargers, DOE disagrees with this approach. EPCA separately defines external power supplies and battery chargers. (42 U.S.C. 6291(32) and (36)) DOE is adopting in today's final rule one test procedure for external power supplies, and a different test procedure for battery chargers into Appendix Y and Appendix Z, respectively, of Subpart B to 10 CFR Part 430. 71 FR 42206.

The Power Sources Manufacturers Association (PSMA) requested that medical equipment be excluded from coverage under this rulemaking, which it stated would be consistent with California and New York regulations. (PSMA, No. 72 at p. 1) DOE notes that its mandate under this rulemaking is to develop test procedures for external power supplies for consumer products. As discussed in this section, DOE intends to develop an appropriate scope of coverage for this product in its determination analysis, and ultimately, if there is a positive determination, in the energy conservation standards rulemaking. DOE will consider whether, and to what extent, external power supplies for medical equipment are used ''to operate a consumer product,'' 42 U.S.C. 6291(36), and if so, the extent to which standards are warranted for such external power supplies.

As discussed in the section on battery chargers, DOE recognizes that in certain instances, the distinction between a battery charger and an external power supply may not always be clear. For these devices, which could understandably be classified as either a battery charger or external power supply, DOE will work cooperatively with stakeholders to develop clear guidelines so there would not be any ambiguity as to which of the two test procedures adopted today would apply. DOE's initial understanding of the principal differentiating characteristic of an external power supply is that it is able to operate the consumer product independent of the battery, whereas a battery charger cannot. This initial understanding will be discussed in a separate proceeding (i.e., the ''Scoping Workshop''). See section N for further detail.

2. *Power Factor.* In DOE's proposed rulemaking, stakeholders were invited to submit comments on power factor.

DOE understands that power factor, defined as the ratio of actual power drawn in watts to apparent power drawn in volt-amperes, affects the efficiency of electric utility distribution systems. Power factor correction processes are used to adjust this ratio (i.e., the power factor) towards a value of 1.0. DOE stated in the July 2006 notice it was concerned that, from a utility distribution system perspective, the aggregate effect of external power supplies with low-power factors would increase distribution system losses. 71 FR 42191. DOE received two comments in response to this request, both suggesting that DOE should include consideration of power factor in its test procedure. (PG&E, No. 77 at p. 2; NRCan, No. 86 at p. 1)

In the July 2006 proposal, DOE expressed concern and solicited stakeholder input on power factor as it relates to external power supplies for consumer products. 71 FR 42191. Part of DOE's motivation behind the request for comments on power factor was the European directive which requires power factor correction on external power supplies with rated capacities greater than 75 watts input power (''Limits for Harmonic Current Emissions (Equipment Input Current Up To And Including 16 A Per Phase,'' EN61000–3–2). However, while preparing the July 2006 proposed rule, DOE's technical review indicated that power factor as it related to the typical wattages of external power supplies for consumer products was not a significant issue. Therefore, DOE requested comment from stakeholders, but did not propose any rule language in the test method for external power supplies to explicitly measure power factor. While two stakeholders did mention power factor, they did not provide any rationale or information to support its consideration in the test procedure. In addition, no other stakeholders commented that this should be taken into account. Thus, DOE is not persuaded that power factor should be an issue of concern in this test procedure rulemaking, and DOE is not including the measurement of power factor in today's final rule.

3. *Test Method.* Finally, DOE proposed to use only the U.S. voltage conditions in the test procedures specified in the July 2006 proposed rule. 71 FR 42191; 42207. CEA submitted a comment supporting DOE using only the U.S. voltage conditions in its test procedure. (CEA, No. 79 at p. 2) No other comments were received on this issue. Under the test procedure adopted today 115 volts at 60 hertz is the only input power for this test procedure as specified in Appendix Z of Subpart B to 10 CFR Part 430. 71 FR 42206.

In addition, several stakeholders provided comment in support of the no-load energy consumption and the active mode efficiency loading percentages (i.e., 25%, 50%, 75% and 100% of rated nameplate output) proposed by DOE in the July 2006 notice. (PSMA, No. 72 at p. 2; PG&E, No. 77 at p. 2; CEA No. 79 at p. 2; NRCan No. 86 at p. 1) DOE is adopting the no-load energy consumption measurement and the active mode efficiency loading percentages as proposed in the July 2006 proposed rule. 71 FR 42191.

P. General Comments and Final Rule

In the July 2006 proposed rule, DOE proposed to add a definition for energy conservation standard as it relates to commercial equipment in § 431.2 of 10 CFR Part 431. 71 FR 42207. DOE initially proposed this definition because it thought it would add clarity for stakeholders when referencing the test procedures covered by the statute. However, DOE is not adopting this definition in today's final rule because DOE feels it is unnecessary and confusing to have two separate definitions for the term ''energy conservation standard'' in its regulations. In addition, DOE believes the EPCA definition of energy conservation standard is sufficient.

IV. Corrections to the Recent Technical Amendment to DOE's Energy Conservation Standards

In the July 2006 proposed rule, DOE announced it intended to incorporate minor revisions to the October 18, 2005, final rule in which it adopted a technical amendment to its energy conservation standards for certain consumer products and commercial and industrial equipment. 70 FR 60407. These revisions consist of editorial corrections, corrections to errors in fact, and clarifying language. Each of the revisions discussed in the July 2006 proposed rule is added to the appropriate section of the CFR by today's final rule. The corrections and clarifications to the October 2005 final rule are as follows:

1. In section 430.2, in the definition of ''Dehumidifier,'' DOE changed ''and mechanically encased assembly'' to ''and mechanically refrigerated encased assembly.''

2. In § 430.32(u), DOE made the following changes in the table on standards for medium base CFLs:

a. In the ''Requirements'' column and opposite ''Lamp Power (Watts) & Configuration,'' change ''Minimum Efficiency: lumen/watt'' to ''Minimum Efficacy: lumens/watt.''

b. In the ''Factor'' column, change ''Base Lamp'' to ''Bare Lamp.''

c. In the ''Factor'' column, delete the reference to ''Covered Lamp (with reflector),'' ''Lamp Power <20,'' and ''Lamp Power >20'' because these products are not covered under EPACT 2005. Correspondingly, delete ''33.0'' and ''40.0'' from the ''Requirements'' column.

d. In the ''Requirements'' column, opposite ''Average Rated Lamp Life,'' delete ''and qualification form.'' The clause reads, ''as declared by the manufacturer on packaging.''

e. In footnote 1, changed ''in the base up an/or'' to ''in the base up and/or.''

3. In § 431.97(b), DOE made the following changes:

a. In the text preceding Table 1 in paragraph (a), DOE added the words ''in the case of air-cooled equipment with a capacity greater than 65,000 Btu per hour,'' after the date ''January 1, 2010.''

b. In the text preceding the table, DOE added the term ''Air-cooled'' at the beginning, and inserted the words ''with cooling capacities equal to or greater than 65,000 Btu/h and less than 760,000 Btu/h'' after the date ''January 1, 2010.'' c. In the table, DOE changed ''Very large commercial package air-conditioning (air-cooled)'' to ''Very large commercial package air-conditioning and heating equipment (air-cooled).''

4. In § 431.226(a) for traffic signal modules and pedestrian modules, DOE changed the requirements from ''a nominal wattage no greater than'' to ''a nominal wattage and maximum wattage no greater than.''

V. Procedural Requirements

A. Review Under Executive Order 12866

The Office of Information and Regulatory Affairs (OIRA) of the Office of Management Budget (OMB) has determined that today's regulatory action is not a ''significant regulatory action'' under section 3(f)(1) of Executive Order 12866, ''Regulatory Planning and Review.'' 58 FR 51735 (October 4, 1993). Accordingly, today's action was not subject to review by OIRA in OMB.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial

number of small entities. A regulatory flexibility analysis examines the impact of the rule on small entities and considers alternative ways of reducing negative impacts. Also, as required by Executive Order 13272, *Proper Consideration of Small Entities in Agency Rulemaking,* 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of General Counsel's Web site: *http://www.gc.doe.gov.*

EPACT 2005 amended EPCA to incorporate into DOE's energy conservation program certain consumer products and commercial and industrial equipment, including the products for which DOE is proposing test procedures in this notice. On October 18, 2005, DOE published in the **Federal Register** a technical amendment to place in the CFR the energy conservation standards, and related definitions, that Congress prescribed in EPACT 2005. 70 FR 60407. Today, DOE is publishing further technical amendments to certain energy conservation standards for consumer products and commercial and industrial equipment published in the **Federal Register** on October 18, 2005. DOE is revising the CFR to incorporate, essentially without substantive change, the energy conservation test procedures that Congress prescribed or otherwise identified in EPACT 2005 for certain consumer products and commercial and industrial equipment. DOE is also adopting test procedures for consumer products and commercial and industrial equipment for which EPACT did not identify specific test procedures.

DOE reviewed today's final rule under the provisions of the Regulatory Flexibility Act and the policies and procedures published on February 19, 2003. DOE conducted its examination for the products and equipment covered under EPACT 2005 in several groups: equipment for which EPACT 2005 amended EPCA to direct DOE to adopt test procedures the statute identifies; products or equipment for which the EPACT 2005 amendments to EPCA do not specifically identify any test procedure; and products or equipment for which the EPACT 2005 amendments mandate that DOE base its test procedures on test procedures the statute identifies.

EPACT 2005 establishes specific test procedures for automatic commercial ice makers; for commercial refrigerators, freezers, and refrigerator-freezers for which the statute prescribes standards; and for very large commercial package air-conditioning and heating equipment (240,000 Btu/h through 760,000 Btu/h). Since EPCA now mandates the test procedures, they are incorporated into today's proposed rule. Any costs of complying with them are imposed by EPCA and not the rule. For this equipment, DOE is merely incorporating by reference into 10 CFR Part 431 the required test procedures as the statute directs. Therefore, DOE concludes that this rule would not impose a significant impact on a substantial number of small businesses producing automatic commercial ice makers; commercial refrigerators, freezers, and refrigerator-freezers for which the statute prescribes standards; or very large commercial package air-conditioning and heating equipment (240,000 Btu/h through 760,000 Btu/h).

EPACT 2005 does not prescribe test procedures for all products and equipment it addresses. For example, EPACT 2005 establishes energy conservation design requirements for commercial unit heaters, torchieres, ceiling fan light kits with sockets other than medium screw base and pin-based, and ceiling fans.

For the remaining products and equipment that EPACT 2005 covers and today's final rule addresses, the test procedures are based on test procedures developed and already in general use by industry. Many manufacturers have been redesigning the products and equipment covered under today's final rule, and testing them for compliance with existing voluntary performance standards such as the ENERGY STAR program requirements, using industry-developed test procedures that are the basis for the test procedures in EPACT 2005. These products and equipment include dehumidifiers, commercial prerinse spray valves, illuminated exit signs, ceiling fan light kits with medium screw base and pin-based sockets, medium-base CFLs, traffic signal modules, and pedestrian modules. To the extent manufacturers already test their products for efficiency using the test procedures identified in EPACT 2005, and incorporated into today's final rule, to assure that the products meet existing energy conservation requirements, manufacturers would experience no additional burdens if DOE adopts these test procedures and requires manufacturers to use them. Furthermore, as to the test procedures adopted today that EPACT 2005 directs DOE to adopt, and arguably for the proposed test procedures that EPACT 2005 specifically identifies and states shall be the basis for the DOE test procedure, any cost of complying with the proposed rule arises from the underlying statutory requirement and not the rule itself. Moreover, for the products and equipment for which EPACT 2005 prescribes energy efficiency standards, implicit in such requirements is that manufacturers must test their products to assure compliance with the standards. For all of these reasons, DOE believes today's final rule would not impose significant economic costs on manufacturers, including small manufacturers, of these products.

Certain products and equipment—ceiling fans, battery chargers, external power supplies, and refrigerated bottled and canned beverage vending machines—are the subject of voluntary standards and/or test procedures but are not yet covered by DOE energy conservation standards. DOE's adoption of test procedures for these products would entail even less burden for their manufactures than described in the previous paragraph, because these manufacturers would not be required to perform testing to establish compliance with standards. Thus, DOE believes today's final rule clearly would not impose significant economic costs on small manufacturers of these products.

For all of these reasons, DOE certifies that today's final rule would not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE will transmit this certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review pursuant to 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

This final rule will impose no new information or recordkeeping requirements since it does not include the manufacturer certification and reporting requirements included in the July 2006 proposed rule. As indicated in the July 2006 proposed rule, the manufacturer certification and reporting requirements contain certain record-keeping requirements. However, those recordkeeping requirements and associated burdens from manufacturer certification and reporting are being considered in a separate rulemaking.

Under the Paperwork Reduction Act, an agency may not conduct or sponsor a collection of information unless the collection displays a currently valid OMB control number. (44 U.S.C. 3506(c)(1)(B)(iii)(V)) The certification and record keeping requirements for consumer products in 10 CFR Part 430

have previously been assigned OMB control number 1910–1400. The certification and record keeping requirements for commercial and industrial equipment in 10 CFR Part 431 must be approved and assigned a control number by OMB. DOE has submitted those proposed certification and recordkeeping requirements to OMB for review and approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

In the July 2006 proposed rule, DOE provided burden estimates for each of the products covered by the proposed rule and invited interested parties to submit comments concerning the estimated paperwork reporting burden to DOE and to the Office of Information and Regulatory Affairs, Office of Management and Budget. DOE will address all of the comments in the final rule adopting manufacturer certification and reporting requirements.

D. Review Under the National Environmental Policy Act of 1969

DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementation of these regulations at 10 CFR part 1021. Specifically, this rule is establishing test procedures that will not affect the quality or distribution of energy and that will not result in any environmental impacts and, therefore, is covered by the Categorical Exclusion in paragraph A6 to subpart D, 10 CFR part 1021. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in developing regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in developing such regulations. 65 FR 13735. DOE examined this final rule and determined that it does 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. Executive Order 13132 requires no further action.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (February 7, 1996), imposes on Federal agencies the duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. For regulatory actions likely to result in a rule that may cause expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. 2 U.S.C. 1532(a) and (b). The UMRA requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate.'' The UMRA also requires an agency plan for giving notice and opportunity for timely input to small governments that may be affected before establishing a requirement that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA (62 FR 12820) (also available at *http://www.gc.doe.gov*). Today's rule contains neither an intergovernmental mandate nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements under the UMRA do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. Today's final rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is unnecessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 18, 1988), that this rule would not result in any takings that might require compensation under the Fifth Amendment to the United States Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. The OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed today's final rule under the OMB and DOE guidelines and has

concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to the OIRA of OMB a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated a final rule or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. Because this final rule would not have a significant adverse effect on the supply, distribution, or use of energy, the rule is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration (FEA) Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. 15 U.S.C. 788. DOE indicated in the July 2006 proposed rule that Section 32 applies to the portion of the proposed rule that incorporates testing methods in six commercial standards not specifically specified in EPACT 2005, requiring consultation with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition. 71 FR 42178, 42200 (July 25, 2006). Based on the comments, DOE is no longer incorporating by reference two of the six commercial standards, IEEE Standard 1515–2000, ''IEEE Recommended Practice for Electronic Power Subsystems; Parameter Definitions, Test Conditions, and Test Methods,'' for battery chargers and external power supplies and IESNA Standard LM 45–2000, ''Approved Method for Electrical and Photometric Measurements of General Service Incandescent Filament Lamps,'' in the final rule. In addition, DOE has determined that the two ENERGY STAR test methods identified in the July 2006, proposed rule, ''ENERGY STAR Test Methodology for Determining the Performance Characteristics of Battery Charging Systems,'' December 2005, and ''ENERGY STAR Test Method for Calculating the Energy Efficiency of Single-Voltage External Ac-Dc and Ac-Ac Power Supplies,'' August 11, 2004, are not commercial standards subject to the section 32 review.

Since publication of the July 2006 proposed rule, DOE submitted two commercial standards, ARI Standard 1200–2006, ''Performance Rating of Commercial Refrigerated Display Merchandisers and Storage Cabinets;'' and ARI Standard 340/360–2004, ''Performance Rating of Commercial and Industrial Unitary Air-Conditioning and Heat Pump Equipment,'' to the Attorney General and the Chairman of the Federal Trade Commission for such review. Neither the Attorney General nor the Chairman of the Federal Trade Commission has recommended against incorporation of these standards.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of today's final rule.

List of Subjects

10 CFR Part 430

Administrative practice and procedure, Energy conservation test procedures, Household appliances, Incorporation by reference.

10 CFR Part 431

Administrative practice and procedure, Commercial products, Energy conservation test procedures, Incorporation by reference.

Issued in Washington, DC, on November 28, 2006.

Alexander A. Karsner,

Assistant Secretary, Energy Efficiency and Renewable Energy.

■ For the reasons stated in the preamble, DOE amends Chapter II, Subchapter D, of Title 10 of the Code of Federal Regulations as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.2 is amended by:
■ a. Adding to the definition of ''basic model'' paragraphs (21) through (26).
■ b. Revising the definition of ''covered product'' and ''dehumidifier.''
■ c. Adding in alphabetical order the definition of ''Battery charger,'' ''External power supply,'' and ''Pin-based.''

The revisions and additions read as follows:

§ 430.2 Definitions.

* * * * *

Basic model * * *

(21) With respect to ceiling fans, which have electrical characteristics that are essentially identical, and which do not have any differing physical or functional characteristics that affect energy consumption.

(22) With respect to ceiling fan light kits, which have electrical characteristics that are essentially identical, and which do not have differing physical or functional characteristics that affect energy consumption.

(23) With respect to medium base compact fluorescent lamps, which have electrical characteristics that are essentially identical, and which do not have any differing physical or functional characteristics that affect energy consumption.

(24) With respect to dehumidifiers, which have electrical characteristics that are essentially identical, and which do not have any differing physical or functional characteristics that affect energy consumption.

(25) With respect to battery chargers, which have electrical characteristics that are essentially identical, and which do not have any differing physical or functional characteristics that affect energy consumption.

(26) With respect to external power supplies, which have electrical characteristics that are essentially identical, and which do not have any differing physical or functional characteristics that affect energy consumption.

* * * * *

Battery charger means a device that charges batteries for consumer products, including battery chargers embedded in other consumer products.

* * * * *

Covered product means a consumer product:

(1) Of a type specified in section 322 of the Act, or

(2) That is a ceiling fan, ceiling fan light kit, medium base compact fluorescent lamp, dehumidifier, battery charger, external power supply, or torchiere.

Dehumidifier means a self-contained, electrically operated, and mechanically refrigerated encased assembly consisting of—

(1) A refrigerated surface (evaporator) that condenses moisture from the atmosphere;

(2) A refrigerating system, including an electric motor;

(3) An air-circulating fan; and

(4) Means for collecting or disposing of the condensate.

* * * * *

External power supply means an external power supply circuit that is used to convert household electric current into DC current or lower-voltage AC current to operate a consumer product.

* * * * *

Pin-based means (1) the base of a fluorescent lamp, that is not integrally ballasted and that has a plug-in lamp base, including multi-tube, multibend, spiral, and circline types, or (2) a socket that holds such a lamp.

* * * * *

■ 3. Section 430.22 is amended by adding new paragraphs (b)(9), (b)(10), and (b)(11) to read as follows:

§ 430.22 Reference Sources.

* * * * *

(b) * * *

(9) Environmental Protection Agency (EPA), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, (202) 272–0167.

1. ''ENERGY STAR Testing Facility Guidance Manual: Building a Testing Facility and Performing the Solid State Test Method for ENERGY STAR Qualified Ceiling Fans,'' Version 1.1, December 9, 2002.

2. ''ENERGY STAR Program Requirements for Residential Light Fixtures,'' Version 4.0, issued January 10, 2005.

3. ''ENERGY STAR Program Requirements for Dehumidifiers,'' effective January 1, 2001.

4. ''Test Methodology for Determining the Energy Performance of Battery Charging Systems,'' December 2005.

(10) U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Forrestal Building, Room 1J–018 (Resource Room of the Building Technologies Program), 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–9127.

1. ''ENERGY STAR Program Requirements for [Compact Fluorescent Lamps] CFLs,'' Version 3.0, issued October 30, 2003.

2. ''ENERGY STAR Program Requirements for [Compact Fluorescent Lamps] CFLs,'' Version August 9, 2001.

(11) California Energy Commission, 1516 Ninth Street, MS–25, Sacramento, CA 95814, (916) 654–4091.

1. ''Test Method for Calculating the Energy Efficiency of Single-Voltage External Ac-Dc and Ac-Ac Power Supplies,'' August 11, 2004.

* * * * *

■ 4. Section 430.23 is amended by revising the section heading, adding new paragraphs (w), (x), (y), (z), (aa), and (bb) to read as follows:

§ 430.23 Test procedures for the measurement of energy and water consumption.

* * * * *

(w) *Ceiling fans.* The airflow and airflow efficiency for ceiling fans, expressed in cubic feet per minute (CFM) and CFM per watt (CFM/watt), respectively, shall be measured in accordance with section 4 of appendix U of this subpart.

(x) *Ceiling fan light kits.* The efficacy, expressed in lumens per watt (lumens/watt), for ceiling fan light kits with sockets for medium screw base lamps or pin-based fluorescent lamps shall be measured in accordance with section 4 of appendix V of this subpart.

(y) *Medium Base Compact Fluorescent Lamps.* The initial efficacy, lumen maintenance at 1,000 hours, lumen maintenance at 40-percent of rated life, rapid cycle stress test, and lamp life shall be measured in accordance with section 4 of appendix W of this subpart.

(z) *Dehumidifiers.* The energy factor for dehumidifiers, expressed in liters per kilowatt hour (L/kWh), shall be measured in accordance with section 4 of appendix X of this subpart.

(aa) *Battery Chargers.* The energy consumption of a battery charger, expressed as the nonactive energy ratio, shall be measured in accordance with section 4 of appendix Y of this subpart.

(bb) *External Power Supplies.* The energy consumption of an external power supply, including active mode efficiency in a percentage and the no-load energy consumption in watts, shall be measured in accordance with section 4 of appendix Z of this subpart.

■ 5. Subpart B of part 430 is amended by adding new appendices U, V, W, X, Y, and Z, to read as follows:

Appendix U to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Ceiling Fans

1. *Scope.* This appendix covers the test requirements used to measure the energy performance of ceiling fans.

2. *Definitions:*

a. *Airflow* means the rate of air movement at a specific fan-speed setting expressed in cubic feet per minute (CFM).

b. *Airflow efficiency* means the ratio of airflow divided by power at a specific ceiling fan-speed setting expressed in CFM per watt (CFM/watt).

3. *Test Apparatus and General Instructions:* The test apparatus and instructions for testing ceiling fans shall conform to the requirements specified in Chapter 3, ''Air-Delivery Room Construction and Preparation,'' Chapter 4, ''Equipment Set-up and Test Procedure,'' and Chapter 6, ''Definitions and Acronyms,'' of the EPA's ''ENERGY STAR Testing Facility Guidance Manual: Building a Testing Facility and Performing the Solid State Test Method for ENERGY STAR Qualified Ceiling Fans,'' Version 1.1, December 9, 2002 (Incorporated by reference, see § 430.22). Record measurements at the resolution of the test instrumentation. Round off calculations to the same number of significant digits as the previous step. Round the final energy consumption value to the nearest whole number as follows:

(i) A fractional number at or above the midpoint between the two consecutive whole numbers shall be rounded up to the higher of the two whole numbers; or

(ii) A fractional number below the midpoint between the two consecutive whole numbers shall be rounded down to the lower of the two whole numbers.

4. *Test Measurement:* Measure the airflow and airflow efficiency for ceiling fans, expressed in cubic feet per minute (CFM) and CFM per watt (CFM/watt), in accordance with the test requirements specified in Chapter 4, ''Equipment Setup and Test Procedure,'' of the EPA's ''ENERGY STAR Testing Facility Guidance Manual: Building a Testing Facility and Performing the Solid State Test Method for ENERGY STAR Qualified Ceiling Fans,'' Version 1.1, December 9, 2002 (Incorporated by reference, see § 430.22). In performing the airflow test, measure ceiling fan power using a RMS sensor capable of measuring power with an accuracy of ±1 %. Prior to using the sensor and sensor software it has selected, the test laboratory shall verify performance of the sensor and sensor software. Measure power input at a point that includes all power consuming components of the ceiling fan (but without any attached light kit energized). Measure power at the rated voltage that represents normal operation continuously over the time period for which the airflow test is conducted, and report the average value of the power measurement in watts (W). Use the average value of power input to calculate the airflow efficiency in CFM/W.

Appendix V to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Ceiling Fan Light Kits

1. *Scope:* This appendix covers the test requirements used to measure the energy performance of ceiling fan light kits.

2. *Definitions:*

a. *Input power* means the actual total power used by all lamp(s) and ballast(s) of the light kit during operation, expressed in watts (W) and measured using the lamp and ballast packaged with the kit.

b. *Lamp ballast platform* means a pairing of one ballast with one or more lamps that can operate simultaneously on that ballast. A unique platform is defined by the manufacturer and model number of the ballast and lamp(s) and the quantity of lamps that operate on the ballast.

c. *Lamp lumens* means a measurement of luminous flux expressed in lumens and measured using the lamp and ballast shipped with the fixture.

d. *System efficacy per lamp ballast platform* means the ratio of measured lamp lumens expressed in lumens and measured input power expressed in watts (W).

3. *Test Apparatus and General Instructions:*

(a) The test apparatus and instruction for testing screw base lamps packaged with ceiling fan light kits that have medium screw base sockets shall conform to the requirements specified in section 2, ''Definitions,'' section 3, ''Referenced Standards,'' and section 4, ''CFL Requirements for Testing'' of DOE's ''ENERGY STAR Program Requirements for [Compact Fluorescent Lamps] CFLs,'' Version 3.0, (Incorporated by reference, see § 430.22). Record measurements at the resolution of the test instrumentation. Round off calculations to the same number of significant digits as the previous step. Round off the final energy consumption value to a whole number as follows:

(i) A fractional number at or above the midpoint between the two consecutive whole numbers shall be rounded up to the higher of the two whole numbers; or

(ii) A fractional number below the midpoint between the two consecutive whole numbers shall be rounded down to the lower of the two whole numbers.

(b) The test apparatus and instruction for testing pin-based fluorescent lamps packaged with ceiling fan light kits that have pin-based sockets shall conform to the requirements specified in section 1, ''Definitions,'' and section 3, ''Energy Efficiency Specifications for Qualifying Products'' of the EPA's ''ENERGY STAR Program Requirements for Residential Light Fixtures,'' Version 4.0, (Incorporated by reference, see § 430.22). Record measurements at the resolution of the test instrumentation. Round off calculations to the same number of significant digits as the previous step. The final energy consumption value shall be rounded to a whole number as follows:

(i) A fractional number at or above the midpoint between the two consecutive whole numbers shall be rounded up to the higher of the two whole numbers; or

(ii) A fractional number below the midpoint between the two consecutive whole numbers shall be rounded down to the lower of the two whole numbers.

4. *Test Measurement:*

(a) For screw base compact fluorescent lamps packaged with ceiling fan light kits that have medium screw base sockets, measure the efficacy, expressed in lumens per watt, in accordance with the test requirements specified in section 4, ''CFL Requirements for Testing,'' of the ''ENERGY STAR Program Requirements for Compact Fluorescent Lamps,'' Version 3.0 (Incorporated by reference, see § 430.22).

(b) For pin-based compact fluorescent lamps packaged with ceiling fan light kits that have pin-based sockets, measure the efficacy, expressed in lumens per watt, in accordance with the test requirements specified in section 3, ''Energy-Efficiency Specifications for Qualifying Products'' and Table 3 in section 4, ''Qualification Process, Testing Facilities, Standards, and Documentation,'' of the ''ENERGY STAR Program Requirements for Residential Light Fixtures,'' Version 4.0 (Incorporated by reference, see § 430.22).

Appendix W to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Medium Base Compact Fluorescent Lamps

1. *Scope:* This appendix covers the test requirements used to measure the initial efficacy, lumen maintenance at 1,000 hours, lumen maintenance at 40 percent of rated life, rapid cycle stress, and lamp life of medium base compact fluorescent lamps.

2. *Definitions:*

a. *Average rated life* means the length of time declared by the manufacturer at which 50 percent of any large number of units of a lamp reaches the end of their individual lives.

b. *Initial performance values* means the photometric and electrical characteristics of the lamp at the end of 100 hours of operation. Such values include the initial efficacy, the rated luminous flux and the rated lumen output.

c. *Lumen maintenance* means the luminous flux or lumen output at a given time in the life of the lamp and expressed as a percentage of the rated luminous flux or rated lumen output, respectively.

d. *Rated luminous flux or rated lumen output* means the initial lumen rating (100 hour) declared by the manufacturer, which consists of the lumen rating of a lamp at the end of 100 hours of operation.

e. *Rated supply frequency* means the frequency marked on the lamp.

f. *Rated voltage* means the voltage marked on the lamp.

g. *Rated wattage* means the wattage marked on the lamp.

h. *Self-ballasted compact fluorescent lamp* means a compact fluorescent lamp unit that incorporates, permanently enclosed, all elements that are necessary for the starting and stable operation of the lamp, and does not include any replaceable or interchangeable parts.

3. *Test Apparatus and General Instructions:* The test apparatus and instructions for testing medium base compact fluorescent lamps shall conform to the requirements specified in section 2, ''Definitions,'' section 3, ''Referenced Standards,'' and section 4, ''CFL Requirements for Testing,'' of DOE's ''ENERGY STAR Program Requirements for [Compact Fluorescent Lamps] CFLs,'' Version dated August 9, 2001, (commonly referred to as Version 2.0), (Incorporated by reference, see § 430.22). Record measurements at the resolution of the test instrumentation. Round off calculations to the same number of significant digits as the previous step. Round the final energy consumption value, as applicable, to the nearest decimal place or whole number as follows:

(i) A fractional number at or above the midpoint between two consecutive decimal places or whole numbers shall be rounded up to the higher of the two decimal places or whole numbers; or

(ii) A fractional number below the midpoint between two consecutive decimal places or whole numbers shall be rounded down to the lower of the two decimal places or whole numbers. Round the final initial efficacy to one decimal place. Round the final lumen maintenance at 1,000 hours to a whole number. Round the final lumen maintenance at 40 percent of rated life, the final rapid cycle stress, and the final lamp life for medium base compact fluorescent lamps to whole numbers.

4. *Test Measurement:* Measure the initial efficacy expressed in lumens per watt; lumen maintenance at 1,000 hours expressed in lumens; lumen maintenance at 40 percent of rated life expressed in lumens; rapid cycle stress expressed in the number of lamps that meet or exceed the minimum number of cycles; and lamp life expressed in hours in accordance with the test requirements specified in section 4, ''CFL Requirements for Testing'' of DOE's ''ENERGY STAR Program Requirements for [Compact Fluorescent Lamps] CFLs,'' Version dated August 9, 2001 (Incorporated by reference, see § 430.22).

Appendix X to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Dehumidifiers

1. *Scope:* This appendix covers the test requirements used to measure the energy performance of dehumidifiers.

2. *Definitions:*

a. *Product capacity for dehumidifiers* means a measure of the ability of a dehumidifier to remove moisture from its surrounding atmosphere, measured in pints collected per 24 hours of continuous operation.

b. *Energy factor for dehumidifiers* means a measure of energy efficiency of a dehumidifier calculated by dividing the water removed from the air by the energy consumed, measured in liters per kilowatt hour (L/kWh).

3. *Test Apparatus and General Instructions:* The test apparatus and instructions for testing dehumidifiers shall conform to the requirements specified in section 1, ''Definitions,'' section 2, ''Qualifying Products,'' and section 4, ''Test Criteria,'' of the EPA's ''ENERGY STAR Program Requirements for Dehumidifiers,'' effective January 1, 2001 (Incorporated by reference, see § 430.22). Record

measurements at the resolution of the test instrumentation. Round off calculations to the same number of significant digits as the previous step. Round the final minimum energy factor value to two decimal places as follows:

(i) A fractional number at or above the midpoint between two consecutive decimal places shall be rounded up to the higher of the two decimal places; or

(ii) A fractional number below the midpoint between two consecutive decimal places shall be rounded down to the lower of the two decimal places.

4. *Test Measurement:* Measure the energy factor for dehumidifiers, expressed in liters per kilowatt hour (L/kWh) and product capacity in pints per day (pints/day), in accordance with the test requirements specified in section 4, ''Test Criteria,'' of EPA's ''ENERGY STAR Program Requirements for Dehumidifiers,'' effective January 1, 2001 (Incorporated by reference, see § 430.22).

Appendix Y to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Battery Chargers

1. *Scope:* This appendix covers the test requirements used to measure battery charger energy consumption.

2. *Definitions:* The following definitions are for the purposes of understanding terminology associated with the test method for measuring battery charger energy consumption.[1]

a. *Accumulated nonactive energy* is the sum of the energy, in watt-hours, consumed by the battery charger in battery-maintenance mode and standby mode over time periods defined in the test procedure.

b. *Active mode* is the condition in which the battery is receiving the main charge, equalizing cells, and performing other one-time or limited-time functions necessary for bringing the battery to the fully charged state.

c. *Battery* or *battery pack* is an assembly of one or more rechargeable cells intended to provide electrical energy to a consumer product, and may be in one of the following forms: (a) detachable battery: a battery that is contained in a separate enclosure from the consumer product and is intended to be removed or disconnected from the consumer product for recharging; or (b) integral battery: a battery that is contained within the consumer product and is not removed from the consumer product for charging purposes.

d. *Battery energy* is the energy, in watt-hours, delivered by the battery under the specified discharge conditions in the test procedure.

e. *Battery maintenance mode* or *maintenance mode* is the mode of operation when the battery charger is connected to the main electricity supply and the battery is fully charged, but is still connected to the charger.

f. *Energy ratio* or *nonactive energy ratio* means the ratio of the accumulated nonactive energy divided by the battery energy.

g. *Multi-port charger* means a battery charger that is capable of simultaneously charging two or more batteries. These chargers also may have multi-voltage capability, allowing two or more batteries of different voltages to charge simultaneously.

h. *Multi-voltage a la carte charger* means a separate battery charger that is individually packaged without batteries, and is able to charge a variety of batteries of different nominal voltages.

i. *Standby mode* or *no-load mode* means the mode of operation when the battery charger is connected to the main electricity supply and the battery is not connected to the charger.

3. *Test Apparatus and General Instructions:* The test apparatus, standard testing conditions, and instructions for testing battery chargers shall conform to the requirements specified in section 4, ''Standard Testing Conditions,'' of the EPA's ''Test Methodology for Determining the Energy Performance of Battery Charging Systems,'' December 2005 Incorporated by reference, see § 430.22). The test voltage specified in section 4.1.1, ''Voltage,'' shall be 115 volts, 60 Hz. The battery charger should be tested using the full test methodology, which has a test duration of 48 hours. In section 4.3.1, ''Precision Requirements,'' append this sentence to the end: ''The test equipment must be capable of accounting for crest factor and frequency spectrum in its measurement of the UUT input current.''

4. *Test Measurement:*

(a) Inactive Mode Energy Consumption Measurement. The measurement of the battery charger energy ratio shall conform to the requirements specified in section 5, ''Determining BCS Energy Ratio,'' of the EPA's ''Test Methodology for Determining the Energy Performance of Battery Charging Systems, December 2005'' (Incorporated by reference, see § 430.22).

(b) Active Mode Energy Consumption Measurement. [RESERVED]

Appendix Z to Subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of External Power Supplies

1. *Scope:* This appendix covers the test requirements used to measure the active mode efficiency and the no-load energy consumption of external power supplies.

2. *Definitions:* The following definitions are for the purposes of understanding terminology associated with the test method for measuring external power supply energy consumption.[1]

a. *Active mode* is the mode of operation when the external power supply is connected to the main electricity supply and the output is connected to a load.

b. *Active mode efficiency* is the ratio, expressed as a percentage, of the total real output power produced by a power supply to the real input power required to produce it.

c. *No load mode* means the mode of operation when the external power supply is connected to the main electricity supply and the output is not connected to a load.

d. *Single voltage external AC–AC power supply* means an external power supply that is designed to convert line voltage AC input into lower voltage AC output and is able to convert to only one AC output voltage at a time.

e. *Single voltage external AC–DC power supply* means an external power supply that is designed to convert line voltage AC input into lower voltage DC output and is able to convert to only one DC output voltage at a time.

f. *Total harmonic distortion,* expressed as a percent, is the RMS value of an AC signal after the fundamental component is removed and interharmonic components are ignored, divided by the RMS value of the fundamental component.

g. *True power factor* is the ratio of the active (also referred to as real) power consumed in watts to the apparent power, drawn in volt-amperes.

3. *Test Apparatus and General Instructions:* The test apparatus, standard testing conditions, and instructions for testing external power supplies shall conform to the requirements specified in section 4, ''General Conditions for Measurement,'' of the CEC's ''Test Method for Calculating the Energy Efficiency of Single-Voltage External AC–DC and AC–AC Power Supplies,'' August 11, 2004. The test voltage specified in section 4.d, ''Test Voltage,'' shall only be 115 volts, 60 Hz.

4. *Test Measurement:* The measurement of the external power supply active mode efficiency and no-load energy consumption shall conform to the requirements specified in section 5, ''Measurement Approach,'' of the CEC's ''Test Method for Calculating the Energy Efficiency of Single-Voltage External AD–DC and AC–AC Power Supplies,'' August 11, 2004 (Incorporated by reference, see § 430.22).

■ 6. Section 430.32 is amended by revising the table in paragraph (u) to read as follows:

§ 430.32 Energy and water conservation standards and effective dates.

* * * * *

(u) * * *

[1] For clarity on any other terminology used in the test method, please refer to IEEE Standard 1515–2000.

Factor	Requirements
Lamp Power (Watts) & Configuration [1]	Minimum Efficacy: lumens/watt(Based upon initial lumen data). [2]
Bare Lamp:	
Lamp Power <15	45.0.
Lamp Power ≥15	60.0.
Covered Lamp (no reflector):	
Lamp Power <15	40.0.
15≥ Lamp Power <19	48.0.
19≥ Lamp Power <25	50.0
Lamp Power ≥25	55.0.
1,000-hour Lumen Maintenance	The average of at least 5 lamps must be a minimum 90.0% of initial (100-hour) lumen output @ 1,000 hours of rated life.
Lumen Maintenance	80.0% of initial (100-hour) rating at 40 percent of rated life (per ANSI C78.5 Clause 4.10).
Rapid Cycle Stress Test	Per ANSI C78.5 and IESNA LM–65 (clauses 2,3,5, and 6). *Exception:* Cycle times must be 5 minutes on, 5 minutes off. Lamp will be cycled once for every two hours of rated life. At least 5 lamps *must meet or exceed* the minimum number of cycles.
Average Rated Lamp Life	≥6,000 hours as declared by the manufacturer on packaging. At 80% of rated life, statistical methods may be used to confirm lifetime claims based on sampling performance.

[1] Take performance and electrical requirements at the end of the 100-hour aging period according to ANSI Standard C78.5. The lamp efficacy shall be the average of the lesser of the lumens per watt measured in the base up and/or other specified positions. Use wattages place on packaging to select proper specification efficacy in this table, not measured wattage. Labeled wattages are for reference only.

[2] Efficacies are based on measured values for lumens and wattages from pertinent test data. Wattages and lumens placed on packages may not be used in calculation and are not governed by this specification. For multi-level or dimmable systems, measurements shall be at the highest setting. Acceptable measurement error is ±3%.

* * * * *

PART 431—ENERGY EFFICIENCY PROGRAM FOR CERTAIN COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 7. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 6291–6317.

■ 8. Section 431.2 is amended by revising the definition of ''Covered equipment,'' to read as follows:

§ 431.2 Definitions.

* * * * *

Covered equipment means any electric motor, as defined in § 431.12; commercial heating, ventilating, and air conditioning, and water heating product (HVAC & WH product), as defined in § 431.172; commercial refrigerator, freezer, or refrigerator-freezer, as defined in § 431.62; automatic commercial ice maker, as defined in § 431.132; commercial clothes washer, as defined in § 431.152; distribution transformer, as defined in § 431.192; illuminated exit sign, as defined in § 431.202; traffic signal module or pedestrian module, as defined in § 431.222; unit heater, as defined in § 431.242; commercial prerinse spray valve, as defined in § 431.262; mercury vapor lamp ballast, as defined in § 431.282; or refrigerated bottled or canned beverage vending machine, as defined in § 431.292.

* * * * *

■ 9. Section 431.62 is amended by adding, in alphabetical order, new definitions for ''Basic model,'' ''Ice-cream freezer,'' and ''Test package,'' to read as follows:

§ 431.62 Definitions concerning commercial refrigerators, freezers, and refrigerator-freezers.

Basic model means, with respect to commercial refrigerators, freezers, and refrigerator-freezers, all units of a given type of commercial refrigerator, freezer, or refrigerator-freezer (or class thereof) manufactured by one manufacturer that have the same primary energy source, which have electrical characteristics that are essentially identical, and which do not have any differing electrical, physical, or functional characteristics that affect energy consumption.

* * * * *

Ice-cream freezer means a commercial freezer that is designed to operate at or below −5 °F (−21 °C) and that the manufacturer designs, markets, or intends for the storing, displaying, or dispensing of ice cream.

* * * * *

Test package means a packaged material that is used as a standard product temperature-measuring device.

■ 10. Subpart C of part 431 is amended by revising the undesignated center heading following § 431.62 and adding new §§ 431.63 and 431.64, to read as follows:

Test Procedures

§ 431.63 Materials incorporated by reference.

(a) *General.* The Department incorporates by reference the following test procedures into subpart C of part 431. The Director of the Federal Register has approved the material listed in paragraph (b) of this section for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Any subsequent amendment to this material by the standard-setting organization will not affect the DOE test procedures unless DOE amends its test procedures. The Department incorporates the material as it exists on the date of the approval by the Federal Register and a notice of any change in the material will be published in the **Federal Register**.

(b) *Test procedures incorporated by reference.* (1) American National Standards Institute (ANSI)/Association of Home Appliance Manufacturers (AHAM) Standard HRF–1–2004, ''Energy, Performance and Capacity of Household Refrigerators, Refrigerator-Freezers and Freezers.''

(2) Air-Conditioning and Refrigeration Institute (ARI) Standard 1200–2006, ''Performance Rating of Commercial Refrigerated Display Merchandisers and Storage Cabinets.''

(c) *Availability of references*—(1) *Inspection of test procedures.* The test procedures incorporated by reference are available for inspection at:

(i) National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) U.S. Department of Energy, Forrestal Building, Room 1J–018 (Resource Room of the Building Technologies Program), 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–9127, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

(2) *Obtaining copies of standards.* (i) Anyone can purchase a copy of ANSI/AHAM HRF–1–2004, ''Energy, Performance and Capacity of Household Refrigerators, Refrigerator-Freezers and Freezers,'' from the American National Standards Institute, 1819 L Street, NW., 6th floor, Washington, DC 20036, (202) 293–8020, or *http://www.ansi.org.*

(ii) Anyone can obtain a copy of ARI Standard 1200–2006, ''Performance Rating of Commercial Refrigerated Display Merchandisers and Storage Cabinets,'' from the Air-Conditioning and Refrigeration Institute, 4100 N. Fairfax Dr., Suite 200, Arlington, VA 22203 or *http://www.ari.org/std/standards.html.*

§ 431.64 Uniform test method for the measurement of energy consumption of commercial refrigerators, freezers, and refrigerator-freezers.

(a) *Scope.* This section provides the test procedures for measuring, pursuant to EPCA, the daily energy consumption in kilowatt hours per day (kWh/day) for a given product category and volume or total display area of commercial refrigerators, freezers, and refrigerator-freezers.

(b) *Testing and calculations.* (1) Determine the daily energy consumption of each covered commercial refrigerator, freezer, or refrigerator-freezer by conducting the test procedure set forth in the Air-Conditioning and Refrigeration Institute (ARI) Standard 1200–2006, ''Performance Rating of Commercial Refrigerated Display Merchandisers and Storage Cabinets,'' section 3, ''Definitions,'' section 4, ''Test Requirements,'' and section 7, ''Symbols and Subscripts.'' (Incorporated by reference, see § 431.63) For each commercial refrigerator, freezer, or refrigerator-freezer with a self-contained condensing unit, also use ARI Standard 1200–2006, section 6, ''Rating Requirements for Self-contained Commercial Refrigerated Display Merchandisers and Storage Cabinets.'' (Incorporated by reference, see § 431.63) For each commercial refrigerator, freezer, or refrigerator-freezer with a remote condensing unit, also use ARI Standard 1200–2006, section 5, ''Rating Requirements for Remote Commercial Refrigerated Display Merchandisers and Storage Cabinets.'' (Incorporated by reference, see § 431.63)

(2) Conduct the testing required in paragraphs (b)(1) of this section, and determine the daily energy consumption, at the applicable integrated average temperature in the following table. The integrated average temperature is determined using the required test method.

Category	Test procedure	Integrated average temperatures
(i) Refrigerator with Solid Door(s)	ARI Standard 1200–2006*	38 °F (±2 °F).
(ii) Refrigerator with Transparent Door(s)	ARI Standard 1200–2006*	38 °F (±2 °F).
(iii) Freezer with Solid Door(s)	ARI Standard 1200–2006*	0 °F (±2 °F).
(iv) Freezer with Transparent Door(s)	ARI Standard 1200–2006*	0 °F (±2 °F).
(v) Refrigerator-Freezer with Solid Door(s)	ARI Standard 1200–2006*	38 °F (±2 °F) for refrigerator compartment. 0 °F (±2 °F) for freezer compartment.
(vi) Commercial Refrigerator with a Self-Contained Condensing Unit Designed for Pull-Down Temperature Applications and Transparent Doors.	ARI Standard 1200–2006*	38 °F (±2 °F).
(vii) Ice-Cream Freezer	ARI Standard 1200–2006*	−15.0 °F (±2 °F).
(viii) Commercial Refrigerator, Freezer, and Refrigerator-Freezer with a Self-Contained Condensing Unit and without Doors.	ARI Standard 1200–2006*	(A) For low temperature applications, the integrated average temperature of all test package averages shall be 0 °F (±2 °F). (B) For medium temperature applications, the integrated average temperature of all test package averages shall be 38.0 °F (±2 °F).
(ix) Commercial Refrigerator, Freezer, and Refrigerator-Freezer with a Remote Condensing Unit.	ARI Standard 1200–2006*	(A) For low temperature applications, the integrated average temperature of all test package averages shall be 0 °F (±2 °F). (B) For medium temperature applications, the integrated average temperature of all test package averages shall be 38.0 °F (±2 °F).

* Incorporated by reference, see § 431.63.

(3) Determine the volume of each covered commercial refrigerator, freezer, or refrigerator-freezer using the methodology set forth in the ANSI/AHAM HRF–1–2004, ''Energy, Performance and Capacity of Household Refrigerators, Refrigerator-Freezers and Freezers,'' (Incorporated by reference, see § 431.63) section 3.21, ''Volume,'' sections 4.1 through 4.3, ''Method for Computing Total Refrigerated Volume and Total Shelf Area of Household Refrigerators and Household Wine Chillers,'' and sections 5.1 through 5.3, ''Method for Computing Total Refrigerated Volume and Total Shelf Area of Household Freezers.''

■ 11. Section 431.95 is amended by revising paragraph (b)(2) to read as follows:

§ 431.95 Materials incorporated by reference.

* * * * *

(b) * * *

(2) ARI Standard 340/360–2004, ''Performance Rating of Commercial and Industrial Unitary Air-Conditioning and Heat Pump Equipment.''

* * * * *

■ 12. Section 431.96 is revised to read as follows:

§ 431.96 Uniform test method for the measurement of energy efficiency of small, large, and very large commercial package air conditioning and heating equipment, packaged terminal air conditioners, and packaged terminal heat pumps.

(a) *Scope.* This section contains test procedures for measuring, pursuant to EPCA, the energy efficiency of any small, large, or very large commercial package air-conditioning and heating equipment, packaged terminal air conditioner, or packaged terminal heat pump.

(b) *Testing and calculations.* Determine the energy efficiency of each covered product by conducting the test procedure(s) listed in the rightmost column of Table 1 of this section, that apply to the energy efficiency descriptor for that product, category, and cooling capacity.

TABLE 1 TO § 431.96.—TEST PROCEDURES FOR ALL SMALL COMMERCIAL PACKAGE AIR-CONDITIONING AND HEATING EQUIPMENT, FOR LARGE COMMERCIAL PACKAGE AIR-CONDITIONING AND HEATING EQUIPMENT, FOR VERY LARGE COMMERCIAL PACKAGE AIR-CONDITIONING AND HEATING EQUIPMENT, AND FOR PACKAGED TERMINAL AIR-CONDITIONERS, AND PACKAGED TERMINAL HEAT PUMPS

Product	Category	Cooling capacity	Energy efficiency descriptor	Use tests, conditions and procedures [1] in
Small Commercial Packaged Air Conditioning and Heating Equipment.	Air Cooled, 3 Phase, AC and HP.	<65,000 Btu/h	SEER	ARI Standard 210/240–2003.
			HSPF	ARI Standard 210/240–2003.
	Air Cooled AC and HP.	≥65,000 Btu/h and <135,000 Btu/h	EER	ARI Standard 340/360–2004.
			COP	ARI Standard 340/360–2004.
	Water Cooled and Evaporatively Cooled AC.	<65,000 Btu/h	EER	ARI Standard 210/240–2003.
		≥65,000 Btu/h and <135,000 Btu/h.	EER	ARI Standard 340/360–2004.
	Water-Source HP	<135,000 Btu/h	EER	ISO Standard 13256–1 (1998).
			COP	ISO Standard 13256–1 (1998).
Large Commercial Packaged Air-Conditioning and Heating Equipment.	Air Cooled AC and HP.	≥135,000 Btu/h and <240,000 Btu/h.	EER	ARI Standard 340/360–2004.
			COP	ARI Standard 340/360–2004.
	Water Cooled AC	≥135,000 Btu/h and <240,000 Btu/h.	EER	ARI Standard 340/360–2004.
	Evaporatively Cooled AC.	≥135,000 Btu/h and <240,000 Btu/h.	EER	ARI Standard 340/360–2004.
Very Large Commercial Packaged Air-Conditioning and Heating Equipment.	Air Cooled AC and HP.	≥240,000 Btu/h and <760,000 Btu/h.	EER	ARI Standard 340/360–2004.
			COP	ARI Standard 340/360–2004.
Packaged Terminal Air-Conditioners and Heat Pumps.	AC and HP	All	EER	ARI Standard 310/380–2004.
	HP	All	COP	ARI Standard 310/380–2004.

[1] Incorporated by reference, see § 431.95.

■ 13. Section 431.97 is amended by revising paragraph (a) (Tables 1 and 2 remain unchanged), (b), and amending the table to paragraph (b) by revising the third entry under the ''Product'' column to read as follows:

§ 431.97 Energy efficiency standards and their effective dates.

(a) Each commercial air conditioner and heat pump manufactured on or after January 1, 1994 (except for large commercial package air-conditioning and heating equipment, for which the effective date is January 1, 1995) and before January 1, 2010, in the case of air-cooled equipment with a capacity equal to or greater than 65,000 Btu per hour, must meet the applicable minimum energy efficiency standard level(s) set forth in Tables 1 and 2 of this section.

* * * * *

(b) Air-cooled commercial package air-conditioning and heating equipment manufactured on or after January 1, 2010, with cooling capacities equal to or greater than 65,000 Btu/h and less than 760,000 Btu/h, shall have Energy Efficiency Ratio and Coefficient of Performance no less than:

Product	Cooling capacity (Btu/h)	Category	Efficiency level†
* * * * *	*	*	*
Very large commercial package air-conditioning and heating equipment (air-cooled)			
* * * * *	*	*	*

* * * * *

■ 14. Section 431.132 is amended by adding in alphabetical order new definitions for ''Basic model,'' ''Cube type ice,'' ''Energy use,'' ''Ice-making head,'' ''Maximum condenser water use,'' ''Remote compressor,'' ''Remote condensing,'' and ''Self-contained'' to read as follows:

§ 431.132 Definitions concerning automatic commercial ice makers.

* * * * *

Basic model means, with respect to automatic commercial ice makers, all units of a given type of automatic commercial ice maker (or class thereof) manufactured by one manufacturer and which have the same primary energy

source, which have electrical characteristics that are essentially identical, and which do not have any differing electrical, physical, or functional characteristics that affect energy consumption.

Cube type ice means ice that is fairly uniform, hard, solid, usually clear, and generally weighs less than two ounces (60 grams) per piece, as distinguished from flake, crushed, or fragmented ice.

Energy use means the total energy consumed, stated in kilowatt hours per one-hundred pounds (kWh/100 lb) of ice and stated in multiples of 0.1. For remote condensing automatic commercial ice makers, total energy consumed shall include condenser fan power.

* * * * *

Ice-making head means automatic commercial ice makers that do not contain integral storage bins, but are generally designed to accommodate a variety of bin capacities. Storage bins entail additional energy use not included in the reported energy consumption figures for these units.

Maximum condenser water use means the maximum amount of water used by the condensing unit (if water-cooled), stated in gallons per 100 pounds (gal/100 lb) of ice, in multiples of 1.

Remote compressor means a type of automatic commercial ice maker in which the ice-making mechanism and compressor are in separate sections.

Remote condensing means a type of automatic commercial ice maker in which the ice-making mechanism and condenser or condensing unit are in separate sections.

Self-contained means a type of automatic commercial ice maker in which the ice-making mechanism and storage compartment are in an integral cabinet.

■ 15. Subpart H of part 431 is amended by revising the undesignated center heading following § 431.132 and adding new §§ 431.133 and 431.134, to read as follows:

Test Procedures

§ 431.133 Materials incorporated by reference.

(a) *General.* The Department incorporates by reference the following test procedures into subpart H of part 431. The Director of the Federal Register has approved the material listed in paragraph (b) of this section for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Any subsequent amendment to this material by the standard-setting organization will not affect the DOE test procedures unless DOE amends its test procedures. The Department incorporates the material as it exists on the date of the approval by the Federal Register and a notice of any change in the material will be published in the **Federal Register**.

(b) *Test procedures incorporated by reference.* (1) Air-Conditioning and Refrigeration Institute (ARI) Standard 810–2003, ''Performance Rating of Automatic Commercial Ice-Makers.''

(2) American National Standards Institute (ANSI)/American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 29–1988 (RA 2005), ''Methods of Testing Automatic Ice Makers.''

(c) *Availability of references*—(1) *Inspection of test procedures.* The test procedures incorporated by reference are available for inspection at:

(i) National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) U.S. Department of Energy, Forrestal Building, Room 1J–018 (Resource Room of the Building Technologies Program), 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–9127, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

(2) *Obtaining copies of test procedures.* (i) Anyone can obtain a copy of ARI Standard 810–2003 from the Air-Conditioning and Refrigeration Institute, 4100 N. Fairfax Dr., Suite 200, Arlington, VA 22203 or *http://www.ari.org/std/standards.htm.*

(ii) Anyone can purchase a copy of ASHRAE Standard 29–1988 (RA 2005), ''Methods of Testing Automatic Ice Makers,'' from the American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc., 1791 Tullie Circle, NE, Atlanta, GA 30329, (404) 636–8400, or *http://www.ashrae.org.*

§ 431.134 Uniform test methods for the measurement of energy consumption and water consumption of automatic commercial ice makers.

(a) *Scope.* This section provides the test procedures for measuring, pursuant to EPCA, the energy use in kilowatt hours per 100 pounds of ice (kWh/100 lbs ice) and the condenser water use in gallons per 100 pounds of ice (gal/100 lbs ice).

(b) *Testing and Calculations.* Determine the energy consumed and the condenser water use rate of each covered product by conducting the test procedures, set forth in the Air-Conditioning and Refrigeration Institute's Standard 810–2003, ''Performance Rating of Automatic Commercial Ice-Makers,'' section 4, ''Test Requirements,'' and section 5, ''Rating Requirements.'' (Incorporated by reference, see § 431.133) Do not use the formula in section 8.3 of ANSI/ASHRAE Standard 29–1988 (RA 2005) for calculating the power consumption, but instead calculate the energy use rate (kWh/100 lbs Ice) by dividing the energy consumed during testing by the total mass of the ice produced during the time period over which energy consumption is measured, normalized to 100 pounds of ice as follows:

$$\text{Energy Consumption Rate (per 100 lbs ice)} = \frac{\text{Energy Consumed During Testing (kWh)}}{\text{Mass of Ice Collected During Testing (lbs)}} \times 100\%$$

■ 16. Section 431.202 is amended by adding in alphabetical order new definitions for ''Basic model,'' ''Face,'' and ''Input power demand'' to read as follows:

§ 431.202 Definitions concerning illuminated exit signs.

Basic model means, with respect to illuminated exit signs, all units of a given type of illuminated exit sign (or class thereof) manufactured by one manufacturer and which have the same primary energy source, which have electrical characteristics that are essentially identical, and which do not have any differing electrical, physical, or functional characteristics that affect energy consumption.

Face means an illuminated side of an illuminated exit sign.

* * * * *

Input power demand means the amount of power required to

continuously illuminate an exit sign model, measured in watts (W). For exit sign models with rechargeable batteries, input power demand shall be measured with batteries at full charge.

■ 17. Subpart L of part 431 is amended by revising the undesignated center heading following § 431.202 and adding new §§ 431.203 and 431.204, to read as follows:

Test Procedures

§ 431.203 Materials incorporated by reference.

(a) *General.* The Department incorporates by reference the following test procedures into subpart L of part 431. The Director of the Federal Register has approved the material listed in paragraph (b) of this section for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Any subsequent amendment to this material by the standard-setting organization will not affect the DOE test procedures unless and until DOE amends its test procedures. The Department incorporates the material as it exists on the date of the approval by the Federal Register and a notice of any change in the material will be published in the **Federal Register.**

(b) *Test procedure incorporated by reference.* Environmental Protection Agency ''ENERGY STAR Program Requirements for Exit Signs,'' Version 2.0 issued January 1, 1999.

(c) *Availability of reference*—(1) *Inspection of test procedure.* The test procedure incorporated by reference are available for inspection at:

(i) National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) U.S. Department of Energy, Forrestal Building, Room 1J–018 (Resource Room of the Building Technologies Program), 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–9127, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

(2) *Obtaining copies of the standard.* Copies of the Environmental Protection Agency ''ENERGY STAR Program Requirements for Exit Signs,'' Version 2.0, may be obtained from the Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, (202) 272–0167 or at *http://www.epa.gov.*

§ 431.204 Uniform test method for the measurement of energy consumption of illuminated exit signs.

(a) *Scope.* This section provides the test procedure for measuring, pursuant to EPCA, the input power demand of illuminated exit signs. For purposes of this part 431 and EPCA, the test procedure for measuring the input power demand of illuminated exit signs shall be the test procedure specified in § 431.203(b).

(b) *Testing and Calculations.* Determine the energy efficiency of each covered product by conducting the test procedure, set forth in the Environmental Protection Agency's ''ENERGY STAR Program Requirements for Exit Signs,'' Version 2.0, section 4 (Test Criteria), ''Conditions for testing'' and ''Input power measurement.'' (Incorporated by reference, see § 431.203)

■ 18. Section 431.222 is amended by adding in alphabetical order new definitions for ''Basic model,'' ''Maximum wattage,'' and ''Nominal wattage,'' to read as follows:

§ 431.222 Definitions concerning traffic signal modules and pedestrian modules.

Basic model means, with respect to traffic signal modules and pedestrian modules, all units of a given type of traffic signal module or pedestrian module (or class thereof) manufactured by one manufacturer and which have the same primary energy source, which have electrical characteristics that are essentially identical, and which do not have any differing electrical, physical, or functional characteristics that affect energy consumption.

Maximum wattage means the power consumed by the module after being operated for 60 minutes while mounted in a temperature testing chamber so that the lensed portion of the module is outside the chamber, all portions of the module behind the lens are within the chamber at a temperature of 74 °C and the air temperature in front of the lens is maintained at a minimum of 49 °C.

Nominal wattage means the power consumed by the module when it is operated within a chamber at a temperature of 25 °C after the signal has been operated for 60 minutes.

* * * * *

■ 19. Subpart M of part 431 is amended by revising the undesignated center heading following § 431.222 and adding new §§ 431.223 and 431.224, to read as follows:

Test Procedures

§ 431.223 Materials incorporated by reference.

(a) *General.* The Department incorporates by reference the following test procedures into subpart M of part 431. The Director of the Federal Register has approved the material listed in paragraph (b) of this section for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Any subsequent amendment to this material by the standard-setting organization will not affect the DOE test procedures unless and until DOE amends its test procedures. The Department incorporates the material as it exists on the date of the approval by the Federal Register and a notice of any change in the material will be published in the **Federal Register**.

(b) *List of test procedures incorporated by reference.* (1) Environmental Protection Agency, ''ENERGY STAR Program Requirements for Traffic Signals,'' Version 1.1 issued February 4, 2003.

(2) Institute of Transportation Engineers (ITE), ''Vehicle Traffic Control Signal Heads: Light Emitting Diode (LED) Circular Signal Supplement,'' June 27, 2005.

(c) *Availability of references*—(1) *Inspection of test procedures.* The test procedures incorporated by reference are available for inspection at:

(i) National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) U.S. Department of Energy, Forrestal Building, Room 1J–018 (Resource Room of the Building Technologies Program), 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–9127, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

(2) *Obtaining copies of standards.* Standards incorporated by reference may be obtained from the following sources:

(i) Copies of the Environmental Protection Agency ''ENERGY STAR Program Requirements for Traffic Signals,'' Version 1.1, may be obtained from the Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, (202) 272–0167 or at *http://www.epa.gov.*

(ii) Institute of Transportation Engineers, 1099 14th Street, NW., Suite 300 West, Washington, DC 20005–3438, (202) 289–0222, or *ite_staff@ite.org.*

§ 431.224 Uniform test method for the measurement of energy consumption for traffic signal modules and pedestrian modules.

(a) *Scope.* This section provides the test procedures for measuring, pursuant to EPCA, the maximum wattage and nominal wattage of traffic signal modules and pedestrian modules. For purposes of 10 CFR part 431 and EPCA, the test procedures for measuring the maximum wattage and nominal wattage of traffic signal modules and pedestrian modules shall be the test procedures specified in § 431.223(b).

(b) *Testing and Calculations.* Determine the nominal wattage and maximum wattage of each covered traffic signal module or pedestrian module by conducting the test procedure set forth in Environmental Protection Agency, ''ENERGY STAR Program Requirements for Traffic Signals,'' Version 1.1, section 1, ''Definitions,'' and section 4, ''Test Criteria.'' (Incorporated by reference, see § 431.223) Use a wattmeter having an accuracy of ±1% to measure the nominal wattage and maximum wattage of a red and green traffic signal module, and a pedestrian module when conducting the photometric and colormetric tests as specified by the testing procedures in VTCSH 2005.

■ 19a. Amend § 431.226 by revising paragraph (a) to read as follows:

§ 431.226 Energy conservation standards and their effective dates.

* * * * *

(a) Have a nominal wattage and maximum wattage no greater than:

* * * * *

■ 20. Section 431.242 is amended by adding in alphabetical order new definitions for ''Automatic flue damper,'' ''Automatic vent damper,'' ''Intermittent ignition device,'' ''Power venting,'' and ''Warm air furnace'' to read as follows:

§ 431.242 Definitions concerning unit heaters.

Automatic flue damper means a device installed in the flue outlet or in the inlet of or upstream of the draft control device of an individual, automatically operated, fossil fuel-fired appliance that is designed to automatically open the flue outlet during appliance operation and to automatically close the flue outlet when the appliance is in a standby condition.

Automatic vent damper means a device intended for installation in the venting system of an individual, automatically operated, fossil fuel-fired appliance either in the outlet or downstream of the appliance draft control device, which is designed to automatically open the venting system when the appliance is in operation and to automatically close off the venting system when the appliance is in a standby or shutdown condition.

Intermittent ignition device means an ignition device in which the ignition source is automatically shut off when the appliance is in an off or standby condition.

Power venting means a venting system that uses a separate fan, either integral to the appliance or attached to the vent pipe, to convey products of combustion and excess or dilution air through the vent pipe.

* * * * *

Warm air furnace means commercial warm air furnace as defined in § 431.72.

* * * * *

■ 20a. Amend § 431.246 by revising paragraph (b) to read as follows:

§ 431.246 Energy conservation standards and their effective dates.

* * * * *

(b) Have power venting or an automatic flue damper. An automatic vent damper is an acceptable alternative to an automatic flue damper for those unit heaters where combustion air is drawn from the conditioned space.

■ 21. Section 431.262 is amended by adding in alphabetical order a new definition for ''Basic model'' to read as follows:

§ 431.262 Definitions concerning commercial prerinse spray valves.

Basic model means, with respect to commercial prerinse spray valves, all units of a given type of commercial prerinse spray valve (or class thereof) manufactured by one manufacturer and which have the identical flow control mechanism attached to or installed within the fixture fitting, or the identical water-passage design features that use the same path of water in the highest flow mode.

* * * * *

■ 22. Subpart O of part 431 is amended by revising the undesignated center heading following § 431.262 and adding new §§ 431.263 and 431.264, to read as follows:

Test Procedures

§ 431.263 Materials incorporated by reference.

(a) *General.* The Department incorporates by reference the following test procedure into subpart O of part 431. The Director of the Federal Register has approved the material listed in paragraph (b) of this section for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Any subsequent amendment to this material by the standard-setting organization will not affect the DOE test procedures unless DOE amends its test procedures. The Department incorporates the material as it exists on the date of the approval by the Federal Register and a notice of any change in the material will be published in the **Federal Register**.

(b) *Test procedure incorporated by reference.* American Society for Testing and Materials (ASTM) Standard F2324–03, ''Standard Test Method for Prerinse Spray Valves,'' October, 2003.

(c) *Availability of reference*—(1) *Inspection of the test procedure.* The test procedure incorporated by reference is available for inspection at:

(i) National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(ii) U.S. Department of Energy, Forrestal Building, Room 1J–018 (Resource Room of the Building Technologies Program), 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–9127, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

(2) *Obtaining a copy of the standard.* The standard incorporated by reference may be obtained from the following source: Copies of ASTM Standard F2324–03 can be obtained from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, or telephone (610) 832–9585.

§ 431.264 Uniform test method for the measurement of flow rate for commercial prerinse spray valves.

(a) *Scope.* This section provides the test procedure for measuring, pursuant to EPCA, the water consumption flow rate of commercial prerinse spray valves.

(b) *Testing and Calculations.* The test procedure to determine the water consumption flow rate for prerinse spray valves, expressed in gallons per minute (gpm) or liters per minute (L/

min), shall be conducted in accordance with the test requirements specified in sections 4.1 and 4.2 (Summary of Test Method), 5.1 (Significance and Use), 6.1 through 6.9 (Apparatus) except 6.5, 9.1 through 9.5 (Preparation of Apparatus), and 10.1 through 10.2.5. (Procedure), and calculations in accordance with sections 11.1 through 11.3.2 (Calculation and Report) of the ASTM F2324–03, ''Standard Test Method for Prerinse Spray Valves.'' (Incorporated by reference, see § 431.263) Perform only the procedures pertinent to the measurement of flow rate. Record measurements at the resolution of the test instrumentation. Round off calculations to the same number of significant digits as the previous step. Round the final water consumption value to one decimal place as follows:

(1) A fractional number at or above the midpoint between two consecutive decimal places shall be rounded up to the higher of the two decimal places; or

(2) A fractional number below the midpoint between two consecutive decimal places shall be rounded down to the lower of the two decimal places.

■ 23. Part 431 is amended by adding a new subpart Q to read as follows:

Subpart Q—Refrigerated Bottled or Canned Beverage Vending Machines

Sec.
431.291 Scope.
431.292 Definitions concerning refrigerated bottled or canned beverage vending machines.

Test Procedures

431.293 Materials incorporated by reference.
431.294 Uniform test method for the measurement of energy consumption of refrigerated bottled or canned beverage vending machines.

Subpart Q—Refrigerated Bottled or Canned Beverage Vending Machines

§ 431.291 Scope.

This subpart specifies test procedures for certain commercial refrigerated bottled or canned beverage vending machines, pursuant to part C of Title III of the Energy Policy and Conservation Act, as amended, 42 U.S.C. 6311–6316.

§ 431.292 Definitions concerning refrigerated bottled or canned beverage vending machines.

Basic model means, with respect to refrigerated bottled or canned beverage vending machines, all units of a given type of refrigerated bottled or canned beverage vending machine (or class thereof) manufactured by one manufacturer and which have the same primary energy source, which have electrical characteristics that are essentially identical, and which do not have any differing electrical, physical, or functional characteristics that affect energy consumption.

Refrigerated bottled or *canned beverage vending machine* means a commercial refrigerator that cools bottled or canned beverages and dispenses the bottled or canned beverages on payment.

Test Procedures

§ 431.293 Materials incorporated by reference.

(a) *General.* The Department incorporates by reference the following test procedures into subpart Q of part 431. The Director of the Federal Register has approved the material listed in paragraph (b) of this section for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Any subsequent amendment to this material by the standard-setting organization will not affect the DOE test procedures unless DOE amends its test procedures. The Department incorporates the material as it exists on the date of the approval by the Federal Register and a notice of any change in the material will be published in the **Federal Register**.

(b) *Test procedures incorporated by reference.* (1) American National Standards Institute (ANSI)/American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. (ASHRAE) Standard 32.1–2004, ''Methods of Testing for Rating Vending Machines for Bottled, Canned, and Other Sealed Beverages.''

(2) American National Standards Institute (ANSI)/Association of Home Appliance Manufacturers (AHAM) Standard HRF–1–2004, ''Energy, Performance and Capacity of Household Refrigerators, Refrigerator-Freezers and Freezers.''

(c) *Availability of references*—(1) *Inspection of test procedures.* The test procedures incorporated by reference are available for inspection at:

(i) National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(ii) U.S. Department of Energy, Forrestal Building, Room 1J–018 (Resource Room of the Building Technologies Program), 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–9127, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

(2) *Obtaining copies of the standard.* (i) Anyone can purchase a copy of ANSI/ASHRAE Standard 32.1–2004, ''Methods of Testing for Rating Vending Machines for Bottled, Canned, and Other Sealed Beverages'' from the American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc., 1791 Tullie Circle NE., Atlanta, GA 30329–2305, (404) 636–8400, or *http://www.ashrae.org.*

(ii) Anyone can purchase a copy of ANSI/AHAM HRF–1–2004, ''Energy, Performance and Capacity of Household Refrigerators, Refrigerator-Freezers and Freezers,'' from the American National Standards Institute, 1819 L Street, NW., 6th floor, Washington, DC 20036, (202) 293–8020, or *http://www.ansi.org.*

§ 431.294 Uniform test method for the measurement of energy consumption of refrigerated bottled or canned beverage vending machines.

(a) *Scope.* This section provides test procedures for measuring, pursuant to EPCA, the energy consumption of refrigerated bottled or canned beverage vending machines.

(b) *Testing and Calculations.* (1) The test procedure for energy consumption of refrigerated bottled or canned beverage vending machines shall be conducted in accordance with the test procedures specified in section 4, ''Instruments,'' section 5, ''Vending Machine Capacity,'' section 6, ''Test Conditions,'' and sections 7.1 through 7.2.3.2, under ''Test Procedures,'' of ANSI/ASHRAE Standard 32.1–2004, ''Methods of Testing for Rating Vending Machines for Bottled, Canned, and Other Sealed Beverages.'' (Incorporated by reference, see § 431.293) In Section 6.2, ''Voltage and Frequency,'' test equipment with dual nameplate voltages at the lower of the two voltages only.

(2) Determine ''vendible capacity'' of refrigerated bottled or canned beverage vending machines in accordance with the second paragraph of section 5, ''Vending Machine Capacity,'' of ANSI/ASHRAE Standard 32.1–2004, ''Methods of Testing for Rating Vending Machines for Bottled, Canned, and Other Sealed Beverages,'' (Incorporated by reference, see § 431.293) and measure ''refrigerated volume'' of refrigerated bottled or canned beverage vending machines in accordance with the methodology specified in section 5.2, ''Total Refrigerated Volume,'' (excluding subsections 5.2.2.2 through 5.2.2.4) of the ANSI/AHAM HRF–1–2004, ''Energy, Performance and Capacity of Household Refrigerators, Refrigerator-Freezers and Freezers,'' (Incorporated by reference, see §§ 431.63 and 431.293).

[FR Doc. E6–20481 Filed 12–7–06; 8:45 am]
BILLING CODE 6450–01–P

Federal Register

Friday,
December 8, 2006

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 482

Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS–3018–F]

RIN 0938–AN30

Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights

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

ACTION: Final rule.

SUMMARY: This final rule finalizes the Patients' Rights Condition of Participation (CoP) which is applicable to all Medicare- and Medicaid-participating hospitals and contains standards that ensure minimum protections of each patient's physical and emotional health and safety. It responds to comments on the following standards presented in the July 2, 1999 interim final rule: Notice of rights; exercise of rights; privacy and safety; confidentiality of patient records; restraint for acute medical and surgical care; and seclusion and restraints for behavior management. As a result of comments received, we have revised the standards regarding restraint and seclusion and set forth standards regarding staff training and death reporting.

DATES: *Effective Date:* These regulations are effective on January 8, 2007.

FOR FURTHER INFORMATION CONTACT: Patricia Chmielewski, RN, MS (410) 786–6899, Janice Graham, RN, MS (410) 786–8020, Monique Howard, OTR/L (410) 786–3869, Jeannie Miller, RN, MPH (410) 786–3164, Rachael Weinstein, RN, MPA (410) 786–6775.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
A. Overview
B. Key Statutory Provisions
C. Regulatory Background
D. Requirements for Issuance of Regulations
E. Restraint and Seclusion in Other Settings
II. Provisions of the Proposed and Interim Final Rules Regarding Patients' Rights
III. Comments on and Responses to the Provisions of the Interim Final Rule With Comment Period
A. General Comments on the Requirements for Use of Restraint and Seclusion
1. Is There Cause for Concern?
2. The Difference Between Standards (e) and (f)
3. The Roles of CMS and JCAHO
4. Applicability of the Patients' Rights CoP
5. Debriefing After the Use of Restraint/Seclusion
B. Comments Received on Specific Provisions
1. The Right to Be Free From Restraint (§§ 482.13(e)(1) and (f)(1))
2. Definition of ''Restraint'' and ''Physical Restraint'' (§§ 482.13(e)(1) and (f)(1))
3. Definition of a ''Drug Used as a Restraint'' (§§ 482.13(e)(1) and (f)(1))
4. Use of Restraints (§§ 482.13(e)(2) and (e)(3)(i))
5. Ordering of Restraint/Seclusion (§§ 482.13(e)(3)(ii) and (f)(3)(ii))
a. Definition of Licensed Independent Practitioner (LIP) (§§ 482.13(e)(3)(ii) and (f)(3)(ii))
b. Physician Only
c. Elimination of Protocols
d. Initiate versus Order
6. Prohibition on Standing and PRN Orders (§§ 482.13(e)(3)(ii)(A) and (f)(3)(ii)(A))
7. Consultation with the Treating Physician (§§ 482.13(e)(3)(ii)(B) and (f)(3)(ii)(B))
8. Written Modification of the Plan of Care (§§ 482.13(e)(3)(iii) and (f)(3)(iii))
9. Implementation of and Appropriate Use of Restraint/Seclusion (§§ 482.13(e)(3)(iv), (e)(3)(v), (f)(3)(iv), and (f)(3)(v))
10. Discontinuing the Use of Restraint/Seclusion (§§ 482.13(e)(3)(vi) and(f)(3)(vi))
11. Assessment, Monitoring, and Evaluation of the Restrained/Secluded Patient (§§ 482.13(e)(4) and (f)(5))
12. Staff Training in the Use of Restraints/Seclusion (§§ 482.13(e)(5) and (f)(6))
13. Definition of Seclusion (§ 482.13(f)(1))
14. Use of Restraint/Seclusion for Behavior Management (§ 482.13(f)(2))
15. One Hour Rule (§ 482.13(f)(3)(ii)(C))
a. Comments Objecting to a Physician or LIP Seeing the Patient Within 1 Hour
b. Comments Supporting Telephone Consultation with a Nurse Onsite Performing the Patient Assessment
c. Comments Opposing Telephone Orders, Nurse Evaluation, and LIP Involvement
d. Comments Stating that the 1-Hour Rule Did Not Address the Problem
16. Limits for Restraint/Seclusion Orders (§ 482.13(f)(3)(ii)(D))
17. Simultaneous Use of Restraint and Seclusion (§ 482.13(f)(4))
18. The Use of Video and Audio Monitoring
19. Reporting of Death(s) Related to Restraint/Seclusion (§ 482.13(f)(7))
IV. Provisions of the Final Rule
V. Collection of Information Requirements
VI. Regulatory Impact Analysis
A. Overall Impact
B. Anticipated Effects
1. Effects on Providers
a. Section 482.13(e) Standard: Restraint or Seclusion
b. Section 482.13(f) Standard: Restraint or Seclusion: Staff Training Requirements
c. Section 482.13(g) Standard: Death Reporting Requirements
2. Effect on Beneficiaries
3. Effect on the Medicare and Medicaid Programs
C. Alternatives Considered

Regulations Text

I. Background

A. Overview

This rule set forth final requirements for Patients' Rights in hospitals, provides strong patient protections, provides flexibility to providers, and is responsive to comments. This regulation focuses on patient safety and the protection of patients from abuse. These standards support and protect patients' rights in the hospital setting; specifically, the right to be free from the inappropriate use of restraint and seclusion with requirements that protect the patient when use of either intervention is necessary. It recognizes the legitimate use of restraint for acute medical and surgical care as a measure to prevent patient injury, as well as the use of restraint or seclusion to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. In addition, this rule finalizes, without modification, the standards for Notice of Rights, Exercise of Rights, Privacy and Safety, and Confidentiality of Patient Records.

B. Key Statutory Provisions

Sections 1861(e) (1) through (8) of the Social Security Act (the Act) define the term ''hospital'' and list the requirements that a hospital must meet to be eligible for Medicare participation. Section 1861(e)(9) of the Act specifies that a hospital must also meet such other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Under this authority, the Secretary has established in regulations at 42 CFR part 482 the requirements that a hospital must meet to participate in the Medicare program.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Regulations at § 440.10(a)(3)(iii) require hospitals to meet the Medicare CoPs to qualify for participation in Medicaid.

The Children's Health Act of 2000 (CHA) (Pub. L. 106–310) was enacted October 17, 2000. Section 3207 of the CHA amended Title V of the Public Health Service Act (PHSA) by adding a new part H, which contains requirements relating to the rights of residents of certain facilities. Specifically, section 591 of the PHS Act, as added by the CHA (42 U.S.C. 290ii), establishes certain minimum requirements with regard to the use of restraint and seclusion in facilities that receive support in any form from any program supported in whole or in part

with funds appropriated to any Federal department or agency. In addition, Sections 592 and 593 of the PHS Act (42 U.S.C. 290ii and 290ii–3) establish minimum mandatory death reporting and staff training requirements. This final rule conforms to the requirements of the CHA.

As implementing regulations are issued, a critical point for consideration is that Title V, part H of the PHS Act is not an isolated enactment, but part of a trend of legislation and regulations aimed at protecting and promoting resident, patient, and client rights. Part H, section 591(c) of the PHS Act states ''This part shall not be construed to affect or impede any Federal or State law or regulations that provide greater protections than this part regarding seclusion and restraint.'' The value of preserving existing law and regulations is recognized while extending protections to those facilities that are currently without the protection intended by the Congress.

C. Regulatory Background

In the December 19, 1997 **Federal Register** (62 FR 66726), we published a proposed rule entitled ''Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval'' to revise the entire set of CoPs for hospitals found at 42 CFR part 482. This proposed rule included a CoP for patients' rights. In the July 2, 1999 **Federal Register** (64 FR 36070), we published the Patients' Rights CoP as an interim final rule with comment. This CoP was separated from the other proposed hospital CoPs in response to Congressional and public interest. Although we have modified some of the provisions to address public comments, these modifications do not lessen protections afforded patients who are restricted or secluded. We note that we have revised the regulation to expand training requirements and have added a requirement that the attending physician or other licensed independent practitioner (LIP) responsible for the care of the patient be consulted as soon as possible when the ''one hour'' evaluation of a patient in restraint or seclusion is conducted by a trained registered nurse (RN) or physician assistant (PA).

D. Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances. In a notice published December 30, 2004 (69 FR 78442), we implemented section 902 of the Act by announcing that all outstanding interim final rules as of December 8, 2003 would be finalized by December 8, 2006 or expire.

This final rule finalizes provisions set forth in the July 2, 1999 interim final rule with comment. In accordance with section 902 and our notice of 2004, this final rule is being published within 3 years of the date of enactment of the MMA, which was December 8, 2003, in order to finalize the 1999 interim final rule with comment.

E. Restraint and Seclusion in Other Settings

In the preamble of the July 2, 1999 interim final rule with comment period, we explained that we were considering the advisability of adopting a consistent restraint and seclusion standard that would apply not only to hospitals but to other kinds of health care entities with which CMS has provider agreements, including those that provide inpatient psychiatric services for individuals under 21 years of age (a program under Medicaid). We asked the public whether we should adopt the same standards that appeared in the July 2, 1999 interim final rule with comment period, or whether we should adopt more stringent standards.

Consumer advocacy groups that commented on extending these requirements to other settings generally argued for more stringent expectations for the care of children, citing special hazards and concerns that arise when children and adolescents are restrained. Some commenters encouraged CMS to apply the restraints and seclusion standards of the interim final rule with comment period to all other Medicaid-funded facilities, particularly residential treatment centers for children and adolescents.

Other commenters did not agree with this approach, arguing that the fields of mental health and developmental disabilities are very different and that similarities between the two should not be assumed. For example, some commenters stated that little research exists on the use of restraint/seclusion in mental health, but that in contrast, a considerable amount of research in the developmental disabilities field supports the effectiveness of restraint and seclusion for severe behavior problems. Thus, the field of developmental disabilities already has extensive guidelines, standards, and rules governing the use of restraint and seclusion.

Some of those commenters who supported uniform restraint and seclusion standards across settings offered detailed suggestions for what those standards should require. For example, commenters suggested that the regulation forbid the use of mechanical restraints for children under a certain age (these commenters offered varying suggestions regarding the threshold age (17 and 21 years of age were two of these suggestions)), or permit therapeutic holding for periods no longer than 15 minutes. Some of the commenters expressed concern about proposing requirements that paralleled existing requirements for hospitals because of the differences in patient acuity and characteristics and treatment.

We considered the comments we received in developing specific restraint and seclusion requirements for inpatient psychiatric services for individuals under 21 years of age. These requirements were published in an interim final rule with comment period entitled, ''Medicaid Program; Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Services to Individuals under Age 21'' in the January 22, 2001 **Federal Register** (66 FR 7148). In the May 22, 2001 **Federal Register** (66 FR 28110), we published an additional interim final rule with comment period to amend and further clarify the January 22, 2001 interim final rule with comment period.

There was little comment on extending restraint and seclusion requirements to specific non-behavioral or non-psychiatric types of settings or providers, such as home health agencies, ambulatory surgical centers, or providers of x-ray services. While a few commenters gave blanket support to this idea, they did not supply a rationale for applying one set of standards versus another. Several commenters discussed their concern about extending the restraint and seclusion requirements to the nursing home setting and strongly disagreed with any adoption of the standards presented in the interim final rule with comment period in that setting. One nursing home industry association argued for consistency in terminology and philosophy, but recognized that the settings where beneficiaries receive services are diverse, as are the beneficiaries

themselves, and that adopting a blanket approach might not be practical or appropriate.

After considering these comments and engaging in internal deliberations, we have decided that it would not be appropriate to adopt a detailed, technical approach that would create an identical standard for all of the providers with which CMS has agreements. Instead, the needs of specific treatment populations and settings should drive the types of standards developed. Therefore, we do not plan to adopt the hospital requirements verbatim for other provider types.

However, we are concerned about beneficiaries receiving care in settings where no regulatory protections regarding the use of restraint or seclusion currently exist. The CHA provides statutory protection to patients at any facility receiving Federal funding. While it is impractical, in our view, to take the requirements for hospitals, nursing homes, or intermediate care facilities for the mentally retarded and adopt them as a whole in any other given setting, we can instead develop any new requirements with the same philosophical foundation that underlies the three existing sets of standards and requirements. This foundation encompasses the belief that the patient has the right to be free from unnecessary restraint or seclusion, that using a restraint for convenience, punishment, retaliation, or coercion is never acceptable, and that each patient should be treated with respect and dignity. These beliefs are true in every care setting and are legally enforceable in accordance with the CHA. As appropriate, we will develop regulations that support these concepts. However, given the variations in treatment populations and settings, the individual case setting will drive the type of standards developed which will vary as appropriate.

II. Provisions of the Proposed and Interim Final Rules Regarding Patients' Rights

The December 19, 1997 hospital CoP proposed rule included a patients' rights CoP that proposed to establish standards for the following:

- Notice of rights.
- Exercise of rights regarding care.
- Privacy and safety.
- Confidentiality of patient records.
- Seclusion and restraint.

With the exception of the standard for seclusion and restraint, we received few comments in response to these proposed requirements.

In the July 2, 1999 **Federal Register**, we published an interim final rule with comment period that separated the patients' rights CoP from the other hospital CoPs and introduced modifications to proposed standard (e) and added a new standard (f), governing the use of restraint and seclusion. Because we received few comments on the other provisions of the patients' rights section (standards a through d), these four provisions were not reopened for public comment in the July 2, 1999 interim final rule with comment period.

In the 1997 proposed rule, standard (e) was entitled ''Seclusion and restraint,'' and covered the patient's right to be free of restraint or seclusion used as a means of coercion, convenience, or retaliation by staff. The proposed language set forth several basic ideas and expectations; namely, that restraint (including psychopharmacological drugs used as restraints) and seclusion must be used in accordance with the patient's plan of care; that restraints or seclusion may be used only as a last resort and in the least restrictive manner possible to protect the patient or others from harm; and that restraint or seclusion must be removed or ended at the earliest possible time.

The interim final rule with comment period introduced two standards on restraint and seclusion—one governing the use of restraint in the provision of acute medical and surgical care and the other governing the use of seclusion and restraint for behavior management. The revised standard (e) included definitions that had not specifically appeared in the proposed rule and also included: (1) A prohibition on standing orders or orders on an as needed basis (that is, PRN) for restraint; (2) an emphasis on continual assessment and monitoring; and re-evaluation of the condition of the restrained patient; (3) a requirement that the hospital notify the patient's treating physician if he/she did not issue the restraint order personally; and (4) a training requirement for all staff with direct patient contact. Standard (f) offered definitions and provided more prescriptive requirements than the proposed or revised standard (e). The focus on behavior management in standard (f) was intended to apply in situations where the patient's aggressive or violent behavior creates an emergency situation that places his or her safety or that of others at risk. The more prescriptive elements, such as—(1) requiring a physician or licensed independent practitioner (LIP) to see and evaluate the need for restraint or seclusion within 1-hour of the initiation of the intervention; (2) the limitation on the length of orders and required re-evaluation; and (3) the requirement for continual face-to-face monitoring or continual monitoring using both video and audio equipment if restraint and seclusion are used simultaneously, were meant to be commensurate with the increased risk to patient health and safety when these interventions are used to address violent or aggressive patient behavior.

In both standards (e) and (f) of the July 2, 1999 interim final rule with comment period, the phrase ''psychopharmacological drugs used as restraints'' was replaced with the phrase ''drug used as a restraint,'' in recognition of the idea that singling out one type of medication encourages the misperception that only one class of drugs is used to restrain patients.

Concern for patient health and safety prompted us to make these requirements effective on August 2, 1999. However, given the changes to the proposed standard (e) and the addition of standard (f), we believed that the public should have an opportunity to comment on the revised restraint and seclusion provisions. For these reasons, we published the July 2, 1999 rule as an interim final rule with comment period.

III. Comments on and Responses to the Provisions of the Interim Final With Comment Period

We received approximately 4,200 timely comments on the interim final rule with comment period. Comments were received from hospitals, mental health treatment facilities, physicians, nurses, attorneys, professional associations, accrediting bodies, state agencies, national and State patient protection and advocacy groups, and members of the general public. Many commenters applauded the addition of the restraint and seclusion provisions in the Patients' Rights CoP, even if they disagreed with specific requirements or concepts. A summary of the comments received on these provisions (standards (e) and (f)) and our responses follows.

We received comments on issues out of the scope of the interim final rule with comment period; these comments will not be addressed in this final rule.

A. General Comments on the Requirements for the Use of Restraint and Seclusion

Some commenters suggested that the 1-hour physician or LIP visit and assessment were not consistent with the goal of creating a government that works better and costs less. A few commenters stated that the rapid introduction of standards (e) and (f) was a ''knee-jerk

reaction'' to the lobbying of certain groups and the sensationalized media coverage of a limited number of cases. One commenter stated, ''It is time the legislature and administrative agencies stop reacting to sensational headlines and layering the health care system with costly and time consuming regulations to meet.'' Another commenter questioned the validity of the 1998 Hartford Courant series of articles (cited in the preamble to the interim final rule with comment period), asserting that the articles did not clearly determine that the use of restraint and seclusion were the proximate and sole cause of deaths in the cases cited. The same commenter asked in which setting these deaths occurred, stating that it makes no sense to regulate a hospital on this point if there is no evidence that restraint-related deaths are problematic in hospitals. Another commenter questioned the FDA's estimate of at least 100 deaths per year from improper use of restraints, specifically noting that he believes that these are not cases where restraint use was unmerited. Another commenter stated that while the abuse and deaths that have occurred are unfortunate, they do not represent an emergency situation meriting the actions that were taken by CMS. The commenter made the following statement:

> While 142 deaths in 10 years is unfortunate, the number pales when compared to the 3 million people hospitalized per year for adverse drug reactions and 150,000 deaths resulting from drugs taken properly as prescribed by the physician.

A commenter stated that CMS has given too much credence to over-dramatized accounts of restraint and seclusion use. Many hospitals reported having no injuries or deaths associated with restraint or seclusion use. A number of physicians also noted that none of their patients have suffered serious injuries or died due to the use of restraints. One commenter stated that it was unfair to subject the industry as a whole to highly prescriptive requirements when the events that triggered such concern occurred in a handful of facilities. The commenter argued that only the hospitals where the deaths occurred should be governed by these rules. Another commenter suggested that in the situations where these deaths occurred, the practices used were out of compliance with the hospitals' own policies and procedures. Accordingly, the commenter stated that prescriptive regulations do not represent the gateway to reduced injuries and deaths, and that enforcement of existing requirements would be more effective. Still other commenters have suggested that even if death and injury are of concern, CMS has not yet hit upon the correct solution.

To balance these comments, we mention those received from advocacy groups, patients, and hospital staff. Some of the anecdotal information provided was clearly disturbing, including accounts of patients being choked during takedowns even though staff had been trained in proper procedures, and patients suffering broken limbs or other injuries. Other commenters described situations where patients had been placed in restraints for extended periods of time (up to 10 consecutive hours) and staff did not take vital signs regularly, did not offer food, fluids, or use of the toilet at all, or offered them only once while the patient was restrained. Comments also related concerns about the over use and inappropriate use of restraint or seclusion. One commenter stated that a lawsuit was filed on behalf of a patient dually diagnosed with mental retardation and organic brain syndrome who was placed in restraints 48 times within a six month period. The commenter stated that in the six months after the lawsuit was settled, the patient had only been restrained twice.

Many commenters applauded the regulatory action. Commenters stated that the action was long overdue and important for the safety of vulnerable populations most in need of protection from abuse of restraints and seclusion. Commenters see this rule as a major step forward in addressing issues surrounding the use of restraint and seclusion in inpatient facilities and support further movement toward the goals of ultimately eliminating the use of seclusion and restraint, and preserving patients' rights and dignity. In addition, many commenters stated that they would like to see even more stringent requirements for the use of restraint and seclusion for behavior management.

1. Is There Cause for Concern?

Given the prevalence of restraint use, we believe that awareness and vigilance are justified. On October 11, 1998, the Hartford Courant reported that of the 142 deaths it confirmed, 59.6 percent occurred in the hospital setting (including psychiatric hospitals and psychiatric wards of general hospitals). The Courant further stated that 47.2 percent of the 142 deaths involved physical restraints or therapeutic holds, while 44.1 percent involved mechanical restraint, 3.1 percent involved a combination of the two, and the remaining 5.5 percent were seclusion-related. Although the Courant did not claim that restraint and seclusion use were the sole and proxmate cause of death in each case, we question the usefulness of this criterion in determining whether restraint and seclusion pose significant risk to health and safety. Obviously, when a patient's trachea is crushed during a takedown, restraint would constitute the ''sole and proximal'' cause of death. However, a case cited by one commenter illustrates how this characterization may fail to take into account the many times that restraint or seclusion can play a part in injury. The commenter reported that one young man died after suffering a severe asthma attack soon after fighting with another patient and being restrained. The death was ruled to be due to natural causes, even though the medical examiner found that both the stress of the fight and the restraint triggered the asthma attack. One cannot only consider whether restraint or seclusion is the sole cause of death when examining whether the use of restraint or seclusion poses a significant risk to the patient.

One commenter questioned the statistical significance of 142 deaths over a 10-year period. This number may not reflect the actual number of such deaths that occur each year. In explaining how it conducted its investigation, the Courant noted, ''Throughout the reporting * * * it became clear that many deaths go unreported.'' To better determine the national annual death rate, the Courant hired statistician Roberta Glass, a research specialist for the Harvard Center of Risk Analysis at the Harvard School of Public Health. The Courant reported the following:

> Glass projected that the annual number of deaths could range as high as 150. ''Admittedly, the estimates are only rough approximations,'' Glass said. ''The data needed for precise estimation are not collected in a systematic way nationwide.''

On October 26, 1999, Associate Director Leslie Aronovitz of the U.S. Government Accountability Office provided testimony before the Senate Committee on Finance entitled, ''Extent of Risk from Improper Restraint or Seclusion is Unknown.'' Aronovitz testified to the following:

> Neither the federal government nor the states comprehensively track the use of restraint or seclusion or injuries related to them across all types of facilities that serve individuals with mental illness or mental retardation * * * Because reporting is so piecemeal, the exact number of deaths in which restraint or seclusion was a factor is not known. We contacted the P&As

[protection and advocacy agencies] for each state and the District of Columbia and asked them to identify people in treatment settings who died in fiscal year 1998 and for whom restraint or seclusion was a factor in their death. The P&As identified 24, but this number is likely to be an understatement, because many states do not require all or some of their facilities to report such incidents to P&As.

The lack of systemic information collection is an important point. The Joint Commission on Accreditation for Healthcare Organizations (JCAHO), which accredits 80 percent of the hospitals that participate in Medicare and Medicaid, does not require hospitals to report ''sentinel events'' such as injuries or deaths related to restraint or seclusion use, but encourages voluntary reporting through its sentinel event program. JCAHO defines a sentinel event as ''an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.'' Even if each of the accredited hospitals scrupulously and voluntarily reports sentinel events, the 20 percent of Medicare- and Medicaid-participating hospitals that are non-accredited do not provide this information to JCAHO. Since reporting is voluntary rather than mandatory, accredited hospitals may choose not to inform JCAHO. Hospitals may fear that reported information might be used against them in court, which would provide a clear disincentive to consistent and voluntary reporting.

Even if Glass' projection of up to 150 deaths per year is correct, some may question its statistical significance when compared with the number of deaths that result from other factors, such as medical errors. We believe that while deaths are a focal point, it is important not to discount patient injuries. If deaths are under-reported, injury data are even more elusive. Estimating the psychological and social impact of restraint or seclusion is more challenging still. We do not imply that most of the nation's providers recklessly seclude or restrain patients without regard to their emotional well-being. To the contrary, many who commented on this regulation stated that restraint or seclusion are measures of last resort and that they do not undertake these interventions unless absolutely necessary. However, even when a restraint or seclusion is needed, the patient may feel dehumanized, isolated, or depressed as a result. Physical impact, although arguably not simple to measure, is more easily monitored and reported than impact on the spirit.

In summary, we suspect that patient deaths and injuries are underreported, and, even if all parties voluntarily report incidents involving restraint or seclusion or comply with State and local reporting requirements, there are gaps in the system that thwart conclusive calculation of the number of physical injuries and deaths associated with restraint and seclusion use. Given the prevalence of use, the potential for injury, death, or adverse psychological impact, we maintain our original position—that this area deserves regulatory attention to safeguard patient health and safety.

2. The Difference Between Standards (e) and (f)

Comment: Many commenters stated that it is unclear which standard applies in any given situation. One commenter recommended that we delineate a clear, objective explanation of when application of the behavior management standard outside the psychiatric care setting is expected. One commenter objected to the creation of separate requirements for the care of psychiatric patients versus those receiving acute medical treatment, and asserted that all patients should be treated equally. However, most commenters agreed that different requirements should apply to restraints used for violent, aggressive patients as opposed to restraints used in the provision of medical care; some suggested that setting-specific requirements are more reasonable than behavior-specific ones.

Response: Based on public comment regarding the lack of clarity between the application of standard (e) Restraint for acute medical and surgical care, and the application of standard (f) Restraint and seclusion for behavior management, we have revised and combined these requirements into a single standard in the final rule. This combined standard, entitled ''Restraint or seclusion,'' is subparagraph (e) under § 482.12 Patients' Rights in the final rule. This combined standard (e) applies to all uses of restraint or seclusion regardless of the patient's location. Although we have modified some of the provisions to address public comments, these modifications do not lessen protections afforded patients who are restricted or secluded. We note that we have revised the regulation to expand training requirements, and have added a requirement that the attending physician or other licensed independent practitioner (LIP) responsible for the care of the patient be consulted as soon as possible when the one-hour restraint or seclusion evaluation of the violent or self-destructive patient is conducted by a trained registered nurse (RN) or physician assistant (PA).

Comment: A few commenters noted the challenge of making a determination on the standard of care for a patient with multiple diagnoses and behaviors.

Response: We agree that multiple diagnosis and behaviors can make determination on the standard of care a challenge. Therefore, even though several requirements were revised based on public comments, none of the current requirements in standards (e) and (f) have been deleted. All of the requirements contained in the current standard (e) are also contained in the current standard (f). These requirements, in their entirety, have been moved to the combined standard (e) in the final rule. All of the requirements contained in the current standard (f), have also been moved, in their entirety, to the combined standard (e) in the final rule.

Comment: One commenter noted the difficulty in enforcing behavior-specific standards. However, another commenter supported writing the standards to focus on patient behavior or circumstances rather than on the setting. Some commenters requested clarification on what ''behavior management'' means.

Response: For the purpose of clarity we have eliminated the term ''behavior management'' and are using more specific language. The management of violent or self-destructive behavior can occur as part of medical and surgical care as well as part of psychiatric care. The use of the language ''violent or self-destructive behavior'' is intended to clarify the application of these requirements across all patient populations. It is not intended to single out any particular patient population. Based on public comments, we have eliminated the language ''behavior management,'' and have used clearer, more descriptive language in the final rule. Specifically, we have revised the regulations text at 482.13(e) to provide that restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others, and must be discontinued at the earliest possible time. This combined standard clearly outlines the requirements any time restraint or seclusion is used, regardless of the patient's location. We do not support a setting-based approach because interventions and protections provided without considering the patient's behavior and symptoms may fail to adequately safeguard the health and safety of patients. In addition, this standard is not targeted only at patients on psychiatric units or those with behavioral/mental health care needs. The patient protections contained in this standard apply to all patients when

the use of restraint or seclusion becomes necessary.

Although a patient's violent or self-destructive behavior may jeopardize the immediate physical safety of the patient, a staff member, or others more frequently in a psychiatric unit or in a psychiatric hospital, this behavior also appears in the acute medical/surgical care settings, including emergency and critical care settings. Some examples follow. A patient may experience a severe medication reaction that causes him or her to become violent. A patient may be withdrawing from alcohol and having delirium tremors (DTs). The patient is agitated, combative, verbally abusive, and attempting to hit staff. Regardless of facility type, such emergencies generally pose a significant risk for patients and others. For the safety of the patient and others, the use of restraint or seclusion may be necessary to manage the patient's violent or self-destructive behavior that jeopardize the immediate physical safety of the patient, a staff member, or others when less restrictive interventions have been determined to be ineffective to protect the patient, staff, or others from harm. It is not targeted only at patients on psychiatric units or those with behavioral/mental health care needs. The patient protections contained in this standard apply to all patients when the use of restraint or seclusion becomes necessary.

Comment: One commenter suggested adding language in § 482.13(f)(2) to indicate that standard (f) applies when a restraint or seclusion is used, ''In an emergency situation to manage an unanticipated outburst of severely aggressive or destructive behavior that poses an imminent danger to the patient or others.'' Several commenters suggested changing the title of standard (f), examples include, ''Emergency behavior management'' and ''Seclusion/restraint for patients with primary behavioral health care needs.''

Response: The current standard (e) contains two requirements that are more stringent, if restraint or seclusion is used when a patient jeopardizes the immediate physical safety of the patient, a staff member, or others. They are: time limits on length of each order, and the 1-hour face-to-face evaluation. The intent of these more stringent requirements is to add additional patient protections when restraint or seclusion is used for behavior management. We do not intend for these two more stringent requirements to apply to all uses of restraint. We have added clarifying language in the final rule that these requirements apply when restraint or seclusion are used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. We have also specified that seclusion is only permitted to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Since publication of the interim final rule with comment period, we have repeatedly responded to inquiries regarding the criteria for differentiating between emergency situations where the patient's behavior is violent or self-destructive and jeopardizes the immediate physical safety of the patient, a staff member, or others versus the non-emergency use of restraint. Most of the individuals to whom we spoke indicated that this distinction was clear and understandable. Clinicians are adept at identifying behavior and symptoms, and can readily recognize violent and self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Asking them to act based on evaluation of the patient's behavior is no different than relying on the clinical judgment that they use daily in assessing the needs of each patient and taking actions to meet those individual needs.

In the final rule, we adopted the restraint definition contained in the CHA. Because the requirements governing the use of restraint or seclusion have been combined in a single standard, we also have a single, consistent definition of restraint. A restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. The final rule also clarifies that a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). The devices and methods described above are typically used in medical/surgical care, and would not be considered restraints, and thus not subject to these requirements.

The final, combined standard (e) applies to the use of restraint, the use of seclusion, as well as the simultaneous use of restraint and seclusion. To clarify this point, we have adopted use of the word ''or'' in the final, combined standard for restraint and seclusion. The use of ''or'' imports the ''and,'' whereas ''and'' standing alone requires that both happen. It is not our intent that the requirements in this standard only apply when both restraint and seclusion are used. Therefore, throughout the regulation text, we have deleted ''and'' and inserted ''or.'' The regulations apply to the use of restraint or seclusion. This means they also apply when both restraint and seclusion are used.

3. The Roles of CMS and JCAHO

Comment: Regarding any provision that was not identical to JCAHO's policy, a host of commenters expressed concern that CMS's standards did not parallel or actually ran counter to JCAHO's. One commenter stated that these discrepancies would create an implementation burden for hospitals. A number of commenters expressed concern that CMS was straying from its stated intent of maintaining consistency between Federal and accreditation standards.

Response: In the interim final rule with comment period (64 FR 36079), we stated, ''We believe it is appropriate to recognize JCAHO's work in this area [regarding the length of physician or LIP orders] and maintain consistency between Federal and accreditation standards when possible.'' We adopted JCAHO's standard for time limited orders because, upon examination, we found nothing to suggest that these timeframes have been found faulty or that any more appropriate ones have been scientifically determined. However, we did not intend to suggest that we planned to follow JCAHO's standards in all respects.

Comment: One commenter suggested that the requirement that a physician or LIP see a patient who is restrained or secluded for behavior management within 1-hour is unnecessary because current practice provides good patient care. The commenter cited JCAHO's revision of its standards regarding restraints and seclusion and noted that the hospital agreed with JCAHO and implemented those standards. Further, the commenter reported that the hospital has an ongoing improvement process, which has significantly decreased the use of restraints and seclusion for its adult population.

To govern the use of restraint and seclusion for children, another commenter suggested an approach similar to JCAHO's. The commenter further suggested that national accreditation bodies could establish a certification and approval process for nonviolent intervention regimes. Additionally, the commenter suggested that accreditation surveys or regulatory reviews could include thorough individual and aggregate review of documentation of restraint and seclusion use.

Response: The hospital CoPs are minimum health and safety standards that hospitals must meet to participate in the Medicare and Medicaid programs. The CoPs are intended to protect patient health and safety and to ensure that high quality care is provided to all patients. While we applaud JCAHO's progress in the areas of examining restraint and seclusion use, JCAHO accreditation is voluntary and not the only way hospitals participate in the Medicare and Medicaid programs. Twenty percent of the hospitals that participate in Medicare and Medicaid are non-accredited. Non-accredited hospitals are surveyed by State survey agencies to determine compliance with the CoPs. We have the responsibility to ensure that all Medicare- and Medicaid-participating hospitals have certain protections in place. Before July 2, 1999, the CoPs contained no requirements concerning Patients' Rights.

Our minimum requirements need to exist in regulatory form in order to carry the weight of the law and be enforceable. This final rule informs the public and provider community of our minimum requirements for the protection of patient health and safety while providing a sound basis for legal action if we find that those requirements are not met. While quality improvement initiatives and other internal efforts to track restraints and seclusion use and eliminate inappropriate use are important, we do not believe that they serve as a substitute for stated minimum Federal requirements.

Comment: One commenter stated, ''Let's leave the seclusion and restraint abusers to the civil courts and JCAHO, who are quite capable of creating over-regulations without help from CMS.'' Conversely, another commenter asserted,

''CMS bears a great deal of the blame for the deaths, injuries, and serious long-term psychological harm which those aforementioned patients and their families have endured because it did not amend its CoPs to assure such desirable outcomes. The JCAHO standards were available to CMS during those many years but it chose—for unexplainable and unacceptable reasons—to maintain the status-quo.''

Response: There were other such polarized responses to the interim final rule with comment period. However, many commenters acknowledged the appropriateness of regulation in this area even if they disagreed with individual provisions of the interim final rule with comment period.

The Congress has charged us with creating standards that protect the nation's Medicare and Medicaid beneficiaries and ensure that these beneficiaries receive high quality care. Many commenters came forward with ideas about how the regulation could be changed and improved. Our task is to reconcile these ideas when feasible, and determine the best, most reasonable approach that promotes patient health and safety and yet does not create a disincentive for providers to serve those populations who most critically need their help.

Comment: A commenter stated that CMS's interest in alerting the public to the potential dangers associated with the use of restraint and seclusion is ''faddish.''

Response: This commenter's statement stood in stark contrast to those of many of his contemporaries who wrote of their tireless efforts to avert the potential hazards associated with the use of restraint and seclusion, and of the seriousness with which they undertake such interventions. While accounts of efforts to minimize use of restraint and seclusion and assure patient safety were heartening, a few of the letters we received were disturbing in their conceptualization of a restraint or seclusion not only as wholly appropriate, but as a ''time-honored'' standard of care. To that argument, we reply that standards of care continually evolve. For example, at one time patient shackles were considered a standard intervention. Habit does not justify the continued use of an intervention when alternative methods that are safer or more effective are available. The numerous training programs that emphasize alternative techniques for handling violent or self-destructive behavior and symptoms demonstrate that clinicians recognize the risks inherent in the use of restraint and seclusion. Practitioners in the field of medicine are constantly searching for better ways to manage symptoms and conditions that have been traditionally treated through the use of restraint or seclusion or both. We fully support these efforts.

4. Applicability of the Patients' Rights CoP

Comment: One commenter stated that the preamble should explain the application and effect of the new regulation on psychiatric hospitals. If the regulation applies to psychiatric hospitals, the commenter stated the requirements specified in standard (f) (among others) might not be appropriate.

Response: In the summary of the interim final rule with comment period (64 FR 36070), we explained, ''The Patients'' Rights CoP, including the standard regarding seclusion and restraint, applies to all Medicare- and Medicaid-participating hospitals, that is, short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug.'' This final rule, including its provisions concerning the use of restraint and seclusion, is explicitly intended to apply in the psychiatric hospital setting.

We disagree with the opinion that the requirements in the current standard (e) might not be appropriate for the psychiatric hospital setting. While violent or self-destructive patient behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others occasionally occurs on an acute care unit in a hospital, it occurs more often on a psychiatric unit or in a psychiatric hospital. When a patient's behavior becomes violent or self-destructive, the immediate physical safety of the patient, a staff member, or others is at risk. In such an emergency situation, it is critical to ensure that staff is well trained in alternative interventions and techniques; to ensure the safety and well being of the patient and others; to manage the patient's behavior; and, to competently apply restraints or use seclusion. Additionally, the protections provided ensure that: the restrained or secluded patient is appropriately monitored and that the patient's condition is reassessed; the patient's medical and psychological conditions are evaluated; and, the intervention is ended as quickly as possible. Therefore, we believe that the protections in the current standard (f) that have been relocated to the combined standard (e) in the final rule are appropriate for the psychiatric care setting.

Comment: One commenter suggested that we need to develop a separate category of patient rights for children that address their developmental needs rights and other basic needs.

Response: The provisions contained in the Patients' Rights CoP apply universally to all hospital patients,

including children. Although there is no separate category for patient's rights on the basis of age, the regulations recognize differences. Timeframes on orders for the use of restraints or seclusion are different based on age. For example, for children and adolescents 9 to 17 years of age, orders for restraint or seclusion are limited to a maximum of 2 hours. When implementing these regulations, we expect hospitals to develop and implement an approach that meets the individualized needs of the patient populations that they serve.

Comment: One commenter stated that since there are no attending physicians in religious non-medical facilities, amendments should be made to incorporate the provisions of section 1861(ss) of the Act.

Response: Effective January 31, 2000, religious non-medical facilities are not governed by the hospital CoPs, but by their own requirements. The new requirements for religious non-medical facilities do not permit the use of restraint or involuntary seclusion (§§ 403.730(c)(4) and (5)). (For additional information, see the November 30, 1999 and November 28, 2003 **Federal Registers** (64 FR 67028) and (68 FR 66710), respectively).

5. Debriefing After the Use of Restraint/Seclusion

Comment: Many consumer advocates suggested creating a requirement for debriefing staff and patients following each incident of restraint or seclusion, and documenting the use of either procedure in the patient's record. The debriefing's purpose would be to—(1) develop an understanding of the factors that may have evoked the behaviors necessitating the use of restraint or seclusion; (2) give the patient time to verbalize his or her feelings and concerns; and (3) identify strategies to avoid future use of seclusion or restraint. Another commenter recommended that staff debriefing, followed by patient debriefing, occur within 24 hours of each incident of restraint or seclusion. One commenter noted that its hospital requires staff debriefing as part of an approach that has dramatically reduced its incidence of restraint and seclusion use.

Another commenter argued that debriefing is unnecessary in many cases of restraint use. The commenter further stated that requiring debriefing after each use of restraint or seclusion would create unnecessary work.

''It is not uncommon for patients to require restraint or seclusion for multiple episodes of aggression in a 24-hour time period. The underlying rationale for debriefings, to avoid future uses of restraint or seclusion, can be handled by other means, including consultation with the physician or advance practice nurse who authorizes restraint use. There could be debriefings when incidents are critical in nature.''

Response: We agree that debriefing can be a useful, productive exercise that helps both the patient and staff understand what has happened and how such situations can be averted in the future. However, we see the argument made by the opposing commenter as valid. The use of restraint or seclusion is only permitted while the unsafe situation persists, and must be discontinued at the earliest possible time. A patient may have multiple uses of restraint or seclusion in a fairly short timeframe. Requiring that a debriefing occur after each use may be impractical or unnecessary. We believe that hospitals and clinicians will use debriefing as a component of the treatment plan designed to safely manage violent or self-destructive patient behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others as necessary. Therefore, we are not requiring debriefing.

Comment: One commenter suggested that a multidisciplinary team should review each incident within 24 hours. Their review should be part of the hospital's quality assurance and peer review procedures.

Response: We believe that hospitals will monitor restraint and seclusion use through their Quality Assessment Performance Improvement (QAPI) programs. Mandating that a multidisciplinary team review each incident within 24 hours would be unnecessarily burdensome. Therefore, we are not specifying that this must occur in this rule.

B. Comments Received on Specific Provisions

1. The Right To Be Free From Restraint (§§ 482.13(e)(1) and (f)(1))

We stated that the patient has the right to be free from restraints of any form that are not medically necessary, or are used as a means of coercion, discipline, convenience, or retaliation by staff. Section 482.13(f)(1) paralleled this requirement and stated that the patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.

Comment: Many commenters agreed with this general statement and applauded our efforts to eliminate the inappropriate use of restraint. However, some commenters stated that the procedural requirements specified in the interim final rule for the appropriate use of restraint were too idealistic.

Response: We appreciate the support expressed by many commenters. Regarding concerns about the practicality of the current requirements, we believe that some commenters have interpreted current standard to require face-to-face monitoring in every clinical situation. Our intent is that the restrained or secluded patient's condition be assessed and monitored by a physician, other licensed independent practitioner or trained staff at an interval determined by hospital policy. In this final rule, we have amended the regulatory language at § 482.13(e)(10) to reflect this. Hospital policies should address the frequency of assessment and the assessment parameters (for example, vital signs, circulation checks, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity). Hospital policies should guide staff in how to determine an appropriate interval for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used. It may be that a specific patient needs continual face-to-face monitoring; or that the patient's safety, comfort, and well-being are best assured by periodic checks. Continual face-to-face monitoring is only required when restraint and seclusion are used simultaneously to address violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. The hospital is responsible for providing the level of monitoring and frequency of reassessment that will ensure the patient's safety. In this final rule, we have also added language to clarify that a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

Comment: One commenter stated that he could not find legal authority for health professionals to restrain their patients, absent specific court orders. The commenter also noted that health professionals might be excused for restraining patients only if the purpose of restraint is to minimize an imminent risk of great bodily harm, and only

when the need for restraint is not provoked by the health professional.

Response: We agree that consideration of the safety of the patient, staff, or others is the basis for applying a restraint. We have supported this approach in combined standard (e) by stating that all patients have the right to be free from physical or mental abuse, and corporal punishment, and have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, staff or others and must be discontinued at the earliest possible time. In the final rule, we have also stated that restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm. Finally, we have stated that the type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient or others from harm.

Comment: Several commenters argued that few effective means of therapeutic intervention for significant behavioral problems exist, and that disallowing the use of restraint or seclusion might result in a denial of treatment for individuals with significant problems because of the limitation on what providers can do to address symptoms. These commenters argued that providers would be unwilling to jeopardize staff and others' safety or incur any liability associated with untreated behaviors. Some commenters suggested that this regulation would result in the increased use of other interventions, such as psychotropic medications, to address behavioral challenges. Some suggested that without the use of restraint or seclusion, patients would remain incapacitated by their problems. Several commenters said that CMS inappropriately excluded ''therapeutic'' uses of restraint, such as therapeutic holding and medications.

Response: This final rule does not ban the use of restraint or seclusion. However, it does prohibit the use of restraint or seclusion that are imposed as a means of coercion, discipline, convenience, or retaliation by staff. This final rule also establishes parameters to assure patient safety when less restrictive interventions have been determined to be ineffective to protect the patient, staff, or others from harm. In the final rule, a restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort. The devices and methods listed here that would not be considered restraints, and thus not subject to these requirements, are typically used in medical surgical care. Although physical holding of a patient for the purpose of conducting routine physical exams or tests is not considered a restraint, all patients have the right to refuse treatment. This patient right is addressed at § 482.13(b)(2). The use of therapeutic holds to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others would be considered a form of restraint and therefore, would be subject to the requirements contained in this final rule. If the definition of restraint is met, then that practice or device (whether it is therapeutic holding or a mechanical device) is considered a form of restraint and may be employed so long as all of the requirements for restraint use are met.

In the interim final rule with comment period, the definition of ''drug used as a restraint'' specifically exempted medications that are used as a standard treatment for the patient's medical or psychiatric condition. Some commenters criticized this definition as being too broad and subjective. This regulation is not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need appropriate therapeutic doses of medications to improve their level of functioning so that they can more actively participate in their treatment. Similarly, the regulation is not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia or anti-anxiety medication prescribed to calm a patient who is anxious. Thus, those medications that are a standard treatment for a patient's condition are not subject to the requirements of this regulation.

In this final rule, we have defined a drug used as a restraint as a drug or medication that is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. We believe this revised definition more clearly supports the role of medications that facilitate the patient's participation in their care and maintenance of the patient's functional status.

Comment: A commenter suggested that the word ''discipline'' should be replaced with ''punishment,'' since the two words are not the same in meaning and there are situations where patient discipline is necessary.

Response: The distinction between the word ''discipline'' and ''punishment'' is a more relevant issue in the developmental disability/mental retardation setting, as opposed to the psychiatric and acute care settings. Therefore, we have retained the use of the word ''discipline.''

Comment: One commenter opined that this regulation provides the ''right to fall and break a hip'' or ''crack your head open.'' Another commenter who provides care to patients with dementia who ''need a vest restraint [commonly referred to as a Posey vest] at night to prevent them from falling out of bed, or getting up and falling in the bathroom,'' questioned whether allowing these patients to fall unnecessarily is more humane than restraining them. The commenter also stated that while some patients can be medicated and restrained briefly on an occasional basis, others—those with dementia or Alzheimers or both, for example, need some type of restraint most of the time on a permanent basis for their own safety.

Response: The final regulation states that devices that protect the patient from falling out of bed are not restraints. However, when the clinician raises all four side rails in order to restrain a patient, (defined in this regulation as immobilizing or reducing the ability of a patient to move his or her arms, legs, body, or head freely) to ensure the immediate physical safety of the patient then the rule applies. Raising fewer than four side rails when the bed has more than two side rails, would not necessarily immobilize or reduce the ability of a patient to move as defined in this regulation.

Practitioners and hospitals utilize a variety of measures to ensure patient safety. Use of a restraint is only one of the possible interventions.

Comprehensive assessment of the patient and the environment, in conjunction with individualized patient care planning, should be used to determine those interventions that will best ensure the patient's safety and well-being with the least risk. However, as part of clinician's decision-making, we would expect such an assessment to be conducted regardless of whether or not the intervention to ensure patient safety is considered a restraint under this regulation. Clinical decision making, which includes assessments, would govern the use of restrictions that are not covered by these requirements.

Regarding the idea that some patients require permanent restraint, we contend that every patient is entitled to an individualized assessment and treatment that takes into account the patient's individual strengths, weaknesses, choices, needs, and concerns. For example, most adults sleep at home in their beds each night without being tied down or otherwise protected from falling out of bed. All use of restrictions, whether governed by these regulations or not, should be based on an individualized patient assessment and the use of all available innovative alternatives and approaches to address patient care needs. Again, we have not prohibited the use of restraints; but we do prohibit using restraints as a substitute for adequate staffing, monitoring, assessment, or investigation of the reasons behind patient behavior such as wandering or getting up in the night, which may be indicative of unmet patient care needs. When the use of restraints is necessary, the combined standard (e) applies.

Comment: One commenter suggested adding the words, ''Or as a replacement for adequate levels of staff,'' to the statement that restraint may not be used as a means of coercion, discipline, convenience, or retaliation by staff.

Response: The final regulation language states that all patients have the right to be free from restraint or seclusion, of any form, imposed for convenience. This language precludes using restraint or seclusion as a substitute for adequate staffing levels. Therefore, we have not accepted this comment.

Comment: One commenter suggested removing the words, ''medically necessary,'' from (e)(1), arguing that physicians would not order treatments that were not medically necessary. Another commenter, however, described just such a case; namely, interventions undertaken at the voluntary request of the patient, such as a cognitively intact patient asking to have his or her bed's side rails put up. This commenter asked if a voluntary request would be exempted from meeting the regulatory requirements.

Response: In the final rule, ''not medically necessary'' has been removed from the definition of restraint. Restraint may only be used to ensure the immediate physical safety of the patient, staff, or others. In addition, a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

Often with the best of intentions, a patient or the patient's family may ask for a restraint to be applied. For example, a concerned husband may ask that his frail elderly wife be tied into bed to prevent her from wandering. In both examples, the concern may be valid, and a responsive intervention may be appropriate. However, a patient or family member may be unfamiliar with the many innovative, less restrictive alternatives available to address a patient's needs. Such a request, like any other patient or family request for an intervention, should prompt a patient and situational assessment to determine whether an intervention is needed. If a need is confirmed, the practitioner must then determine the type of intervention that will meet the patient's needs with the least risk and most benefit to the patient. A request from a patient or family member for the application of a restraint which they would consider to be beneficial is not a sufficient basis for the use of a restraint intervention. Regardless of whether restraint use is voluntary or involuntary, if restraint (as defined by the regulation) is used, then the requirements of the regulation must be met. Finally, this rule would not preclude a patient, or a patient's family member from requesting that his or her side rail be raised.

Comment: One commenter asked whether the rule requires adding the rights provided by standards (e) and (f) to the hospital's patients' rights policies and procedures and/or a written notification provided to the patient. The commenter argued that specifically stating these rights would require increased staff time, would be a risk management ''nightmare,'' and would require a patient/family member release form to be signed authorizing the use of a restraint, even when a restraint is medically necessary.

Response: Standard (a), Notice of rights, requires patient notification of his or her rights. We are not convinced that notifying the patient of the right to be free from restraint or seclusion imposed as a means of coercion, discipline, convenience, or retaliation by staff, will take significantly more time than informing the patient of his or her other rights, particularly since the hospital retains extreme flexibility in how and when this notice is provided. We are also uncertain why informing the patient of his or her rights would present a risk management ''nightmare.'' Concerning the commenter's third point, the rule does not require that the patient or his or her representative sign release forms. A hospital may choose to introduce this policy; however, depending on the mechanism the hospital uses to provide this notification (for example, as a standard part of each admissions packet; in posted forms in the admissions office or emergency room area; bundled with existing required notices) such a step may be unnecessary.

2. Definition of ''Restraint'' and ''Physical Restraint'' (§§ 482.13(e)(1) and (f)(1))

In the interim final rule with comment period, we stated that the term ''restraint'' includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

Comment: One commenter recommended uniform definitions of restraint and physical restraint across care settings to avoid confusion. Another commenter suggested defining restraint as, ''the forcible and involuntary deprivation of the liberty to move about.'' The same commenter recommended classifying restraints in three categories: least restrictive (manual restraint or holding); intermediate (seclusion, to be defined as ''restricting voluntary movement by locking a patient in a room. If an individual cannot leave the room at will, the room is considered locked, whether the door is actually locked or not''); and most restrictive and intrusive (mechanical restraints such as belts, cuffs, or soft ties). Several other commenters argued for similar categorization, with corresponding monitoring and ordering requirements

(that is, with consideration for the differences between interventions such as a four-point restraint and a restraint used for frail patients). One commenter argued that physical and mechanical restraints should be defined separately rather than lumped into one category.

Response: We agree that a uniform definition of restraint across care settings is a good approach, adds clarity, and avoids confusion. In the final rule, we have combined the regulations governing the use of restraint or seclusion into a single standard, and have adopted a single, consistent restraint definition. This definition applies to all uses of restraint in all hospital care settings. A restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. The final rule also clarifies that a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). This definition renders unnecessary the otherwise impossible task of naming each device and practices that can inhibit a patient's movement.

The concept of liberty of movement as proposed in this comment is incorporated in the final rule at the beginning of combined standard (e). All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to insure the immediate physical safety of the patient, staff, or others and must be discontinued at the earliest possible time.

However, we did not break restraints into three classes or view seclusion as a subset of restraint. We believe that the categorization proposed by the commenter is somewhat arbitrary, particularly in light of the fact that several of the deaths reported by the Hartford Courant occurred during physical holds, which the commenter would have categorized as ''least restrictive.'' This fact makes us wary of suggesting, even implicitly, that physical holds are preferable to mechanical restraint. The deaths resulting from other traditional mechanical devices also persuade us of the hazards of using mechanical restraints. The type of restraint used is not the defining hazard—other variables, such as lack of patient assessment in choosing the restraint, inappropriate application of the physical restraint mechanism or technique, or inadequate patient monitoring could render many interventions dangerous. Accordingly, given the unique circumstances presented by each patient, we believe that it would be inappropriate and would place patients at risk to arbitrarily suggest that one form of restraint is categorically preferable to another.

Finally, we have streamlined and clarified monitoring requirements in combined standard (e). The final rule states that the condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff at an interval determined by hospital policy. When restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen and evaluated face-to-face within one hour after the initiation of the intervention. This final rule provides flexibility for trained staff to determine the monitoring parameters necessary when a restraint or seclusion is used. The more stringent continual monitoring requirements have been retained only for patients who are simultaneously restrained and secluded for management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Comment: Some commenters asked whether the following constitute restraint: therapeutic holding; comforting children through holding; escorting or touching for de-escalation; virtually any type of touching, like holding a patient's arm to prevent him from hitting the wall; basket holds; or touching to encourage the patient to lie still for a procedure. Many commenters argued that therapeutic holding is necessary, and that the regulation should allow individualized treatment.

Response: Several commenters mentioned different types of holding, including therapeutic holding. For the purposes of this regulation, a staff member picking up, redirecting, or holding an infant, toddler, or preschool-aged child to comfort the patient is not considered restraint. If an intervention meets the regulatory definition of restraint, then that intervention constitutes a restraint and the standards for restraint use must be followed. A restraint is any method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely. A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort. The devices and methods listed here that would not be considered restraints, and thus not subject to these requirements, are typically used in medical surgical care.

The regulation permits the physical holding of a patient for the purpose of conducting routine physical examinations or tests. However, patients do have the right to refuse treatment. See § 482.13(b)(2). This includes the right to refuse physical examinations or tests. Holding a patient in a manner that restricts the patient's movement against his or her will would be considered a restraint. This includes therapeutic holds. Many deaths have involved these practices and may be just as restrictive and potentially dangerous as restraining methods that involve devices. However, the opportunity for individualized treatment of the patient is still available, since the regulation does not prohibit the use of any particular type of restraint. This regulation requires individualized patient assessment and use of the least restrictive intervention when restraint is needed to protect the patient, a staff member, or others from harm.

Comment: Several commenters asked whether a side rail was a physical restraint. One commenter stated that ''the majority'' of hospitals require that side rails be raised for safety reasons, and that patients do not perceive this common safety practice as a restraint. This commenter also cited a need for side rails to be raised to protect patients who are confused or disoriented by narcotics or controlled substances. Another commenter wanted to know if crib rails are a restraint.

Response: The final rule states that a restraint does not include methods that protect the patient from falling out of

bed. It is standard practice to raise the side rails when a patient is on a stretcher, recovering from anesthesia, sedated, experiencing involuntary movement, or on certain types of therapeutic beds to prevent the patient from falling out of the bed. However, the use of side rails to prevent a patient from exiting a hospital bed may pose risk to the patient's safety, particularly for the frail elderly who may be at risk for entrapment between the mattress and the bed frame. A disoriented patient may see the side rail as a barrier to be climbed over or may attempt to wriggle through split rails or to the end of the bed to exit the bed. As a result, this patient may have an increased risk for a fall or other injury by attempting to exit the bed with the side rails raised. The risk presented by side rail use should be weighed against the risk presented by the patient's behavior as ascertained through individualized assessment. Clinical judgment determines whether or not the use of siderails is governed by the rule. When the clinician raises all four siderails in order to restrain a patient, defined in this regulation as immobilizing or reducing the ability of a patient to move his or her arms, legs, body, or head freely to ensure the immediate physical safety of the patient, then the rule applies. Raising fewer than four siderails when the bed has more than two siderails, would not necessarily immobilize or reduce the ability of a patient to move as defined in the regulation.

Regarding the question of whether crib rails are a restraint, placement in a crib with raised rails is an age-appropriate standard safety practice for every infant or toddler. Therefore, placement of an infant or toddler in the crib with raised rails would not be regarded as a restraint. Age or developmentally appropriate protective safety interventions, such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers, that a safety-conscious child care provider outside a health care setting would utilize to protect an infant, toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of these regulations. The use of these safety interventions should be addressed in hospital policies or procedures.

Comment: Several commenters believed that mechanical restraints should never be used in the mental health treatment of children and adolescents. One commenter suggested banning both mechanical restraint and seclusion for patients who are 17 years of age or younger. Several commenters offered permutations of this suggestion, such as a ban on the use of mechanical restraint for patients under 17 years of age.

Response: Situations exist where it may become necessary to restrain or seclude a child or adolescent to ensure the safety of the patient or others. Regardless of age, the selection of an intervention must be individualized for each patient. When a restraint is used to manage self-destructive or violent behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a variety of factors, such as medical condition, disability, psychiatric condition, history of abuse, height, and weight, as well as age, must be assessed and evaluated to determine the least restrictive intervention that will effectively ensure the safety of the patient and others. In unique emergencies, a mechanical restraint may be necessary for a patient under 17 years of age. For example, if a 250-pound 16-year old male is physically attacking another patient, staff may have limited options to stop the attack. At times, the child's size may eliminate the ability to safely use a physical hold with the staff available. The child's medical condition (for example, asthma or a fractured limb) could also contraindicate the use of a physical hold.

However, we recognize that children and adolescents, as well as adults, are vulnerable and at risk when restrained or secluded to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Therefore, we have retained the time limits on each order for restraint or seclusion to manage aggressive destructive in combined standard (e). Orders are limited to 4 hours for adults 18 years of age or older; 2 hours for children and adolescents 9 to 17 years of age; and 1-hour for children under 9 years of age. The restraint or seclusion order may only be renewed in accordance with these limits for up to a total of 24 hours. Before writing a new order, a physician or licensed independent practitioner must see and assess the patient.

Comment: Many commenters indicated that the restraint definition is too broad and includes items that are typically used in the provision of care, such as catheters, drainage tubes, plastic casts, and bandages, which can restrict freedom of movement. Several commenters asked whether adaptive or protective devices such as helmets, or devices that are used for postural support, meet the definition of restraint. One commenter asked whether CMS would permit the use of devices to assist with chronic conditions or for physically frail patients. One commenter asked that we address the use of restraint for dental, diagnostic, and surgical procedures. The commenter stated that devices used for medical immobilization are given an exemption by JCAHO. The commenter asked if CMS would create a mirroring exemption.

Response: In response to comments, we have added language that limits the application of this definition. In the final rule, a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). The devices and methods listed here that would not be considered restraints, and thus not subject to these requirements, are typically used in medical surgical care. Adaptive devices or mechanical supports used to achieve proper body position, balance, or alignment to allow greater freedom of mobility than would be possible without the use of such a mechanical support is not considered a restraint. For example, some patients are unable to walk without the use of leg braces, or are unable to sit upright without neck, head or back braces. Such devices generally permit the patient to participate more fully in activities without the risk of physical harm.

Comment: Several commenters suggested that devices used for security purposes should be exempt from the regulatory requirements. Another commenter argued that forensic hospitals or units should be exempted from the regulatory requirements because they compromise the hospital's ability to manage behavior.

Response: The use of handcuffs or other restrictive devices applied by law enforcement officials who are not employees of the hospital for custody, detention, and public safety reasons are not governed by this rule. The law enforcement officers who maintain custody and direct supervision of their prisoner (the hospital's patient) are responsible for the use, application, and monitoring of these restrictive devices in accordance with Federal and State law. However, the hospital is still responsible for providing safe and appropriate care to the patient.

Comment: One commenter argued for the need for ''programmatic'' use of restraint for mentally retarded patients

in a psychiatric or an acute care unit and stated that the interim final rule with comment period created a barrier to using a restraint as part of a treatment plan.

Response: Our expectation is that restraint or seclusion will not be a standard response to a particular behavior or situation. The use of such interventions is a temporary measure that protects the safety of patients and others, but is not a long-term solution for handling problematic behavior.

3. Definition of ''Drug Used as a Restraint'' (§§ 482.13(e)(1) and (f)(1))

We stated that a drug used as a restraint is a medication used to control behavior or restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.

Comment: Some commenters indicated that the definition of ''drug used as a restraint'' was too broad, subjective, and confusing. One commenter suggested that we adopt the definition of chemical restraint found in the long-term care interpretive guidelines—that is, ''A medication used for discipline or convenience that is not required to treat medical symptoms.''

Several commenters argued that the determination of what constitutes a ''standard treatment'' for certain medical or psychiatric conditions is too subjective. One commenter observed that physicians may legitimately order nonstandard treatments for their patients. Another commenter noted that problems present in mentally retarded patients do not correspond closely to any medical or psychiatric diagnosis and that the rule only discusses these two sorts of standard uses of medication. One commenter explained that in acute care, medications are changed based on the patient's medical condition and symptoms. This commenter also stated that this regulation creates a burden for the administrative staff that will have to distinguish a drug used as ongoing medical management from a drug that, at some point, has evolved into a restraint that is not part of standard treatment.

Other commenters grappled with how to characterize the appropriate role of medications in a patient's care. For example, one commenter expressed alarm at the apparent ban on PRN orders for medications that might affect a patient's behavior or restrict a patient's movement. The commenter argued that medications for behavioral health patients are used precisely to affect behavior so that the patient can participate more fully in his or her care, treatment, and therapy. The commenter stated that they are administered in order to avoid the emergence or escalation of specific behaviors that might prompt the use of more restrictive physical restraints or seclusion. The commenter also stated behavioral health providers recognize that the use of the same drug may be therapeutic in one instance and not in another, and have indicated that a drug used as a restraint should not be applied when its use impedes a person's ability to participate in his or her care. Some commenters noted that drug therapy should be part of an effective treatment plan to manage behavior.

There was little agreement among commenters as to how drugs used to restrain patients should be handled. While a few commenters agreed with the concept that a drug used as a restraint is not a standard treatment (one stating that ''prohibition is critical''), several recommended deleting any reference to a drug used as a restraint. One commenter argued that the use of medications is already closely scrutinized through pharmacy oversight and the physician ordering process. The requirements of the interim final rule with comment period add an unnecessary layer of oversight.

Another commenter stated that the use of a drug as a restraint should appear in its own standard, as the use of a medication differs from physical interventions.

The idea of a medication ''controlling'' behavior garnered considerable comments which included the following:

- All psychotropic medications control behavior to the extent that they reduce psychiatric symptoms;
- The idea of a medication controlling behavior is not as straightforward as it appears;
- No medication ''controls'' behavior. A better word would be ''directs,'' ''contains,'' or ''ameliorates;''
- All drugs have effects as a restraint; and
- The phrase ''control behavior'' should be removed, and a drug used as a restraint should be defined as a drug used with the intent to restrain or restrict the patient's freedom of movement.

One commenter asked for clarification regarding the classification of paralytic drugs, sedatives, and analgesics, and how they would be affected by the regulation.

A commenter suggested that if a patient has consented to the use of a medication, it should not be classified as a drug used as a restraint. Another commenter argued that if a drug is used as a one-time dose to help aid in the plan of care but is not part of the care plan, it is not a drug used as a restraint.

Many commenters characterized the use of a drug as possibly the least restrictive alternative to deal with violent or aggressive behavior, arguing that its use is more humane than allowing the patient to escalate and lose self-control.

Response: Patients have a fundamental right to be free from restraints that are imposed for coercion, discipline, convenience, or retaliation by staff, including drugs that are used as restraints. In the interim final rule with comment period, the definition of ''drug used as a restraint'' was phrased so that medications that are used as part of a patient's standard medical or psychiatric treatment would not be subject to the requirements of standards (e) or (f). These regulations are not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need therapeutic doses of medication to improve their level of functioning so that they can more actively participate in their treatment. Similarly, these regulations are not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia, anti-anxiety medication prescribed to calm a patient who is anxious, or analgesics prescribed for pain management. This language was intended to provide flexibility and recognize the variations in patient conditions.

A standard treatment for a medication used to address a patient's condition would include all of the following:

- The medication is used within the pharmaceutical parameters approved by the Food and Drug Administration (FDA) and the manufacturer for the indications it is manufactured and labeled to address, including listed dosage parameters.
- The use of the medication follows national practice standards established or recognized by the medical community and/or professional medical association or organization.
- The use of the medication to treat a specific patient s clinical condition is based on that patient's symptoms, overall clinical situation, and on the physician's or other LIP's knowledge of that patient's expected and actual response to the medication.

An additional component of ''standard treatment'' for a medication is the expectation that the standard use of a medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around them than would be

possible without the use of the medication. If the overall effect of a medication is to reduce the patient's ability to effectively or appropriately interact with the world around the patient, then the medication is not being used as a standard treatment for the patient's condition. We believe that trained practitioners possess the skills and abilities necessary to identity when a drug or medication is being used as a standard treatment for the patient's condition and when it is not.

Whether or not the use of a medication is voluntary, or even whether the drug is administered as a one time dose or PRN are not factors in determining if a drug is being used as a standard treatment. The use of PRN medications is only prohibited if the drug is being used as a restraint. The regulation supports existing State laws that provide more vigorous promotion of the patient's choice and rights.

Of course, as with any use of restraint, staff must conduct a patient assessment to determine the need for other types of interventions before using a drug as a restraint. For example, a patient may be agitated due to pain, an adverse reaction to an existing medication, or other unmet care need or concern.

There are situations where the use of a medication is clearly outside the standard for a patient or a situation, or a medication is not medically necessary but is used for patient discipline or staff convenience (neither of which is permitted by the regulation). In such situations, the patient has the right to be free from the use of a drug as a restraint.

For example, a patient has Sundowner's Syndrome, a syndrome in which a patient's dementia becomes more apparent at the end of the day than the beginning of the day. The patient may become agitated, angry, or anxious at sundown. This may lead to wandering, pacing the floors, or other nervous behaviors. The unit's staff find the patient's behavior bothersome, and ask the physician to order a high dose of a sedative to ''knock out'' the patient and keep him in bed. The patient has no medical symptoms or condition that indicates that he needs a sedative. In this case, for this patient, the sedative is being used as a restraint for staff convenience. Such use is not permitted by the regulation. The regulation does not allow a drug to be used to restrain the patient for staff convenience, to coerce or discipline the patient, or as a method of retaliation.

While the characterization of medications as more humane and less invasive was quite common in comments on the interim final rule with comment period, we put forth the caveat offered by one physician—that overuse of antipsychotic medications can result in severe, sometimes irreversible neurological side effects or Neuroleptic Malignant Syndrome, which is potentially fatal. Also increased psychotropic medication use may lead to excessive sedation and cognitive dulling that impairs the patient's ability to benefit from therapy. While medications can be a beneficial part of a carefully constructed, individualized treatment plan for the patient, medication use should be based on the assessed needs of the individual patient and the effects of medications on the patient should be carefully monitored.

We agree with the many comments regarding the idea of a medication ''controlling'' behavior. To further clarify our intent and respond to public comments, we have revised the definition of ''drugs used as a restraint.'' In this final rule, a drug used as a restraint is now defined as ''a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.''

Comment: One commenter asked whether the time-limited orders and the assessment, documentation, and monitoring requirements of standards (e) and (f) apply to a drug used as a restraint.

Response: Yes. If the use of the medication for the patient meets the definition of a drug used as a restraint, the requirements of combined standard (e) apply.

Comment: One commenter asked that orders for PRN medications be deemed appropriate. Many commenters objected to the ban on PRN orders for drugs used as a restraint.

Response: In the final rule, PRN orders for medications are not prohibited. The use of PRN orders is only prohibited for drugs or medications that are being used as restraints. We believe that ongoing assessment, monitoring, and re-evaluation by the ordering practitioner are even more critical when a patient is receiving treatment that is not standard, or is administered in amounts or at a frequency greater than recommended by the manufacturer or current standard of practice, for the patient's condition. Therefore, we are retaining this requirement.

4. Use of Restraints (§§ 482.13(e)(2) and (e)(3)(i))

Section 482.13(e)(2) states that a restraint can only be used if needed to improve the patient's well-being and less restrictive interventions have been determined to be ineffective. Section 482.13(e)(3)(i) states that the use of a restraint must be selected only when other less restrictive measures have been judged to be ineffective to protect the patient or others from harm. These two provisions are redundant, and in the final rule we have collapsed them into one requirement. We will discuss them together, as the public comments tended to apply to both.

Comment: One commenter believed that the regulation should include illustrations of less restrictive interventions and alternative methods for handling behavior, including a requirement that when there is a history of a particular less restrictive intervention being ineffective, other interventions must be tried.

Response: Including such illustrations in the regulation is not feasible. Putting aside the fact that regulations generally provide requirements rather than best practice suggestions, each care situation consists of a unique combination of factors. What seems least restrictive for one patient may not be an appropriate option for another patient. The underpinning of this regulation is the concept that good patient care hinges on looking at the patient as an individual and assessing the patient's needs, strengths, weaknesses, and preferences. Such an approach relies on caregivers who are skilled in individualized assessment and in tailoring interventions to individual patient's needs after weighing factors such as the patient's condition, behaviors, and history. A list of progressive interventions that should be taken would undermine the emphasis on individualized care, and could discourage creativity in meeting patient needs. However, there are resources available. For example, the American Psychiatric Association (APA), American Psychiatric Nurses Association (APNA), and the National Association of Psychiatric Health Systems (NAPHS), with support from the American Hospital Association (AHA), have sponsored the publication of a document entitled, ''Learning from Each Other—Success Stories and Ideas for Reducing Restraint/Seclusion in Behavioral Health.'' This document, published in 2003, was developed through dialogue with the field and extensive input from behavioral healthcare providers throughout the country who have been working to reduce the use of restraint and seclusion, and to improve care within their facilities. To access this document and other useful resources, visit the web sites of the sponsoring organizations:

http://www.naphs.org; *http://www.psych.org*; *http://www.apna.org*; *http://www.aha.org*.

Comment: One commenter argued that it would be impossible to comply both with the Patients' Rights CoP standard (c), which protects patient safety and the patient's right to be free from all forms of harassment, and standard (f). The commenter included the following example, a manic or psychotic patient may be verbally abusive to another patient or destructive of that patient's property without actually being a physical threat to the other patient. The commenter stated that such behavior has often been handled by the use of seclusion until medication can relieve the patient's agitation and abusiveness.

Response: Standard (c) provides that each patient has the right to receive care in a safe setting, and the right to be free from all forms of abuse or harassment. This standard clearly prohibits the behavior described by this commenter, and some type of intervention would be warranted. However, such behavior need not prompt the automatic use of restraint or seclusion. The training requirements in standard (f) of this final rule ensure that patients are attended to by staff that are trained and skilled in utilizing an array of techniques and skills for handling aggression. Depending on this situation, various interventions (other than restraint or seclusion) may address the patient's behavior and simultaneously promote the right of others to safety and freedom from harassment and abuse.

Comment: One commenter suggested that seclusion and restraint should be used only when less restrictive interventions, such as time-outs and one-to-one staffing, are ineffective in preventing immediate injury of the patient or others. Several commenters asked whether less restrictive interventions actually had to be tried and shown to fail before a more restrictive intervention was used. A number of these commenters also questioned whether the patient or another person must be injured before more restrictive intervention may be undertaken.

Response: Less restrictive interventions should be considered before resorting to the use of restraint or seclusion. However, it is not always appropriate for less restrictive alternatives to be attempted prior to the use of restraint or seclusion. For example, when a patient physically attacks another patient, immediate action is needed. When a patient's behavior presents an immediate and serious danger to the patient or others, immediate action is needed. While staff should be mindful of using the least intrusive intervention, it is critical that the intervention selected be effective in protecting the patient or others from harm. Therefore, we have retained the requirement that a restraint or seclusion can only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.

Comment: One commenter suggested adding, ''The patient has the right to be treated in a safe manner when special procedures are required for the patient's care.''

Response: While we agree that the patient has the right to be treated in a safe manner, we believe that this right exists regardless of whether or not the patient is undergoing a special procedure.

Comment: One commenter suggested considering an issue raised by a New England Journal of Medicine article; specifically, that the regulation should state plainly that a competent patient may refuse the use of physical restraint in the patient's acute care or treatment. The commenter further suggested that an incompetent patient's representative should be able to exercise this right to refuse physical restraint on the patient's behalf. Similarly, another commenter stated that the regulation should consider the individual's right to make choices regarding their health care. The commenter further stated that after complete information is provided about the method, risks, and effects of these procedures, individuals and families should have the right to either reject their use or select them as part of an overall treatment regime.

Response: The Patients' Rights CoP promotes the patient's right to be involved in and make decision about the patient's health care. Standard (b)(2) states that the patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary. In this context, the use of a restraint would be considered a ''treatment.'' Before the patient decides to request or refuse the use of restraint or seclusion, the patient must be informed of the risks associated with refusing the use of a restraint. While the hospital should work with the patient regarding preferences as much as possible, the hospital is not obligated to come up with a menu of alternative options because of the patient's refusal. The hospital may refuse to perform a procedure or render care if it believes that it is unable to safely and appropriately do so because of the patient's refusal to allow certain aspects of the prescribed treatment. In addition, if the patient's violent or self-destructive behavior jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient does not have the right to refuse the use of restraint or seclusion. In this situation, the use of restraint or seclusion is an emergency measure to protect the safety of the patient, staff, or others. If the patient or the patient's representative requests the use of restraint or seclusion, the attending practitioner would need to decide whether the intervention is appropriate.

In conclusion, the restraint or seclusion requirements do not prevent the patient from making informed decisions or participating in the patient's healthcare. The rule establishes the patient's right to be free from inappropriate restraint or seclusion, and lays out basic protections in the event that these interventions are needed.

Comment: One commenter questioned whether, because of the ''Patients'' Rights'' provisions regarding patient privacy and safety, a restrained patient must be restrained in a separate, private room, and not in the day room.

Response: A hazard of restraining a patient is the damage that may be done to the patient's dignity. The patient may feel dehumanized or humiliated, which could be exacerbated by having peers witness the experience. Certainly, we would not expect that a patient put in four-point restraint would be placed in the midst of the day room in a psychiatric facility since this would be humiliating to the patient. The restrained patient should be afforded as much privacy as possible. Since an underlying therapeutic goal for any psychiatric patient is the development of a strong sense of self-worth and dignity, the hospital should take steps to protect the privacy of the restrained patient.

However, an individual wearing mitts to prevent self-mutilating behaviors is also being restricted. These individuals may desire socialization and group activity notwithstanding these restraints that a patient in the midst of a psychiatric crisis would not. We provide these examples to stress that it is critical for the hospital to use an individualized approach that is in the best interest of the patient and promotes

the patient's health, safety, dignity, self-respect, and self-worth.

Comment: Several commenters believed that the documentation of clinical justification for the use of seclusion and restraint, the alternative methods used, and the reasons for their ineffectiveness should be included in the patient's record. Another commenter was concerned that staff's time for direct patient care would be diverted into creating documentation if we require demonstration that less restrictive interventions were proven ineffective in cases that involve medical immobilization.

Response: We agree with the commenters. In the final rule under combined standard (e), we have specified that when restraint or seclusion is used, the following must be documented in the patient s medical record:

- The 1-hour face-to-face medical and behavioral evaluation when restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others;
- A description of the patient's behavior and the intervention used;
- Alternatives or less restrictive interventions attempted (as applicable);
- The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and
- The patient's response to the intervention used, including the need for continued use of the intervention.

We believe that such documentation is a usual and customary recordkeeping practice. This information will provide a valuable tool for charting the patient's course of treatment as well as examining trends of use.

In response to comments, we have added language that limits the application of the restraint definition. In the final rule, a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). The devices and methods listed here, typically used in medical/surgical care, would not be considered restraints and, therefore, not subject to these requirements. We believe that this addresses the commenter's concern regarding the burden of documentation in such cases.

Comment: Several commenters asked that the word ''determined'' be replaced with the word ''found.''

Response: We consulted the dictionary to determine whether there was some significant difference between these two words. We found none. When we combined the two requirements, we retained the word ''determined.''

Comment: One commenter suggested moving the sentence, ''A restraint can only be used if needed to improve the patient's well-being and less restrictive interventions have been determined ineffective,'' from paragraph (e)(2) to paragraph (e)(1). The commenter stated that this would place a greater emphasis on the fact that less restrictive measures must be demonstrated to be ineffective first.

Response: Although we agree that the language in paragraph (e)(2) is an essential component of standard (e), we do not believe that it is necessary to relocate this language to paragraph (e)(1). We also note that we have revised the regulatory text in the final rule to state that ''a restraint can only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.'' We deleted the language ''to enhance the patient's well-being'' for clarity.

Comment: One commenter asked which individual(s) would be responsible for making the determination that a less restrictive intervention was ineffective, and suggested that we use the phrase ''clinically determined'' to indicate that this decision would be made by the nursing staff.

Response: Since any trained clinical staff could make such decisions, we have decided not to specify further who should determine that a less restrictive intervention is ineffective for a particular patient.

Comment: One commenter stated that positive reinforcement should be used prior to restraint or seclusion.

Response: Combined standard (e) specifies that restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm. The intent, as suggested by the commenter, is to encourage staff to use alternative, less restrictive methods, such as positive reinforcement, in the patient's treatment.

5. Ordering of Restraint/Seclusion (§ 482.13(e)(3)(ii) and (f)(3)(ii))

In this section, we stated that the use of a restraint must be in accordance with the order of a physician or other licensed independent practitioner (LIP) permitted by the State and hospital to order a restraint. Section 482.13(f)(3)(ii) reiterated this requirement when a restraint is used for behavior management, but added that the use of seclusion must also be in accordance with such an order.

a. Definition of Licensed Independent Practitioner (LIP) (§§ 482.13(e)(3)(ii) and (f)(3)(ii))

Comment: Many commenters stated that the definition of LIP was unclear and open to interpretation. These commenters were unsure of how delegated authority affected whether a practitioner was considered an LIP, of which ''independent'' practitioners qualify as LIPs, and of how the counter-signing of orders affected the determination of whether a practitioner is independent.

Several independently licensed health professionals, such as nurse practitioners and physician assistants, applauded our inclusion of the LIP as recognition of highly trained individuals with strong patient assessment skills. These commenters stated that it was important to recognize the contribution of the multidisciplinary team in today's health care settings.

Many commenters asked for an explanation of who would be considered an LIP. Some commenters wanted explicit recognition of registered nurses as LIPs; one commenter suggested replacing ''LIP'' with the term ''health care professional,'' so that registered nurses would clearly be included. Many licensed professionals such as physician assistants, nurse practitioners and advanced practice registered nurses were concerned that narrow interpretation of the term ''LIP'' might limit their ability to be fully involved in patient care. One organization stated that ''LIP'' is the most problematic language in JCAHO's standards and argued that use of this term might result in inappropriate limits on its constituents' scope of practice. This organization explained that the phrase is given wide and varied interpretations by both hospitals and JCAHO surveyors.

Another concern expressed by commenters was that this regulation marked the first appearance of this term in the CoPs. Several commenters questioned how LIPs might be introduced in the remaining hospital CoPs.

One commenter viewed the term ''LIP,'' with its requirement that the practitioner be able to independently order restraint or seclusion, as restricting existing practice. This

commenter argued that such a restriction should only occur after a finding that the existing practice has had an adverse effect on patient care or that limiting this authority to physicians would improve patient care. The commenter believed that neither the former nor the latter point have been demonstrated or proven. This commenter also noted that State law usually addresses when an LIP may order restraints.

Response: The introduction of an alternative practitioner who could order interventions, assess patients, and renew orders was an attempt to accommodate existing State laws that acknowledge the role of non-physicians in patient care and treatment. We originally used the term ''LIP'' to describe these practitioners to be consistent with existing JCAHO standards.

For the purposes of this rule, a LIP is any individual permitted by State law and hospital policy to order restraints and seclusion for patients independently, within the scope of the individual's license and consistent with the individually granted clinical privileges. This provision is not to be construed to limit the authority of a physician to delegate tasks to other qualified healthcare personnel, that is, physician assistants and advanced practice nurses, to the extent recognized under State law or a State's regulatory mechanism, and hospital policy. It is not our intent to interfere with State laws governing the role of physician assistants, advanced practice registered nurses, or other groups that in some States have been authorized to order restraint and seclusion or, more broadly, medical interventions or treatments.

Each State faces the issue of how to best provide its citizens with access to needed health care services. The issue is complex, as some States have special considerations such as geographic barriers to care delivery, medically underserved areas, and special population needs, all of which would affect how a State resolves this issue. To disregard a State's decision about who is qualified to order medical treatments and interventions and render patient care would be unproductive and arbitrary.

To clarify this, in combined standard (e), we have revised the standard to state that the use of a restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

b. Physician Only

Comment: While some commenters supported deferring to the States' determination of which health professionals are allowed to order seclusion or restraint, one contingent opposed allowing anyone other than a physician to order restraint or seclusion, evaluate the patient, or renew an order for restraint or seclusion. This group pushed for the rule to override existing State laws that would allow these functions to be performed by anyone other than a physician. Several of these commenters stated that the clinical skills and qualifications of some licensed therapists are not necessarily indicative of an understanding and knowledge of the medical needs or risks of patients in seclusion or restraint. Without this understanding or knowledge, there continues to be risk to patients if other medical symptoms are overlooked.

Some commenters cited national legislation pending at the time that would permit only a physician to order restraint/seclusion. Advocacy organizations charged that by permitting someone other than a physician to order restraint or seclusion, CMS would be allowing any 1 of over 600,000 mental health professionals to authorize the use of restraint and seclusion, effectively undermining the purpose of the rule. Many commenters reminded us that the motivation behind the promulgation of this rule is the increasing concern regarding injuries, deaths or harm associated with the use of restraint and seclusion. One commenter maintained that by significantly narrowing the categories of clinicians permitted to authorize the use, the risk of misuse or overuse of restraint and seclusion would be minimized.

Several commenters cited the importance of physicians' clinical training, the fact that they are individually accountable, and the fact that they are distanced from the daily stress and conflicts that arise between non-physician staff members and patients. Other commenters asserted that it is reasonable to require that only a physician authorize the use of procedures that can have serious and dangerous consequences for patients. A number of factors may lead to a patient displaying violent or agitated behavior, including inappropriate medication, which often times can be corrected immediately. One national organization representing physicians also opposed the recognition of non-physicians as being able to order restraints and seclusion.

Response: Some States have issues such as geographic barriers to care delivery, medically underserved areas, and special population needs. States have handled these difficult issues through a variety of mechanisms. If a State has decided that a group of practitioners may order medications or treatments exclusively, we defer to State laws.

Physicians are individually accountable for the care of their patients. The physician has the discretion to delegate, or to withhold the delegation of, tasks or responsibilities as he or she deems appropriate. We believe that the physician is more than capable of making the determination regarding whether his or her direct oversight is necessary, or whether in some situations, as permitted by hospital policy, these functions can be performed by another practitioner. The continued physician accountability for actions taken under his or her license provides a direct incentive for taking the decision to delegate very seriously.

As commenters pointed out, clinical psychologists or other practitioners who may be authorized by the State to order restraint or seclusion may lack the technical medical skills and training to conduct a comprehensive physical assessment. Therefore, the practitioner who conducts the 1-hour face-to-face evaluation must be able to complete, under their scope of practice, both a physical and psychological assessment of the patient. To ensure physician oversight of restraint and seclusion, we have retained the requirement that the attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

Comment: Some commenters representing independent residential treatment centers, day programs, skilled nursing facilities, and other non-hospital provider types mistakenly believed that the requirements in these hospital CoPs were applicable to them. Accordingly, a number of the commenters cited physician access as a problem.

Response: We reiterate that these requirements apply to Medicare- and Medicaid-participating hospitals only, that is, short-term, psychiatric, rehabilitation, long-term, children's and alcohol-drug hospitals. The pending regulations based on the CHA will address the use of restraint and seclusion in the other settings noted above.

Comment: Several commenters expressed concern that practitioners without psychiatric training may be allowed to order seclusion or restraint to manage aggressive, self-destructive or violent patient behavior.

Response: We have revised combined standard (e) to specify that the use of restraint or seclusion must be ordered by a physician or other LIP who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with State law. We have also tied the order for restraint or seclusion to the patient's attending physician. The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion. We believe that this modification will alleviate concerns about a practitioner who may not have psychiatric training, or is unfamiliar with the patient's condition or diagnosis providing orders for the patient's care.

Comment: One commenter wrote that when fewer staff at the hospital are allowed to routinely approve seclusions or restraint, there is less likelihood of a serious review and a reduction of their use.

Response: As part of a hospital's QAPI program, we would expect the use of restraint and seclusion to be monitored and evaluated on an ongoing basis. We believe that the number of staff permitted to order restraint or seclusion is irrelevant to the QAPI process.

Comment: Several commenters were concerned that the regulation could be interpreted as precluding physicians enrolled in residency training programs from ordering restraints or seclusion, or from evaluating the need for their continued use. For example, in Maryland, residents generally do not hold a State medical license, but are authorized to practice without completing the usual licensing process. A commenter stated this is permitted because of the close supervision that residents receive during their training, and because required licensing is impractical since residents often move to another State to complete their training or to set up permanent practice.

Response: In many States a resident is authorized by State law to practice as a physician. Therefore, there is no question that a resident can carry out the functions reserved for a physician or LIP by this regulation in accordance with State law.

Comment: One commenter opined that psychologists and behavior analysts, not just physicians, should assume responsibility for the design and oversight of restraint and seclusion. Physicians should regulate chemical restraint and assume principal responsibility for the oversight of psychiatric problems and the design of pharmacological and psychiatric interventions.

Response: We recognize the important role that psychologists and other behavioral health professionals play as members of the multidisciplinary team. We believe that these practitioners should participate in the design and oversight of restraint and seclusion practices, as well as participate in patient care. However, we do not believe Congress gave us the authority to create ordering authority for psychologists or other professionals in States that have not granted them this authority. Wherever State law and hospital policy have afforded ordering rights to these practitioners, we have honored that decision.

Comment: One commenter stated that if the patient or the patient's surrogate voluntarily consents to the use of the restraint in the provision of acute medical and surgical care, an order from the physician or other LIP is not required per JCAHO's requirements. The commenter also stated that if restraints are clinically justified and consent is obtained, the care of the patient is consistent with the standards, and no order should be needed.

Response: The current JCAHO standard at PC.11.40 requires that restraint use be based upon an individual order from an LIP. If an intervention meets the definition of a restraint, the regulatory requirements apply regardless of whether use of the restraint is voluntary or involuntary. This would include the requirement for a physician or other LIP order. The use of restraint is inherently risky. The risks associated with any intervention must be considered within the context of an ongoing process of assessment, intervention, evaluation, and re-evaluation.

c. Elimination of Protocols

Many commenters discussed the key differences between acute medical and psychiatric settings and the use of protocols in specified situations in each of these settings. The more commonly cited examples included the use of arm boards to protect an IV site, or the restraint of a patient's arms to prevent the removal of an endotracheal tube. Commenters argued that in these situations, the need for restraint could be anticipated given the medical procedure or symptoms and condition of the patient. Before publication of the interim final rule with comment period, acute medical and postsurgical protocols were used to handle such situations. Use was triggered by the existence of specified criteria. Some commenters argued that disallowing acute medical and postsurgical protocols increases the risk of needless reintubating or replacement of IVs. Most hospitals use physician-reviewed protocols to determine the need for restraint in the medical/surgical context, a practice that is accepted by JCAHO. JCAHO affirmed this, and recommended allowing the use of protocols in certain situations with medical staff approval. JCAHO explained that during the treatment of certain specific conditions (for example, post-traumatic brain injury) or certain specific clinical procedures (for example, intubation), restraints might often be necessary to prevent significant harm to the patient. For those conditions or procedures, protocols for the use of restraint may be established based upon the frequent presentation of patient behavior that seriously endangers the patient or compromises the effectiveness of the procedures. Such protocols would include guidelines for assessing the patient, and criteria for application, monitoring, reassessment, and termination of the restraint. JCAHO stated that it was unaware of any evidence or studies indicating that the use of protocols in this manner has in any way diminished patient care. Some commenters expressed strong support for these types of protocols.

One commenter stated that we should not prohibit the use of such protocols and the use of PRN orders by LIPs or physicians, and asked that we expressly state that those sorts of protocols are acceptable.

One commenter pointed to a passage in the interim final rule with comment period (64 FR 36083) which discussed the initiation of restraint/seclusion according to protocols developed by hospital and medical staff, as permitting the use of acute medical and surgical protocols.

Response: Protocols are not banned by the regulation. A protocol may contain information that is helpful for staff, such as how a restraint is to be applied and monitored. However, a protocol cannot serve as a substitute for obtaining a physician or other LIP order before initiating each episode of restraint or seclusion use, and the requirements of the regulation must still be met. The philosophy that serves as the foundation for the regulation is that restraint or seclusion use is an exception, not a routine response to a certain condition or behavior. Each patient should be thoroughly assessed. Interventions should be tailored to meet the individual patient's needs. The creation

of a protocol can run counter to this philosophy if it sets up the expectation that restraint will be used as a normal part of care. The use of restraint or seclusion is a last resort when less restrictive measures have been determined ineffective to protect the patient or others from harm, not a standard response to a behavior or patient need.

As discussed previously, we have added language to combined standard (e) that limits the application of the definition of restraint. In the final rule, a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). The devices and methods listed here, typically used in medical/surgical care, would not be considered restraints and, therefore, not subject to these requirements. This revision clarifies the definition of a restraint and addresses many of the examples cited by commenters.

When implementing a protocol that includes the use of an intervention that meets the definition of a restraint, a separate order must be obtained for the restraint. In addition, the patient's medical record must include documentation of an individualized patient assessment indicating that the patient's symptoms and diagnosis meet use-triggering criteria listed in the protocol. Hospitals that utilize protocols in the situations commenters described would be expected to provide evidence that there has been medical staff involvement in the development, review, and quality monitoring of their use.

d. Initiate versus Order

Comment: Many facilities stated that they do not have a physician present 24 hours a day. One commenter suggested that the registered nurse be given the ability to assess and respond to emergency life threatening situations. Another commenter suggested that we should permit an emergency protocol that could be initiated by a health care professional if a physician or LIP was not present.

Several commenters questioned whether an order would have to be obtained before initiating restraint or seclusion and requested clarification regarding who may initiate seclusion or restraint. One commenter suggested we require that, ''If an order cannot be obtained prior to instituting restraint or seclusion, their use must be authorized by a registered nurse, who shall document in the patient record both the reasons for restraint or seclusion as well as the need to use them prior to obtaining an order.'' One commenter stated that given the unpredictable frequency of emergencies and the need for intervention for certain conditions and populations, requiring a physician's order for each intervention is impractical. Others expressed concern that the regulations do not specifically say that a registered nurse can initiate restraint in an emergency situation, which is most often what happens.

Response: We understand that physicians are not always onsite when an emergency occurs. Registered nurses play a vital role in ensuring patient safety and well being. We do not expect staff to stand by and let the patient injure himself or others without intervening simply because a physician is not present. The hospital may develop emergency procedures that staff follow before obtaining the order for restraint or seclusion; however, an order must be obtained as soon as possible.

Many types of emergencies can occur, and staff are expected to effectively respond. In some emergency situations, the need for a restraint or seclusion intervention may occur so quickly that an appropriate order cannot be obtained before the application of restraints. In these emergency situations, the order must be obtained either during the emergency application of the restraint or seclusion, or immediately after the restraint has been applied. The hospital should address this process in its restraint policies and procedures. These hospital procedures should specify who could initiate the use of restraint or seclusion in an emergency prior to obtaining an order from a physician or other LIP.

6. Prohibition on Standing and PRN Orders (§ 482.13(e)(3)(ii)(A) and (f)(3)(ii)(A))

We stated that an order for restraint must never be written as a standing or on an as needed basis (that is, PRN). Section 482.13(f)(3)(ii)(A) contains a parallel provision for behavior management that also applies to orders for seclusion.

Comment: We received many comments arguing that PRN orders for medication should be permitted. Many commenters, who objected to the PRN prohibition stated that it represents a departure from current practice. Some commenters supported the use of PRN medications as humane and efficacious, in that their administration may help the patient retain self-control and avert escalation of behavior that would require seclusion or physical restraint. These commenters argued that a professional registered nurse is able to appropriately assess and determine the need to administer a PRN. Other commenters argued that PRN medications are not a form of chemical restraint. One such commenter requested that we clarify that orders for PRN medications are appropriate.

One commenter argued that the elimination of PRN medications could inhibit a patient's efforts to manage his/her own behaviors. Another commenter suggested that prohibiting PRN medications might backfire and lead to more routine orders for behavior-controlling medications, with some patients receiving more medication than they would have received with a PRN order. Other commenters stated that they were unsure of how the ban on PRN orders would effect the administration of medications prescribed for agitation.

Conversely, several commenters stated that in their experience, PRN orders are overused for the convenience of staff, and de-escalation techniques are less likely to be attempted in any meaningful manner if such orders are available.

Response: As discussed earlier, the use of PRN orders for medications is only prohibited when a medication is being used as a restraint. A drug is deemed to be a restraint only if it is not a standard treatment or dosage for the patient's condition. Using a drug to restrain the patient for staff convenience is expressly prohibited.

Comment: Several commenters recommended deleting the word, ''written'' from the provision, ''The order must never be written as a standing or on an as needed basis (that is, PRN).''

Response: As we understand it, the commenters' objection to ''written'' is that it fails to acknowledge that orders may be given verbally. Under § 482.23(c)(2), all orders need to be documented in the patient's medical record either manually or electronically. Verbal orders need to be documented in the medical record by the person accepting the verbal order. This regulation does not prohibit the use of verbal orders for restraint or seclusion, but they must be used infrequently. Regardless of whether the order is written by the ordering practitioner or documented as a verbal order, the order may not be written as a standing or on an as needed basis.

Comment: One commenter asked that we replace the word ''must'' with ''shall'' in this section as well as throughout the regulation.

Response: We currently use the word ''must'' rather than ''shall'' in regulations. Both terms mean that the action/activity is mandatory, and as such, the use of ''must'' provides a solid legal basis for enforcement. Therefore, we have maintained the use of ''must''.

Comment: Several commenters indicated that PRN orders for any type of restraint or seclusion should never be used with children or adolescents and that all orders for seclusion should be time-limited based on the individual needs of the youth.

Response: We agree and have maintained these provisions. An order for restraint or seclusion must never be written on a PRN basis. Orders for restraint or seclusion to manage self-destructive or violent behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others must be time limited and should be tailored to the individual needs of the patient. An individualized assessment that considers the patient's characteristics, such as age, history, size, medical and mental condition, and preferences, should be the basis of any intervention. The regulation identifies maximum time limits on the length of order based on age. The physician or LIP has the discretion to write the order for a shorter length of time. The length-of-order requirement identifies critical points at which there is mandatory contact with a physician or LIP responsible for the care of the patient. In addition, the time limits do not dictate how long a patient is in restraint or seclusion. Staff should be continually assessing and monitoring the patient to ensure that the patient is released from restraint or seclusion at the earliest possible time. Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion must be discontinued. In the final rule, combined standard (e) explicitly states that the intervention must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

7. Consultation With the Treating Physician (§§ 482.13(e)(3)(ii)(B) and (f)(3)(ii)(B))

We stated that this order must be followed by consultation with the patient's treating physician as soon as possible if the restraint is not ordered by the patient's treating physician. § 482.13(f)(3)(ii)(B) paralleled that requirement in the behavior management standard, and imposed the same requirement on seclusion if it is used.

Comment: A few commenters suggested that the requirement for notifying the treating physician be deleted. Most comments on this provision revolved around the question of who the treating physician is, particularly when many physicians or specialists are involved in the patient's care. One commenter suggested that the ''treating physician'' should be the physician responsible for the part of care that requires the use of restraint, for example, the pulmonologist would write the order if the patient was on a ventilator. Another commenter indicated that the treating physician for the purposes of an emergency situation after hours is the medical officer on call. Other commenters stated that each hospital should be permitted to determine who the patient's treating physician is.

Response: We agree with the commenters who recommended that hospital medical staff policies determine who is considered the treating (attending) physician. In addition, we have revised combined standard (e) to change the term ''treating physician'' to ''attending physician.'' We do not believe restraint or seclusion use is the only instance where the question of who is in charge of managing the overall medical care of the patient is of concern. Our intent is to ensure that the physician who has overall responsibility and authority for the management and care of the patient is aware of and involved in the intervention. The attending physician information regarding the patient's history may have significant impact on selection of a restraint or seclusion intervention.

Comment: Several commenters asked what was meant by notification of the treating physician ''as soon as possible.'' Most of those who commented on this provision were not in favor of our use of ''as soon as possible.'' One commenter noted that when a restraint or seclusion incident occurs in the middle of the night, it is not realistic to request a consultation with the treating physician. In such a case, the consultation might be delayed 8 hours, possibly longer if ordered on a Friday evening. The commenter was concerned that an oversight review might not consider this standard practice as being ''as soon as possible.'' To clarify this point, the commenter suggested the following wording after ''as soon as possible': ''or the next working day if after hours, if the restraint or seclusion is not ordered by the patient's treating [that is, attending] physician(s).''

One commenter argued that the more familiar the physician present at the time of the restraint or seclusion intervention is with the individual and the treatment plan, the less urgency there would be to obtain the required notification. One commenter suggested incorporating parameters or standards for how quickly this communication must be initiated and accomplished.

Response: The purpose of attending physician notification is to promote continuity of care, to assure patient safety, and to elicit information from the attending physician that might be relevant in choosing the most appropriate intervention for the patient. Therefore, consultation should occur as soon as possible. Hospital policies and procedures should address the definition of ''as soon as possible'' based on the needs of their particular patient population. We have retained the requirement that the attending physician must be consulted as soon as possible if a restraint or seclusion is ordered by a practitioner other than the patient's attending physician.

Comment: One commenter noted that primary physicians often have another physician on call for their patients when they are unavailable, such as during surgery or vacation. In these instances, the physician on call should be considered the treating physician.

Response: We agree. When the attending physician is unavailable and has delegated responsibility for a patient to another physician, then the covering physician is considered the attending physician.

Comment: A commenter indicated that this provision is ''cumbersome and can lead to problems, especially if the treating physician was listed on the admission and does not come into the hospital for twenty-four hours if the patient was admitted on the weekend.''

Response: This provision does not specify that consultation with the attending physician be face-to-face. The consultation can occur via telephone. In addition, when the attending physician is not available, responsibility for the patient must be delegated to another physician who would then be considered the attending physician.

Comment: One commenter asked that we clarify that the patient can be under the care of a treating LIP other than a physician.

Response: The hospital CoPs do permit the patient to be under the care of a treating LIP other than a physician. Section 482.12(c)(1) requires every Medicare patient to be under the care of a doctor of medicine or osteopathy; or

a doctor of dental surgery or dental medicine, a doctor of podiatry, chiropractor, or clinical psychologist within the scope of their license. The individual overseeing the patient's care may be the attending physician or a health professional practicing with the delegated authority or supervision of a doctor of medicine or osteopathy as permitted by State law and hospital policy. As noted earlier, we also defer to State laws that recognize the ordering rights of other types of practitioners. For the purposes of the use of restraint or seclusion, the attending practitioner must be able to conduct both a physical and psychological assessment of the patient in accordance with State law, their scope of practice, and hospital policy.

Comment: One commenter stated that this requirement was highly prescriptive and unusual to be included in a CoP. Another commenter stated that this notification was unnecessary since the treating physician has the opportunity before the need for restraint or seclusion arises to alert hospital staff and other physicians or LIPs that use of restraint or seclusion would be an inappropriate intervention for the patient. These commenters recommended elimination of this requirement.

Response: It is not the information in the medical record alone that should determine the course of treatment for a patient. Decisions about how best to manage a patient's care, engage the patient in treatment, and ensure continued progress in recovery require the oversight of the person with the authority and responsibility for the patient—the patient's attending physician.

8. Written Modification of the Plan of Care (§§ 482.13(e)(3)(iii) and (f)(3)(iii))

We stated in this provision that an order for a restraint must be in accordance with a written modification to the patient's plan of care. A parallel provision in § 482.13(f)(3)(iii) extended this provision into situations where restraint or seclusion is used to manage violent, self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Comment: Several commenters found this provision confusing and asked for clarification. One commenter was unsure of whether this requirement entails having the nurse explain the patient's behavior in a note, or having the nurse provide a more detailed, written plan. Some of these commenters suggested that the use of seclusion and restraint should not be stated in the patient's plan of care; instead, the behavior(s) that caused the use of seclusion or restraint and other interventions to address the behavior(s) should be documented.

One commenter suggested that as written, this provision indicates that a modification to the plan of care would be required before the order being written for seclusion or restraint. The commenter observed that written modifications might not be possible prior to the renewal of the order because the review and modification should be conducted by the treating physician, while the on-call physician may be involved in assessing an episode of dangerous behavior. This commenter preferred to have a review of the patient's treatment plan within a certain timeframe after the episode, such as the next business day or within 72 hours.

One commenter stated that because restraint and seclusion should be exceptional rather than ordinary interventions, the regulation should incorporate the requirement that multiple restraint and seclusion orders trigger a re-evaluation of the plan of care. Another commenter agreed, recommending that the following language be added at § 482.13(f)(3)(ii)(D):

> Because multiple restraint and seclusion orders may indicate a need to evaluate and change the current placement and/or behavior management plan, where there are two or more restraint and seclusion orders within a one-week period, the chart shall indicate treatment team actions in evaluating the current placement and plan of care and the results of that evaluation.

Response: The regulation does not require that a modification to the patient's plan of care be made before initiating or obtaining an order for the use of restraint or seclusion. The use of a restraint or seclusion intervention should be reflected in the patient's plan of care or treatment plan based on an assessment and evaluation of the patient. The plan of care or treatment plan should be reviewed and updated in writing within a timeframe specified by hospital policy. We have not required that multiple restraint and seclusion episodes trigger a re-evaluation of a placement or behavior management plan. We are retaining the language specified in the interim final rule with comment.

In this final rule, we are specifying that the use of restraint or seclusion be documented in the patient's medical record. In response to comments, we have specified the required elements of documentation under the combined standard. Such documentation is a usual and customary recordkeeping practice. Therefore, we are retaining the language as specified in the interim final rule with comment period.

Comment: Another commenter feared that much detail, such as a description of the event, what led to it, and key data and information typically available to anyone reading the patient's record, will be lost because the provision only requires a written modification to the plan of care. The commenter suggested that facilities would avoid placing such information in the patient's record to assure that the facilities are ''discovery protected.'' To remedy this, the commenter suggested expanding the regulation to require that each instance of seclusion or restraint and certain details must be entered into the patient's record.

Response: We agree. We have revised combined standard (e) to require that the use of restraint or seclusion be documented in the patient's medical record and have specified the documentation elements. Under combined standard (e), the patient's medical record must contain documentation that includes: the 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others; a description of the patient's behavior and the intervention used; alternatives or other less restrictive interventions attempted (as applicable); the patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and the patient's response to the intervention(s), including the rationale for continued use of the intervention. This type of documentation is a usual and customary recordkeeping practice. This information will provide a valuable tool for charting the patient's course of treatment as well as examining trends of use.

Comment: One commenter believed that restraint date, time, and duration should be documented in the patient's record. Another commenter stated that the name, title, and credentials of staff members involved in the procedure should be included in the record.

Response: We have required that when restraint or seclusion is used, certain elements must to be documented in the patient's medical record. We believe that some of the information that the commenter has suggested would indeed appear as part of the patient's medical record. Additional elements of documentation, such as name, title, and credentials of staff members involved in the procedure, should be specified in hospital policy.

Comment: Several commenters recommended removing the word ''written'' from the provision, ''in accordance with a written modification of the patient's plan of care.''

Response: We have retained the word ''written'' in the provision, ''in accordance with a written modification of the patient's plan of care.'' The use of restraint or seclusion constitutes a change in a patient's plan of care. Changes in a patient's plan of care must be documented. Documentation in the patient's medical record can be ''written'' manually or electronically.

Comment: One commenter suggested that the regulations should provide special protections for hearing impaired individuals who communicate in sign language using their hands and arms. To this end, this commenter recommended adding language to § 482.13(f)(3): ''For a person whose mode of communication is through sign language, designed so that the person is able to effectively communicate in sign language despite restraints and/or seclusion.''

Response: Providers are expected to meet the communication needs of their atients, whether those patients speak another language, are hearing or vision impaired, or have other conditions or characteristics that merit special intervention to assure smooth communication. However, there may be situations when it is necessary to place a patient with special communication needs in restraint or seclusion. In these situations, the hospital is expected to make reasonable efforts to meet these needs.

9. Implementation of and Appropriate Use of Restraint/Seclusion (§§ 482.13(e)(3)(iv), (e)(3)(v), (f)(3)(iv), and (f)(3)(v))

We stated that the use of restraint and seclusion must be implemented in the least restrictive manner possible and must be in accordance with safe and appropriate restraining techniques.

No comments were received on these provisions. However, based on inquiries received after closure of the comment period, we have determined that the phrase ''used in the least restrictive manner'' needed further clarification; for example, how would a four-point restraint be used in ''the least restrictive manner''? Our intent is that if a restraint is necessary, the least restrictive intervention (which may vary, depending on the patient's history and condition) that effectively protects the patient's safety or that of others must be selected.

10. Discontinuing the Use of Restraint/ Seclusion (§§ 482.13(e)(3)(vi) and (f)(3)(vi))

We stated that restraint or seclusion, whether for acute medical and surgical care or for behavior management, must be ended at the earliest possible time.

Comment: While some commenters expressed support for this provision as written, many hoped to clarify this language and offered either new wording or guiding concepts to be used in developing new wording. Several commenters recommended amending the regulatory text to read, ''Ended at the earliest possible time, namely when no longer needed to ensure the patient's physical safety or whenever a less restrictive measure would protect the patient or others from harm. If restraint and seclusion are used simultaneously, the restraint and seclusion shall be independently evaluated to determine when either or both may be ended.'' A few commenters suggested that restraint use should be ended when it is no longer justified or when the emergency situation has subsided, rather than being dependent on an arbitrary timeframe. One commenter noted that the patient's release from seclusion and his or her rapid return to the therapeutic environment is desirable. Another commenter stated that a patient should be restrained or secluded only so long as necessary for the patient to regain self-control. One commenter noted that if the patient is able to take a bathroom break or eat a meal without incident, the restraint or seclusion should be discontinued. These commenters believed that the regulation did not clearly state that the intervention would end when the emergency was over.

Response: These comments tended to be aimed at standard (f) rather than (e); overall, they seemed to reflect the concern that what constitutes ''at the earliest possible time'' may be subject to interpretation. To address this concern, we have revised the requirement in combined standard (e) to state that restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

Comment: One group of commenters wanted to allow the patient a trial period out of restraints, during which the patient would be closely observed. If the patient again exhibited the symptoms that had prompted the prior use of restraints, the patient would be placed in restraint again and this episode would be considered as part of the original episode/order.

Response: The approach suggested by these commenters is equivalent to a PRN order, which is not permitted by combined standard (e). If staff ends an ordered intervention, they have no authority to start it again without the initiation of a new order. For example, a patient is released from restraint or seclusion. If this patient later exhibits violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others that can only be handled through the use of restraint or seclusion, a new order would be required. Staff cannot discontinue an order and then restart it because that would constitute a PRN order. However, a temporary release that occurs for the purpose of caring for a patient's needs, for example, toileting, feeding, and range of motion, is not considered a discontinuation of the intervention.

11. Assessment, Monitoring, and Evaluation of the Restrained/Secluded Patient (§§ 482.13(e)(4) and (f)(5))

We stated that the condition of the restrained patient must be continually assessed, monitored, and reevaluated. Section 482.13(f)(5) created a parallel requirement when a patient is restrained or secluded for behavior management.

Comment: There was much confusion over the meaning of ''continually.'' One commenter pointed out that ''continually'' appears to refer to constant face-to-face observation in one portion of the interim final rule with comment period, while in another it seems to mean ongoing, but not constant, monitoring. Several commenters misinterpreted the requirement as forcing physicians and nurses to remain in a restrained patient's room for the duration of the restraint use, and argued that this would be a poor use of resources.

Response: Ongoing assessment and monitoring of the patient's condition are crucial for prevention of patient injury or death. We are still requiring these activities, but leave it to staff discretion how frequently they are conducted based upon hospital policy and an individualized patient assessment. In the final rule, monitoring and assessment may occur periodically (for example, every 15 minutes) or continually (that is, moment to moment), depending on the patient's needs. With the exception of the simultaneous use of restraint and seclusion, one-to-one observation with a staff member in constant attendance is not required. To clarify this point, we have deleted the word ''continually'' from the monitoring requirements in combined standard (e) with one exception. We have retained the word ''continually'' in the monitoring

requirements for the simultaneous use of restraint and seclusion.

We expect hospital policies to guide staff in determining appropriate intervals for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used. For example, placing staff at the bedside of a patient with wrist restraints may be unnecessary. However, for a more restrictive or risky intervention and/or a patient who is suicidal, self injurious, or combative, staff may determine that continual face-to-face monitoring is needed. The hospital is responsible for providing the level of monitoring and frequency of reassessment that will protect the patient's safety. Based on public comments, we have revised combined standard (e) to clarify that the condition of the patient who is in restraint or seclusion must be monitored and assessed by a physician, or other licensed independent practitioner or trained staff at an interval determined by hospital policy. The criteria for staff to be considered ''trained'' are specified under § 482.13(f).

We have also added language to clarify that all requirements specified under combined standard (e) apply in the simultaneous use of restraint and seclusion, which is not permitted unless the patient is continually monitored. If restraint and seclusion are used simultaneously to manage self-destructive or violent patient behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be continually monitored, face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient. For the purposes of this provision, ''continually'' means ongoing without interruption.

Comment: Some commenters requested clarification on the aspects of the patient's physical condition that must be monitored when the patient is in restraint or seclusion (indicators such as vital signs, circulation, hydration, level of distress, agitation), when staff re-evaluate the need for continued use of restraint or seclusion, and when an LIP is deciding whether to renew the order for the intervention. Some commenters also suggested that the patient should be permitted bathroom breaks and the opportunity to eat meals.

Response: The importance of appropriate assessment and monitoring of the patient's physical, emotional and behavioral condition when restraint or seclusion is used cannot be overemphasized. As the interim final rule with comment period stated, research indicates that the potential for injury or harm with the use of restraint is a reality. However, evaluation of the situation and each patient's individual medical needs and health status should be paramount considerations in choosing the intervention method, level of monitoring, and frequency of assessment. Hospital policies should address frequency of assessment and monitoring components of monitoring (for example, vital signs, hydration and circulation, level of distress and agitation, mental status, cognitive functioning, skin integrity), nutritional needs, range of motion, elimination needs, and other care needs. We cannot provide an exhaustive list of the items to be monitored because they will vary with the type of intervention used and the patient's condition. For example, the use of a restraint that keeps the patient immobilized would require a check of the patient's skin integrity and steps to prevent skin breakdown. Depending on the duration of the intervention, range of motion exercises might be necessary. The patient's mental status, as well as vital signs, should be assessed, particularly when the restraint is initiated to manage self-destructive or violent behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. The patient should be provided the opportunity for toileting, hydration, and eating if the intervention used impedes these activities.

Reassessments of the patient's condition are essential to assure that the intervention ends as soon as possible. Again, we expect frequency of reassessments to be addressed by hospital policies. When the patient's self-destructive or violent behavior presents an immediate risk to the patient, a staff member, or others, frequent reassessments ensure the intervention is used only while the unsafe situation continues and is discontinued at the earliest possible time, regardless of the length of time identified in the order.

The interim final rule with comment period did not, and this final rule does not, require that the practitioner who ordered the intervention be physically present to re-evaluate the need for continuing the intervention. The patient's attending practitioner should, however, be contacted with an update on the patient's status and an evaluation of the patient's mental and physical condition when the order for restraint or seclusion is about to expire if it appears that the intervention is still necessary. In this final rule, we have retained and revised the provision under combined standard (e) requiring that after 24 hours, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. We have also specified that each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.

Comment: A commenter asked what time frames were meant for ''continuously assessed'' (that is, every 5 minutes, every 30 minutes). Some members of the public and one hospital argued that we should incorporate required 15-minute checks for restrained and secluded patients, as we had mentioned in the December 19, 1997 proposed rule. One commenter suggested that vital signs be taken every 2 hours, with written documentation of such checks in the medical record. Some commenters urged retaining flexibility in allowing clinical judgment to determine timeframes or intervals. Some commenters questioned the value of continual monitoring for a restrained patient who is sleeping or only awakening intermittently.

Response: As discussed previously, we expect hospital policies to guide staff in determining appropriate intervals for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used.

Regarding the sleeping patient scenario, a staff person may or may not need to be permanently posted at a sleeping, restrained patient's bedside. The fact that a patient is at one point asleep does not guarantee that the patient will remain asleep hours on end and will therefore need no reassessment or monitoring. The selection of an intervention and determination of the necessary frequency of assessment and monitoring should be individualized, taking into consideration variables such as the patient's condition, cognitive status, risks associated with the use of the chosen intervention, and other relevant factors. In some cases, checks every 15 minutes or vital signs taken every 2 hours may not be sufficient to ensure the patient's safety. In others, it may be excessive or disruptive to patient care (for example, mandating that a patient with wrist restraints who

is asleep be checked every 15 minutes and awakened every 2 hours to take the patient's vital signs may be unnecessary). Similarly, depending on the patient's needs and situational factors, seclusion may require either periodic or constant monitoring. We expect staff to determine the appropriate level of monitoring and frequency of assessment based on hospital policy, an individualized patient assessment, and type of intervention used.

Comment: Commenters discussed who should perform the assessment, monitoring, and re-evaluation. Some mental health consumer advocacy groups and their members suggested that a clinically licensed registered nurse should perform these tasks; another commenter suggested that they be performed by licensed professionals trained in mental health procedures.

Response: We have revised combined standard (e) to provide hospitals flexibility in determining which staff performs the assessment and monitoring. This determination, of course, must be in accordance with the practitioner's scope of practice and State law. For example, assessment and monitoring are activities within a registered nurse's scope of practice. However, some trained, unlicensed staff may perform components of monitoring (for example, checking vital signs, hydration and circulation; the patient's level of distress and agitation; or skin integrity), and may also provide for general care needs (for example, eating, hydration, toileting, range of motion). Standard (f) requires that before applying restraints, implementing seclusion, or performing associated monitoring and care tasks, staff be trained and able to demonstrate competency in the performance of these actions. Combined standard (e) has been amended to require that the condition of the restrained patient be assessed and monitored by a physician, other LIP or by trained staff.

Comment: One commenter suggested that a history of sexual victimization should be considered when restraining a patient. The commenter provided the following example: ''Most females who are raped are raped in the supine position, and therefore supine position is more likely to recreate the trauma. Similarly, it seems that most males who are raped are raped in a prone position, therefore prone restraint might well be contraindicated.''

Response: The hospital should conduct a thorough individualized assessment of the patient that integrates the patient's salient history into the treatment plan. However, we will not be mandating this particular consideration in the regulation's text.

Comment: One commenter urged that children not be left alone for long periods of time, as an hour can seem quite long when a child is distressed. Another commenter argued that children in restraint or seclusion should be monitored one-on-one.

Response: We agree that children, as well as adults, may become distressed when left alone. We expect staff to determine the frequency and level of monitoring necessary based on hospital policy, an individualized patient assessment, and the type of intervention used.

Comment: One commenter suggested that because the lack of vigorous physical activity may contribute to behaviors triggering restraint and seclusion, the regulations should include a section requiring vigorous physical activity for children.

Response: The multidisciplinary team that works with each patient is able to create an individualized treatment plan that meets the patient's needs. We do not believe that arbitrarily mandating vigorous physical activity is wise or necessary.

Comment: One commenter asked how continual assessment, monitoring and reevaluation would be documented.

Response: How this information is documented will vary with the policies and practices of each hospital.

Comment: One commenter asked whether a patient restrained for medical purposes could be monitored from a distance as long as the patient is kept within eyesight.

Response: A patient restrained under combined standard (e) does not have to be continually monitored face-to-face unless restraint and seclusion are used simultaneously or continual face-to-face monitoring is clinically indicated.

12. Staff Training in the Use of Restraints/Seclusion (§§ 482.13(e)(5) and (f)(6))

We stated that all clinical staff that have direct patient contact must have ongoing education and training in the proper and safe use of restraints. Section 482.13(f)(6) contains a similar requirement that specifies that all staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.

Comment: These provisions enjoyed much support from commenters. Several commenters quoted the Hartford Courant series (October 11, 1998) as naming better staff training as a low cost mechanism for averting the situations described in the articles. Many hospitals agreed that the key to patient safety is staff training and competency, suggesting that this element more directly affects patient care than other factors suggested by CMS. One commenter stated the following:

> The death of a patient while in restraints or seclusion should never occur. To that end, steps need to be taken to assure that staff that initiate a restraint or seclusion intervention and those who later monitor and evaluate the patient are appropriately educated, trained, and demonstrate competencies in these practices. We see these issues as key to the safety and well being of patients and staff.

One commenter reported that it provides staff with a minimum of 16 hours of annual training that emphasizes verbal de-escalation techniques. This step, in combination with others, has resulted in dramatic reduction in restraint/seclusion use for that hospital in the past 2 years. Many other commenters reported that their hospitals employ extensive training for clinical staff; one commenter noted that training direct care staff is a good investment of its resources. Another commenter voiced its ''complete agreement'' with the training and educational requirements.

One commenter expressed enthusiastic support for stringent and appropriate training, noting that this area needs to be expanded and enforced. This commenter stated, ''Until service providers are adequately trained in the proper use of restraints, all the regulations and rules in the world will not be able to ensure safety.'' Another commenter suggested that CMS should focus on ensuring that restraint and seclusion are used properly by monitoring training, education, proper privileging, and proper/effective staff monitoring by appropriate and available facility staff.

Response: We appreciate the support expressed by commenters and share the belief that without adequate training and competency among the direct care staff, patients, staff and others are placed at risk. Patients have a right to the safe application of restraint or seclusion by trained and competent staff. We recognize the important role that staff training and education play in the reduction of restraint and seclusion use in a hospital. We applaud hospitals that currently provide extensive training and education for staff as part of a comprehensive program to ensure patient safety and minimize the use of restraint and seclusion.

Based on public comments, we have revised our regulatory language to provide additional requirements for staff training that focus on demonstrated competencies and building a skill set for working with patients. We have also moved the training requirements from current standards (e) and (f), and created a separate standard (standard (f)) that addresses staff training. This was done to emphasize the importance of staff training in the safe use of restraint or seclusion.

Standard (f) requires that staff be trained and able to demonstrate competency prior to applying restraints, implementing seclusion, or performing associated monitoring and assessment of, or providing care for a patient in restraint or seclusion. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population. Staff must demonstrate competencies as outlined in standard (f) initially, as part of orientation, and subsequently on a periodic basis. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used by hospitals to address patients' behaviors. Successful completion of training and demonstration of competency must be documented in staff personnel records.

Comment: Many hospitals reported that they have instituted training programs and have made efforts to carefully examine and review their use of restraints. Some argued that such efforts, rather than regulatory standards, are the answer to reducing restraint-related injuries and deaths.

Response: Some of the commenting hospitals stated that they have never had an injury or death related to restraints or seclusion use, and it is appropriate to acknowledge this achievement. As its appearance in our regulation affirms, we believe that a critical piece of ensuring the health and safety of the patient, staff, and others is comprehensive training. However, while training programs are a critical step to assuring patient safety, they do not serve as a substitute for a statement of basic performance expectations.

Comment: One commenter requested that we define, ''direct patient contact.'' Several commenters questioned whether we intended that all staff be trained, including nonclinical personnel or those who have no part in the provision of care (that is, those who would be unlikely to take part in a restraint or seclusion intervention). Some disagreed with a broad training requirement, stating that it would be cost-prohibitive. These commenters argued that the current wording could be construed as including housekeeping staff, service staff, clerical staff, administrative personnel, environmental services staff, dietary staff, laboratory staff, and all clinical staff. Many commenters argued that this level of education should be limited to clinical staff who apply and remove restraints or who provide primary direct care to patients who may require restraints. One commenter suggested that all staff should be trained ''commensurate with the amount of contact with patients'' rather than using direct contact alone as a criterion.

Response: We have accepted the suggestions of these commenters. We have replaced the phrase, ''direct patient contact,'' with more specific language to clarify this requirement. We have revised our standards to require training for the staff who are involved with the application of a restraint, implementation of seclusion, providing care for a patient in restraint or seclusion, or with assessing and monitoring the condition of the restrained or secluded patient.

Comment: One commenter asked whether training would be required for house medical staff/covering psychiatrists.

Response: In the final rule, combined standard (e) specifies that physician and other LIP training requirements must be specified in hospital policy. At a minimum, physicians and other LIPs authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint and seclusion. Hospitals have the flexibility to identify training requirements above this minimum based on the competency level of their physicians and other LIPs and the needs of the patient population that they serve. Physicians receive training in the assessment, monitoring and evaluation of a patient's condition as part of their medical school education. However, physicians generally do not receive training regarding application of restraint or implementation of seclusion as part of their basic education. Depending on the level and frequency of involvement that a physician has in the performance of these activities, the physician or other LIP may or may not require training. If house staff, hospitalists or covering psychiatrists are the medical staff that are directly involved in the care of a patient in restraint or seclusion, a hospital may determine that training is necessary to insure competency of these individuals in this area. We believe the hospital is in the best position to determine if physician training is necessary based on the model of care, level of physician competency, and the needs of the patient population(s) that the hospital serves. Therefore, we have only mandated a minimum level of physician and other LIP training. Instead, we have provided hospitals with the flexibility to specify additional physician and other LIP training requirements, if any, in hospital policy.

Comment: One commenter suggested that staff be required to talk to the patient intermittently to assist the patient's efforts to regain self-control and to explain what the patient needs to do for the restraint or seclusion to end.

Response: The training requirements are intended to equip staff with skills that can be used in this fashion.

Comment: One commenter suggested that there should be Federal compensation for the added cost of providing such training.

Response: Staff training is generally included in administrative costs and is recognized in calculating payments under the hospital inpatient prospective payment system. Therefore, we are not providing separate compensation to fund this training.

Comment: Several commenters asked about the frequency of training. One commenter suggested that the term ''ongoing'' should be replaced with ''annually.''

Response: We have modified the regulatory text to require staff to demonstrate the competencies specified in standard (f) initially as part of orientation and subsequently on a periodic basis consistent with hospital policy. We believe the hospital is in the best position to identify a timeframe for ongoing training based on the level of staff competency, and the needs of the patient population(s) served.

Comment: Commenters had varying ideas about what topics training should cover, and whether the regulation should specify training content in detail. Several commenters asked whether training must be obtained from Federally-specified programs.

One commenter urged that requirements for the training curriculum be described in the regulations. A few commenters suggested that the current standard (f) training requirement should not be limited to the proper and safe use of restraints; one commenter suggested more emphasis on positive behavioral supports and less on ''proper'' use. One commenter supported education on alternatives to restraint use and safe handling of a patient in restraints. Another commenter suggested that the training should include personally experiencing being restrained. One commenter argued that staff should be

trained in values clarification, cultural diversity, and counter-transference since it is commonly acknowledged that patients become more agitated and lose control when staff responds in a manner that provokes the patient.

Response: We have adopted more detailed training requirements in this final rule. In addition, we have moved the training requirements from the current standards (e) and (f), and have created a separate standard (f) that addresses staff training requirements.

Standard (f) states that the hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of restraint or seclusion;
- The use of nonphysical intervention skills;
- Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition;
- The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
- Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary;
- Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including, but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation; and
- The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

Staff need to employ a broad range of clinical interventions to maintain the safety of the patient and others in the provision care. The hospital is expected to provide education and training at the appropriate level to the appropriate staff based upon the specific needs of the patient population being served. For example, staff routinely providing care for violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others (such as in an emergency department or on a psychiatric unit) generally require more in-depth training in the areas included in the regulation than staff routinely providing medical/surgical care.

Lastly, we have not required that training be obtained from Federally-specified programs. Hospitals may develop and implement their own training programs or use an outside training program. However, standard (f) specifies that individuals providing staff training must be qualified as evidenced by education, training and experience in techniques used to address patients' behaviors.

Comment: One commenter suggested that training should include instruction on—(1) how to identify patients who may have conditions that would require special attention, (for example, a history of respiratory or cardiac problems); (2) how to monitor patients in restraints; and (3) what conditions are necessary for a person to be released from restraints. This commenter suggested that in standard (f), the training requirement should include instructions on how to screen patients for special problems that could affect the use, type, or duration of restraints (for example, emotional problems associated with a history of abuse or neglect).

Response: We agree and have incorporated the suggested elements in standard (f).

Comment: One commenter suggested that staff that has not completed training should be prohibited by regulation from initiating and complying with orders for restraint or seclusion.

Response: We agree. In standard (f), we require that staff be trained and able to demonstrate competency before applying restraints, implementing seclusion, or performing associated monitoring and assessment of, or providing care for, a patient in restraint or seclusion. Application of restraint or seclusion by an untrained staff member, including contract staff, would constitute a violation of this requirement.

13. Definition of Seclusion (§ 482.13(f)(1))

We defined seclusion as the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

Comment: Several commenters suggested adding the word ''alone'' to the definition of seclusion. Several commenters pointed out that the definition that appeared in the interim final rule with comment period would define a patient confined involuntarily on a locked unit as being secluded. Additionally, one commenter believed the word ''area'' was too broad and might be read as including being on a unit or ward with others.

Response: In the final rule, we have added the word ''alone'' to this definition for clarity and retained the use of the word ''area''. Seclusion does not include confinement on a locked unit, ward, or other area where the patient is with others. Seclusion is not just confining a patient to an area but involuntarily confining the patient alone in a room or area where the patient is physically prevented from leaving. A situation where a patient is restricted to a room or area alone and staff are physically intervening to prevent the patient from leaving the room or area is also considered seclusion. In addition, we have clarified that seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Comment: One commenter stated that physical restraint is more frequently associated with injury and death than is monitored seclusion. This commenter argued against categorizing seclusion with restraint, stating that its use should not be governed by the same requirements. Another commenter said that linking the terms ''seclusion'' and ''restraint'' is misleading in that it creates the inaccurate perception that the two interventions are equivalent in all respects. This commenter could not imagine a death resulting from seclusion, other than from self-inflicted injury (which would indicate a possible need for restraint initially) or from the total and gross neglect of an acutely ill patient, which no amount of regulation would prevent, since this would represent unacceptable, deviant practice.

One commenter stated that seclusion is therapeutically different from restraint. Seclusion is indicated when a patient's behavior poses a significant threat to others or is profoundly disturbing in the therapeutic environment (such as a patient disrobing in public). This commenter suggested that while this behavior is not violent, it is appropriately, humanely, and therapeutically addressed through seclusion.

Response: The frequency and level of monitoring and assessment of the condition of a patient who is in restraint or seclusion are determined by staff based on hospital policy and an individualized patient assessment. These parameters would differ based on the type of intervention used. We would not necessarily expect these parameters to be identical for all types of restraint and the use of seclusion.

In response to the comment about the therapeutic use of seclusion, we note that the use of seclusion is a means to an end, not the end itself. In the example given, simply secluding a patient who habitually disrobes is not a long-term solution to eliminating this inappropriate behavior. The patient should be assessed and engaged in an active, individualized treatment program.

Comment: A commenter, concerned about the needs of students receiving special education, asked whether this regulation would define a child who has been restricted from attending a school program as having been ''secluded,'' and requested that the regulation prohibit this action except when the requirements of the regulation are met.

Response: Not allowing a patient to attend a school program or removing a patient from a classroom setting would not meet the definition of seclusion as defined in this rule, and also outside the scope of this regulation which addresses restraint and seclusion in hospitals.

Comment: One commenter stated that there should be minimum standards for the cubic dimensions and ventilation of a seclusion room, which were not provided in the interim final rule with comment period.

Response: We believe that setting these types of standards is beyond the scope of this rule.

Comment: Commenters concerned with children's issues discussed the use of ''time outs.'' Several commenters argued that CMS should distinguish between seclusion (where a child is locked in a room) and a time out, and that time outs should not be governed by the regulation. These commenters believed that a ''time out'' should be defined as actions to require the child or adolescent to retire to an alternative setting, either in his or her room or in a separate quiet room, but without restraining or locking up the child. Several commenters expressed concern that the regulation prohibits so called ''open door'' and ''decreased stimulation'' time outs, which are used to prevent the escalation of behavior leading to emergency situations. One commenter asked whether a child voluntarily removing himself from a current activity and spending 15 minutes calming his or her emotions constitutes seclusion.

Response: For the purposes of this final rule, seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior. If a patient is free to leave a time out area whenever the patient chooses, this would not be considered seclusion based on this definition. The key distinction in deciding whether an intervention is seclusion or a time out is whether the patient is physically prevented from leaving a room or area. Another distinction is the patient's level of personal control. In the case of seclusion, boundaries are placed on the patient's behavior based on the clinical determination that the patient's behavior poses a risk to the safety of the patient or others. In a time out, the patient is able to respond to staff direction encouraging a time out or to independently decide that such action is needed. In a time out, the staff and patient collaboratively determine when the patient has regained self-control and is able to return to the treatment milieu. In seclusion, this judgment is made by the clinicians—that is, an agitated patient may feel that he or she should be released, even though the patient's behavior continues to be violent or self-destructive.

Comment: One commenter inquired whether seclusion requires a physician's order and all related monitoring and documentation.

Response: The use of seclusion for the management of violent or self-destructive behavior is regulated by combined standard (e). If an intervention meets the definition of seclusion in standard (e), all of the requirements under standard (e) would apply, including those related to a physician or other LIP's order, the 1-hour face-to-face evaluation, monitoring and documentation.

Comment: One commenter expressed concern that the definition of ''seclusion'' covers typical hospital practices, such as keeping visitors and patients out of certain areas for purposes of infection control, security, patient privacy, or prevention of disruption of treatment.

Response: Our modification to the definition, that is, adding the word ''alone,'' should alleviate this concern. In the cases cited, the hospital is keeping patients or visitors out of an area versus involuntarily confining the patient alone within a room or area from which the patient is physically prevented from leaving for management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. It is not the intent of this rule to interfere with hospital infection control practices, security measures, patient privacy or measures intended to prevent the disruption of treatment. Additionally, State law outlines requirements for quarantining a patient. If the need to quarantine a patient arises, the hospital would follow State law. Quarantining, as governed by State law, would not be considered seclusion.

14. Use of Restraint/Seclusion for Behavior Management (§ 482.13(f)(2))

We stated that seclusion or restraint for behavior management can only be used in emergency situations if needed to ensure the patient's, a staff member, or others' physical safety and less restrictive interventions have been determined to be ineffective.

Comment: Many commenters stated that the use of restraint or seclusion is a treatment failure. In contrast, several commenters argued that the regulation's requirements are not guided by solid clinical information, nor do they take into account the realities of inpatient psychiatric treatment. One commenter stated, ''While I am aware of individuals who think that medications and/or restraints for [violent, aggressive] patients should never be applied, such thinking is naïve, unrealistic, and idealistic.'' The commenter recommended that we study how many deaths/injuries/assaults are prevented by appropriate use of restraints.

Response: The role of restraint and seclusion for behavior management was a point of fundamental disagreement among commenters. While we believe that restraint and seclusion are not desirable interventions, we recognize the diversity of patients and situations that clinicians must address. In some of these situations, the patient poses a real safety risk to self or others, and alternative, less restrictive interventions are not sufficient to assure the safety of the patient or others.

Comment: A few commenters strongly agreed that restraints should only be used for emergency safety situations. Some physicians and hospitals indicated that they view restraint as a last resort which is only used when absolutely necessary to protect the safety of the patient or others. One commenter indicated that seclusion and restraint have a valuable place in treatment, but only when used minimally, such as in cases of extreme violence or when needed to protect clients. One commenter stated that the rule does not define the term ''emergency,'' and cited a Maryland regulation that defines an emergency as a situation in which the patient's behavior poses a serious and imminent danger to the physical safety of self or others.

In contrast, a commenter suggested removing ''in emergency situations.'' Another commenter agreed with this

suggestion, arguing that the rule does not permit the use of seclusion and restraint as therapeutic interventions as part of a treatment plan for serious behavioral problems. The commenter argued that although short-term, crisis-based use of seclusion and restraint is necessary, it is not the only appropriate use of restraint, since short-term behavioral restrictions can be the most humane way to prevent the patient from self-injury and reduce the need for invasive medical therapies that can have serious, long-term adverse consequences.

Response: The use of restraint or seclusion should not be a routine response when a patient's behavior begins to escalate. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient or others. Seclusion may only be used for the management of violent or self-destructive behavior of patients when there is an immediate danger of harm to the patient, a staff member, or others. We recognize that there may be circumstances in which the use of restraint or seclusion may be necessary to prevent a situation from escalating into an emergency situation in which a patient is in immediate danger of harming himself, staff, or others. In the therapeutic environment, staff often skillfully intervene with alternative techniques that redirect the patient, engage the patient in constructive discussion or activity, or otherwise help the patient maintain self-control and avert escalation. Therapy is a building process in which the patient gains the skills necessary to appropriately handle daily stressors and situations. The use of restraint or seclusion to manage violent or self-destructive behavior is an emergency measure that temporarily protects the safety of the patient, staff, and others. However, neither restraint nor seclusion is a long-term solution for handling problematic behavior.

Based on public comment, we have clarified this provision by replacing the reference to emergency situations with more descriptive language. Therefore, combined standard (e) states that restraint or seclusion can only be imposed to ensure the immediate physical safety of the patient, staff, or others, must be discontinued at the earliest possible time, and less restrictive interventions have been determined to be ineffective. Seclusion may only be used to manage violent or self-destructive behavior of patients that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Comment: One commenter suggested permitting the use of restraints to control anticipated catastrophic behavior associated with conditions such as Lesch Nyhan Disease (manifested by self-mutilation) or other self injurious or assaultive behaviors. The commenter argued that such use would be appropriate to address intractable behaviors that have not responded to medications or other treatment interventions. This type of use would be part of an individualized plan of care addressing the underlying cause of the behavior and would involve rigorous monitoring and active treatment to allow for the removal of restraints.

Response: The regulation has not barred the use of restraint to manage catastrophic behavior. If a patient has a diagnosed chronic medical or psychiatric condition such as those associated with Lesch-Nyhan Syndrome, and he or she engages in repetitive self-mutilating behavior, the use of restraint would need to meet the requirements of combined standard (e). In these situations where the patient exhibits chronic self-injurious behavior, a PRN order that is applied in accordance with the specific parameters established in the treatment plan would be permitted (note that PRN application of restraint is not otherwise permitted). Again, this use of restraint would need to be integrated into the plan for the patient's care and treatment. As always, the use of alternative interventions should be pursued when feasible, and use of restraint should be discontinued as quickly as possible. Since the use of restraints to prevent self-injury for these types of rare, severe medical and psychiatric conditions have been intergrated into the patient's care and treatment plan, the requirement for the 1-hour face-to-face evaluation and the limitation of length of orders (4, 2, or 1 hour(s) depending on the patient's age) are not applicable.

Comment: One commenter suggested a series of steps for treating a patient who has a known history of assault or who exhibits aggression. First, the patient must have a treatment plan to address the problem. Second, if the treatment plan does not work, a back-up plan must provide the patient relief from whatever seems to be provoking the attack. Third, if the back-up plan fails, staff should try to coach or encourage some alternative to assault. The commenter suggested that assault is almost always goal directed, and that staff's task is to determine the goal and suggest an alternative to achieve it. If alternatives are not accepted, staff should ''reduce their verbiage'' and ''exaggerate simple non-verbal messages.'' If an attack is initiated, staff should continue the use of verbal de-escalation techniques while physically evading attack. If all these interventions fail and the attack continues, ''some form of bodily restraint may be justified.''

Response: We appreciate the commenter's insights. However, the level of detail provided is more typical of hospital policy on how to handle assaultive behavior than of regulatory text. When a patient is exhibiting violent or self-destructive behavior and the patient is in danger of harming themselves or others, and less restrictive interventions have been determined to be ineffective, we expect staff to implement appropriate interventions to ensure the safety of the patient and others. While the steps described by the commenter may be appropriate in some situations, they may not be appropriate in others. For example, a patient is attacking another patient. In this situation, immediate intervention, that is, restraint or seclusion in conjunction with ongoing verbal de-escalation and communication with the patient may be necessary to ensure the safety of all involved. The use of less restrictive interventions that are ineffective in this scenario may, in fact, further jeopardize the safety of those involved. Therefore, it is critical that staff employ the least restrictive interventions that will be effective in ensuring the safety of the patient, other patients, staff and others.

Comment: One commenter observed that insuring the safety of patients (as required by the Patients' Rights CoP) will not be possible unless restraining patients who endanger the safety of others is permitted. The commenter stated that the interim final rule with comment period precludes this type of use of restraint or seclusion. A second commenter agreed, noting that provision (f)(2) of the interim final rule with comment period contradicts (f)(3)(i) in that only patient safety (not that of others as provided in (3)(i)) is mentioned in (f)(2). One commenter suggested the following rewording for (f)(2) to remedy this contradiction: ''Seclusion or restraint can only be used in emergency situations if needed to ensure the patient's physical safety or the safety of others and less restrictive interventions with the patient have previously been determined to be ineffective.'' Other commenters echoed the concern that the requirement should take the safety of other patients and staff into account.

Response: The interim final rule with comment period stated that the use of restraint or seclusion must be selected only when ''less restrictive measures have been found ineffective to protect

the patient or others from harm.'' We have revised the final rule to state that restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm. In addition, we have specified the type or technique of restraint or seclusion used must be the least restrictive that will be effective to protect the patient or others from harm.

Comment: One commenter stated that ''absolute danger'' cannot be the only qualifier for restraint or seclusion use in behavior management. The hospital cited examples of highly agitated behavior that disrupts the treatment milieu, such as a patient yelling profanities, disrobing, or destroying property. In addition, another commenter stated that Maryland regulation permits the use of seclusion or restraint when an individual presents a serious disruption to a therapeutic environment (behavior of such a grave or protracted nature that it significantly interferes with the emotional well-being of other patients or with their treatment).

Response: We recognize that situations do occur in which highly agitated behaviors can disrupt the therapeutic environment. A disruption to the therapeutic environment that jeopardizes the safety of patients, staff, and others could be a situation where the use of restraint or seclusion may be necessary. In these situations, there may be no other intervention short of the use of restraint or seclusion that will assure the safety of the patients, staff and others. Based on these comments, we have revised combined standard (e) to state that restraint or seclusion can only be used to manage violent or self-destructive behavior of patients when they are in danger of harming themselves or others, and less restrictive interventions have been determined to be ineffective. However, we have not accepted the commenter's recommendation regarding ''agitated behavior.'' A patient's agitated behavior may or may not pose a physical safety threat to the patient, staff or others. We caution against automatic responses, where the situation is oversimplified and the intervention is not tailored to the individual patient. For example, the fact that a patient is yelling profanities is not an automatic trigger for restraint use. A patient might yell because of pain or any number of factors, which could perhaps be addressed by other types of intervention. In the examples cited, the patient's behavior should prompt individualized assessment and treatment. A patient who is shouting profanities may be calmed by one-to-one interaction with a staff member. A patient who is trying to destroy an object can, in some cases, be distracted or encouraged to redirect his or her energies. Again, we emphasize that the decision of how to handle any given situation will depend on the patient, the patient's history, the patient's symptoms, and the seriousness and immediate danger presented by the patient's behavior.

Comment: One commenter stated that each patient who is restrained or secluded should be given a complaint form when the intervention ends, with instructions on how to fill it out, and privacy and protection in submitting it.

Response: The hospital is required by standard (a) to establish a process for prompt resolution of patient grievances and must inform each patient who to contact to file a grievance. If the patient or the patient's representative wants to file a grievance, this can be done verbally or in writing.

Comment: One commenter recommended sanctions against providers who misuse or abuse any chemical or physical intervention be significant, sure, and swiftly applied.

Response: We appreciate this commenter's support for vigorous enforcement. Hospital noncompliance with these requirements is of the same gravity as noncompliance with existing standards, and could result in enforcement action.

Comment: A commenter stated that the regulation should reflect the fact that to reduce the use of restraints, it is necessary for hospital leadership to make clear that this is their policy and their goal. The commenter also stated that leadership must create an atmosphere where the use of restraints is not tolerated, unless absolutely necessary.

Response: We agree that hospital leadership plays a critical role in the reduction of restraint and seclusion use. There are many challenges associated with initiating and sustaining reduced use of restraint and seclusion. Strong organizational leadership is essential in creating the culture change necessary to minimize the use of restraint and seclusion. The responsibilities of the governing body and Medical staff are addressed in other CoPs.

15. One Hour Rule (§ 482.13(f)(3)(ii)(C))

We stated that a physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1-hour after the initiation of this intervention.

This provision was the lightning rod for public comment. Almost every commenting physician opposed the provision as written, and the majority of commenters strenuously objected to it, with most asking that the words, ''see and'' be eliminated to leave only the requirement for a physician or LIP evaluation. A core of commenters from advocacy groups and the general public stated that this provision should be modified by shortening the timeframe to half an hour and eliminating the recognition of an LIP's ability to perform this function.

Many commenters asked what the face-to-face requirement of the interim final rule with comment period accomplished. In the preamble of the July 2, 1999 interim final rule (64 FR 36079) we stated the following:

> In situations where a restraint must be used for behavior management, increased vigilance is required because of the heightened potential for harm or injury as the patient struggles or resists. Furthermore, there is an immediate need for assessment of what has triggered this behavior and for continuous monitoring of the patient's condition. To address the need for quick assessment of the condition, we are specifying that the physician or licensed independent practitioner see the patient face-to-face within 1-hour of the application of the restraint or the use of seclusion.

The one-hour requirement of the interim final rule with comment period was intended to assure patient safety with a quick assessment by a physician or other LIP to rule out possible underlying factors that might be contributing to the patient's behavior, to assess the patient's physical and psychiatric condition, and to decide whether restraint or seclusion continue to be necessary.

Commenters were divided on whether this provision would promote patient safety or address adequately the problems identified by the media. While some commenters stated that deaths that occur during the first hour of restraint or seclusion support the need for this mandated onsite physician or LIP assessment within the first hour, a second group stated that by the time the physician arrived in the 59th minute, if staff were not properly trained, the patient might already be dead. This latter group of commenters argued that our proposed ''fix'' did not directly address the key problem and that we were essentially adding a process without proof of an improved outcome for patients.

Some commenters referred us to a Pennsylvania policy used in its ten State-operated psychiatric hospitals, which requires a physician's face-to-face evaluation within half an hour, and accompanying data that shows a reduction in restraint and seclusion use.

The Commonwealth's policy and data were cited as proof that a half-hour physician face-to-face assessment improves patient care and assures patient safety. In preparing the final rule, we were interested in the Commonwealth's experience, including any outcomes data or research related to its half-hour physician assessment policy. We asked for and received a package of information from the Commonwealth that described its policies regarding restraint and seclusion and data showing use over time.

The Commonwealth's policies provide that—(1) only a physician may order restraint or seclusion; (2) orders may not exceed 1 hour; (3) if a verbal order is given, the physician must physically evaluate the patient within 30 minutes; (4) persons in restraint must be kept under constant observation; (5) each reorder may not exceed 1-hour and requires physical examination; (6) each incident must be followed by patient debriefing; and (7) each use triggers clinical, administrative, and continuous quality improvement review, plus a revision to the treatment plan.

After reviewing the information received, we did not find any claims by the Commonwealth that physician assessment within half an hour had directly contributed to reduced restraint and seclusion use. Furthermore, to make such an attribution would be to ignore the fact that the Commonwealth introduced a multi-pronged approach that embraces many methods to address the issues of patient and staff safety. An important aspect of the approach is that physicians are on staff around the clock in the Commonwealth's psychiatric facilities. The requirements referenced earlier do not exist in isolation, but are part of the Commonwealth's integrated approach and ongoing efforts to work collaboratively toward the goals of restraint and seclusion reduction and patient and staff safety.

To summarize, given the comprehensive restraint and seclusion policies instituted by the Commonwealth, it is simply unclear whether one could point to the half-hour evaluation and demonstrate a direct, causal effect on the reduction in restraint and seclusion initiation and duration in Pennsylvania's State psychiatric hospitals.

Based on our analysis of the information supplied by the Commonwealth, and given the numerous public comments we received on this requirement, we have revised the regulatory language to broaden the types of practitioners who may conduct the 1-hour face-to-face evaluation to include a trained RN or PA unless superseded by State law that is more restrictive. We have also addressed the criteria by which staff are to be considered ''trained'', and specify the components of the 1-hour evaluation. In making these changes, we acknowledge the comments of many psychiatrists and other physicians who noted that they are appropriately consulted within 1-hour of the initiation of restraint or seclusion by the onsite staff. Many such commenters argued that a RN is entirely capable of assessing the patient's condition, and that to suggest otherwise ignores RNs' training and high level of expertise.

How quickly the patient needs to be seen by his or her attending physician (or other practitioner, as noted in the regulation) is left to the medical judgment of the physician or other LIP. We have revised standard (f) to state that if the 1-hour face-to-face evaluation is conducted by a trained RN or PA, the attending physician or other LIP responsible for the care of the patient must be consulted as soon as possible. The attending physician or other LIP is responsible for assuring that the patient receives a timely and adequate face-to-face assessment based on the clinical need presented by the individual patient's case.

Comment: One commenter noted that in California, the contractual relationship between a physician and hospital may affect the hospital's ability to ask physicians to meet the 1-hour requirement.

Response: The comments submitted (some of which came from physicians from California) indicated that a high level of physician involvement in the patient's care already exists. Many reported routine contact with hospital staff if a patient under their care becomes violent or self-destructive and restraint or seclusion may be indicated. Most of these physicians argued for the removal of the word ''see,'' noting that they are willing to be and indeed already are involved with these sorts of decisions, but that their objection was to the onsite visit. We have revised the requirements to permit a trained RN or PA to conduct the 1-hour evaluation, and do not require the physician to come to the hospital to see and evaluate the patient 1-hour after the initiation of the restraint or seclusion. Because this change permits more flexibility and clinical judgment on the physician's part, we believe that the cause for physician objection is largely removed.

a. Comments Objecting to a Physician or LIP Seeing the Patient Within 1 Hour

The majority of commenters objected to our requirement that a physician or LIP see the patient within 1-hour of the initiation of restraint or seclusion for behavior management. They provided the following arguments regarding this requirement as written in the interim final rule with comment period. The rule—

- Is impractical. By the time the physician or LIP arrives, the patient's episode may already be over, leaving some physicians asking what they are supposed to evaluate when they arrive. One physician asked whether he must awaken a patient to perform an evaluation after the intervention has ended if the patient is asleep afterward.
- Forces free standing facilities to hire under qualified and ill-prepared physicians to see and evaluate patients with whom they are unfamiliar.
- Pits the physician against staff.
- Creates hesitation to use an intervention to address violent or aggressive behavior that places the patient, the staff, and other patients at risk. One commenter believed that psychiatrists will tell nursing staff to tolerate aggression or violence until they find time to come and see the patient, which also places those present at the hospital at risk. To provide evidence of the risk to staff, commenters referred to various data sources: the Occupational Safety and Health Administration has named health care workers as one of the most injured-on-the-job occupational groups; the National Institute for Occupational Safety and Health has found that most non-fatal workplace assaults occur in service settings such as hospitals, nursing homes, and social service agencies. Forty-eight percent of nonfatal assaults in the workplace are committed by health care patients; and the Department of Justice has found that mental health professionals rank sixth (behind taxi-drivers, police officers, security guards, prison guards, and bartenders) on a list of occupations with the greatest risk of attack. This requirement, commenters argued, will add risk of on-the-job injury that could otherwise be avoided.
- Inappropriately dictates medical practice. Requiring timely and appropriate medical evaluation is reasonable, but it is not feasible or clinically necessary to require a face-to-face evaluation by a physician in each case. A physician assessment of the situation should always be done, but whether face-to-face evaluation is necessary should be left to the physician's discretion.

• Nullifies the professional clinical decisions of registered nurses and insults their professionalism and training.

• Adversely impacts staff morale, recruitment, and retention. One physician described getting good staff as a continuing challenge since the job is inherently dangerous. He believed that he will lose staff who decide that the increased hassle of inpatient work is not worth the trouble when plenty of outpatient work is available. Other commenters voiced similar concerns, noting that nurses must deal with belligerent and uncontrollable patients, and limiting their available options will make retaining nursing personnel difficult.

• Will cause hospitals to place patients immediately in restraint without trying seclusion (that is, move to the most restrictive intervention first) so that the physician only has to make one visit to assess the patient.

• Will adversely affect patient access to care. Admitting teams will refuse to accept any potentially violent or disruptive patients because of this requirement and thereby increase the number of patients routed to State hospitals, the criminal justice system, or juvenile hall, and increase the number of patients who are put out on the street. Persons with the most severe mental illness will be denied a choice of physicians and hospitals although their treatment needs are the greatest.

• May be impossible to implement. Existing psychiatrist shortages may thwart hospitals' attempts to hire coverage so that this requirement can be met. One facility commented that it has tried to recruit personnel, but was repeatedly told that psychiatrists can make more money with considerably fewer disruptions in their lives by choosing not to do inpatient psychiatry. As a result of these regulations, three of that facility's current physicians are questioning whether they will continue with their inpatient privileges. The commenter also states that a nearby psychiatric unit may close its inpatient services as a result of its entire psychiatric staff resigning. Another hospital reported that no local physicians were willing to be on call and onsite within 1 hour. Many physicians stated that this provision has caused them to question whether they should continue rendering inpatient services.

• Cannot be implemented because of geographical/logistical issues. While large organizations may have house staff and residents with which to meet this requirement, it will be difficult to accomplish in community or rural hospitals.

• May require onsite physicians (usually emergency room physicians) to leave less stable patients simply to comply with this regulation.

• In effect will require all hospitals to have physicians present 24 hours a day, 7 days a week. One hospital noted that hiring an onsite physician would be costly and impractical given the low occurrence of restraint and seclusion.

• Has no clear clinical rationale.

• Will result in patient overmedication in an attempt to avoid such situations. One physician cautioned that overuse of antipsychotic medications can result in severe (sometimes irreversible) neurologic side effects or Neuroleptic Malignant Syndrome, which is potentially fatal. Increased use of psychotropic medications may lead to excessive sedation and cognitive dulling, which could affect the patient's ability to benefit from therapy and other interventions.

• Will be disruptive of care provided to outpatients by requiring that practitioners drop everything to come into the hospital to meet the requirement. This disruptiveness will discourage practitioners from providing inpatient services, and thereby adversely impact patient care and access to good practitioners.

• Is not based in any empirical evidence that suggests that a face-to-face evaluation by a physician or LIP will improve the outcomes of care for patients who are secluded or restrained; nor is it based on any information that suggests that a telephone consultation is less effective than a face-to-face evaluation.

• Will cost too much. Various hospitals provided estimates that ranged from a cost of $62,000 to $750,000 per year. One commenter stated that the economics of small community facilities that provide inpatient psychiatric care are tenuous at best. This regulation may force these facilities to close or go bankrupt. The commenter alleged that we have ''tolled the death knell of inpatient psychiatric services across the country.'' Another commenter believed that most providers will go out of business, and those that remain will have to pass the increased costs on to the payors and patients. One hospital stated that this requirement will force it to ''close its doors.'' One physician reported that nearly all psychiatric facilities and programs operate on a slim margin at best. Studies have shown that mental health program budgets have been reduced by 54 percent over the past decade, compared to 7 percent in non-psychiatric medical programs. Programs that specialize in treating geriatric and juvenile patients will be severely affected by this rule. It is likely, he argued, that administrators will be forced to divert resources for staffing levels, equipment, patient education, case management, and other critical patient care activities to offset the cost of implementing the rule. One hospital sent in a notice of closure as a comment.

• Will be costly, both in time and resources. Each time the physician is required to see a restrained/secluded patient, there will be an additional fee for the visit. Most often, a physician who is unfamiliar with the patient will have to spend time reading the chart and examining the patient, and talking to staff. This may also result in confusion about treatment.

• May be used to manipulate the physician since the patient can escalate his/her behavior, knowing that the physician will have to appear within 1-hour as a response.

• Will be ignored by the medical community. One physician indicated that the unanimous response he has received from colleagues is that ''it ain't gonna happen.''

• Does not allow for treatment that is individualized and based on medical necessity.

• Is unreasonable. Physicians in independent private practice have full out-patient office schedules after hospital rounds and cannot be expected to cancel an entire schedule and ignore the clinical needs of outpatients to drive to the hospital on an unpredictable and irregular basis. Family practitioners and specialists have a full daytime schedule and will not be able to provide quality services if they are exhausted and unpredictable in their schedules.

b. Comments Supporting Telephone Consultation With a Nurse Onsite Performing the Patient Assessment

Many of these commenters suggesting deleting the word ''see'' from the requirement to allow staff consultation with the physician or LIP by phone. A large number of these commenters agreed with the revised language proposed by the American Hospital Association (AHA) and the National Association of Psychiatric Health Systems (NAPHS), ''A physician or other licensed independent practitioner must evaluate the need for restraint or seclusion within one hour after the initiation of this intervention.'' AHA and NAPHS believed that the evaluation may be done by the physician or LIP in consultation with a registered nurse who has demonstrated competency in the evaluation of a patient in restraint or

seclusion and who is in face-to-face contact with the patient. Many commenters argued that this change would be appropriate because qualified registered nurses are more readily accessible in emergency situations. Because of the RN's involvement at the earliest stages of an event, the RN would be able to provide additional information about the situation and provide the physician with rapid, appropriate consultation. The RN would carry out the physician's order and direct staff in the use of least restrictive methods and in the discontinuation of restraint or seclusion at the earliest possible time, as specified in the interim final rule with comment period.

The NAPHS further suggested that the content of the nurse/physician consultation include the following elements in order to promote an informed evaluation of the patient: (1) Consideration of organic causes for the behavior; (2) known medical disorders; (3) the patient's medications; (4) the patient's mental status; (5) a brief neurological examination; and (6) vital signs. If data from this evaluation supported the need for a face-to-face visit, then the physician would come to see the patient.

Other commenters argued that by limiting the ability to assess the patient to an LIP or physician, CMS is contradicting JCAHO standards which permit a RN to assess and document the need for restraint. Many commenters supported RN or psychiatric nurse assessment of the patient.

One commenter noted that the interim final rule with comment period permitted the evaluation to be performed by ANY physician, even one with no training in psychiatry and no direct knowledge of the individual's medical and treatment history—but would not permit the evaluation to be conducted by a psychiatric nurse or other licensed professional who is an integral part of the patient's individual treatment team. This organization urged CMS to ensure that orders for these interventions and evaluations following initiation of the interventions be conducted by licensed practitioners who are specially trained and qualified to assess and monitor both the inherent medical and the psychological risks. This may involve physicians or LIPs, or nurses or psychologists who are more familiar with the individual's psychological history. Another commenter echoed this concern, arguing that non-psychiatric physicians do not necessarily have the competencies for treating people with mental illness.

One commenter interpreted the rule to inappropriately devalue and undermine the profession of psychiatry, as well as psychiatric care, by requiring face-to-face assessment for psychiatrists, but not for other physicians. This commenter asked whether physicians who are not psychiatrists have greater reasoning ability and better judgment in matters that involve assessing the appropriateness of restraint and seclusion, or whether nurses in medical hospitals are somehow more adept at reporting reliable and accurate information to treating physicians than those nurses who work in psychiatric hospitals. The commenter also supported the use of telephone consultation.

A commenter stated that the requirement would in all probability be unproductive. The commenter also stated, ''Patients requiring seclusion or restraint have shown behaviors potentially dangerous to themselves or others; such behaviors are caused by impaired reasoning, distorted thinking, or other irrational stimuli. It is extremely unlikely that such an event would have resolved in an hour; either the patient would continue to be irrational or would be sedated from concomitant therapeutic use of medication so that an assessment would not be possible.'' The commenter stated that telephone contact between staff and physician is perfectly adequate. In addition, the commenter noted that an appropriate review of the circumstances is much more likely several hours (8 to 12) after the initiation of the intervention.

A few commenters' disagreements were based on the idea that episodes requiring restraint and seclusion typically involve such gross behavioral problems that they cannot be mistaken for anything other than emergencies, so a physician's visit to assess the need for restraint is not essential. A commenter who had experience in a hospital with a 2-hour face-to-face rule reported that he has never disagreed with a nurse's assessment that a given patient needed to be restrained.

One commenter pointed out that the physician is always accountable for the medical care his or her patient receives, as well as for what actions are taken under his or her direction or license. Another commenter noted that since the order has already been implemented, the physician has already accepted responsibility, so requiring face-to-face evaluation is unnecessary.

c. Comments Opposing Telephone Orders, Nurse Evaluation, and Other LIP Involvement

Some commenters strongly disagreed with allowing telephone orders for restraint and seclusion and with allowing anyone other than a physician to perform the face-to-face evaluation of the patient. One commenter, an RN/PhD, made the following statements:

> This letter comes to urge members of the regulatory task force to require that physicians complete a face-to-face assessment of the patient within the hour after initiation of the restraint or seclusion and every hour thereafter. There are many reasons for a patient to become ''out of control,'' among which are reactions to medications, delirium secondary to metabolic dysfunction, hypoxia, and so forth. These need to be assessed thoroughly and with all due respect to my own profession [the commenter is a RN and Ph.D.], most practicing nurses are not educationally equipped to make such evaluations. In my years of practice, I have seen patients placed in restraints when they had akathesia and when they were confused as a result of impending pulmonary edema with nurses labeling this as ''out of control.'' In fact, I had opportunity to render an expert opinion in a lawsuit involving the death of a gentleman who died in congestive heart failure—he was hypoxic, became confused, and the nurses tied him down. It is not a pretty thought that he drowned in his own fluid tied to a bed.

Similarly, another commenter wrote,

> Sometimes it is important for us to do what is right instead of what is convenient. For the last 40 years that I can remember, we have looked for easy ways to restrain uncooperative patients without infringing on our own time and effort. There is no proper way to do it. One hour of restraint or seclusion is certainly a maximum that should be allowed before personal examination and evaluation by someone who is authorized to directly give such an order. Think of the patient, a decent human being, not yet properly evaluated for the patient's ''bad'' or ''uncontrollable'' behavior. One hour is a long time to be physically restrained for no or improper reasons. The time allotted to a temporary restraining order must be minimal. The person providing the evaluation and giving the regular order must do so very quickly thereafter and be able to accept responsibility for doing it without proper indication. There will be a lot of opposition to this position, as there has been continuously ever since these treatments were first used. But that does not make it right to use them improperly. There is no other way to treat our fellow men and women.

d. Comments Stating That the 1-Hour Provision Did Not Address the Problem

Other commenters took issue with the idea that the requirement for a physician's onsite visit would prevent the sorts of situations described in the Hartford Courant's series. A physician who serves as an expert consultant to Protection and Advocacy, Inc. has reviewed several cases of deaths occurring in chronic and acute care facilities. He stated,

Several of these deaths occurred among patients who were at the time of their death contained (or in the process of being contained) in seclusion or restraints. These deaths were tragic and in some cases due to serious, preventable errors. However, I do not believe that the outcome in any of these cases that I have reviewed would have been changed by the proposed rule that patients requiring seclusion or restraint be evaluated face-to-face by a physician or LIP within one hour after the initiation of these interventions.

Many facilities that opposed the provision reported having had no injuries or deaths associated with restraints use. Many discussed their use of training programs to assure staff competency and argued that training and monitored staff competency, not the 1-hour requirement for a physician's onsite visit, was the key to assuring patient safety.

Many commenters argued that better training in restraint use, constant or frequent monitoring of patients in restraints, the banning of dangerous techniques such as face-down floor holds, and CPR training for all direct care workers could prevent the deaths associated with restraint use. One hospital reported that during a recent three-month period, it identified 94 patients who would have been covered by the 1-hour provision. Of these 94 cases, no restraint-related injury occurred.

Some commenters believed that this provision was excessive and unnecessary, given that they had no problems with deaths or injuries caused by restraint.

Another commenter argued that the problems that have caused the reported deaths and injuries have been due to the administrative policies of the problematic facilities. The commenter therefore believed that it is unnecessary to develop new rules to cover a ''problem'' that for the most part does not exist. Another commenter affirmed this point, stating,

Several years ago, the California Psychiatric Association investigated the causes of deaths of persons who had died in seclusion and/or restraint in California over a period of several years. Our investigation found that in nearly every case, the seclusion and/or restraint was in violation of the hospital's own policies and procedures. The better answer to seclusion and restraint deaths is enforcement of existing laws, not the enactment of a law which will have the unintended consequence of denying the sickest of the sick hospitalization.

One commenter characterized this requirement as, ''A very arbitrary decision and obviously made without much thought at all.'' The commenter further stated, ''While there have been instances of deaths, to make an unreasonable demand upon all physicians because of a few instances that can be corrected is extremely unreasonable and would greatly change how psychiatrists and physicians practice medicine in a negative way and would not add anything positive in terms of health care. Hospitals and physicians will work hard with CMS to eradicate such abuses as have been reported.'' Another commenter agreed, stating the following:

While it is desirable to remedy the shortcomings of our current restraint and seclusion practices, it is immediately apparent to me that your new requirement will result in more patient injuries because of the difficulty of compliance with the new standard. Since you are demanding a new type of treatment protocol, I suggest that the burden is yours to demonstrate in a controlled trial that your solution will indeed be more effective than the existing policy. This is the same process by which all proposed therapies are judged in our field. To do less is to subject all patients to a cruel mass experiment.

One hospital agreed with many of the points raised by CMS in the interim final rule with comment period, and with the position of the National Alliance for the Mentally Ill (NAMI), and supported standards that protect people with mental illness from abuse or unnecessary risk. The hospital noted that it has adopted most of NAMI's best practices initiatives in their institution. However, the hospital stated this provision provides no additional benefit to the patient and may cripple its ability to provide a high standard of care to its patients.

Response: The revised requirement in no way prohibits a physician from coming to the hospital to assess the patient in person. In the final rule, combined standard (e) requires that if a trained RN or PA conducts the 1-hour face-to-face evaluation, the attending physician or other LIP responsible for the care of the patient must be consulted as soon as possible after completion of the evaluation. As many commenters noted, telephone consultation may be effective in this context. Other steps may be critical in addressing the problems identified in the Hartford Courant series. We are not persuaded that it is practical or necessary in all cases for a physician to physically be present within 1-hour to assess the patient. We believe that the patient's attending physician or other LIP responsible for the care of the patient is sufficiently qualified to determine whether the patient's symptoms, condition, and history indicate the need for an immediate onsite visit.

Based on the arguments and information submitted by the commenters, we have revised these requirements. When restraint or seclusion is used to manage violent or self-destructive behavior, a physician or other LIP, or a RN or PA trained in accordance with the requirements specified under § 482.13(f), must see the patient face-to-face within 1-hour after the initiation of the intervention to evaluate: (1) The patient's immediate situation; (2) the patient's reaction to the intervention; (3) the patient's medical and behavioral condition; and, (4) the need to continue or terminate the restraint or seclusion. As is the case with all CoPs, States are free to have requirements that are more restrictive than these requirements. For example, States have the flexibility to limit who may conduct the 1-hour face-to-face evaluation, require that the evaluation be completed in less than an hour, or require additional training. Finally, if the 1-hour face-to face evaluation is conducted by a trained RN or PA, the attending physician or other LIP who is responsible for the care of the patient as specified under § 482.12(c) must be consulted as soon as possible after completion of the 1-hour face-to-face evaluation.

Comment: One commenter suggested that the psychiatrist be thoroughly informed of the events that led to the need for an intervention, vital signs, and other pertinent clinical information by telephone, and be required to conduct the onsite evaluation ''within a reasonable time, not to exceed two hours.'' This wording, the commenter noted, will allow some flexibility without completely abandoning time limits.

Response: We agree that the attending physician (psychiatrist) should be kept informed about the patient's status. The final rule specifies that the attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion. It also specifies that the attending physician or other LIP responsible for the care of the patient must be consulted as soon as possible after the completion of the 1-hour face-to-face evaluation if this evaluation is completed by a trained RN or PA. During these consultations, we would expect that the patient's status and areas suggested by the commenter are discussed with the attending physician. We do not believe that it is necessary to require that the attending physician conduct an onsite evaluation within 2 hours. How quickly the patient needs to be seen by his or her attending physician (or other practitioner, as noted in the regulation)

is left to the medical judgment of the physician.

Comment: One commenter noted that under Commonwealth of Virginia law, only physicians and licensed clinical psychologists are able to order restraint and seclusion. The commenter stated that the recognition of LIPs in this provision did nothing to lessen the facility's burden.

Response: This regulatory provision is applicable unless superseded by State law that is more restrictive. It is not our intent to interfere with State laws governing who may order restraint and seclusion.

Comment: Some commenters argued that licensed practitioners such as social workers and psychologists (who may be recognized under some State laws as being LIPs) do not have training in physiology or pharmacology and therefore may not be able to assess the patient appropriately in an emergency situation.

Response: In this final rule, we have specified that while these types of practitioners may order restraint or seclusion if permitted to do so by State law and hospital policy, the patient's attending physician (or other practitioner) must be contacted to assure continued medical oversight and continuity of care. The 1-hour face-to-face evaluation includes both a physical and behavioral assessment of the patient. Therefore, the practitioner who conducts this evaluation must be able to complete both a physical and behavioral assessment of the patient in accordance with State law, his or her scope of practice, and hospital policy. Generally, practitioners such as social workers, psychologists and other mental health workers are not qualified to conduct a physical assessment, nor is it in their scope of practice.

Comment: One hospital association questioned why we distinguished restraint and seclusion from other medical interventions initiated when the patient undergoes a sudden change in condition.

Response: Our focus on restraint and seclusion is not to distinguish these interventions from others initiated when a patient suddenly undergoes a change in status; to the contrary, this focus only serves to bring the use of these interventions the same level of attention and concern. As we read through comments, we found that many commenters use restraint or seclusion only when individualized assessment for that particular patient indicates that one or both are necessary as a last resort. However, some seemed to think that restraining a patient was not only acceptable, but a standard, sound, or unavoidable practice. Restraint and seclusion are not standard, benign, or desirable interventions to address a patient's behavior. The use of restraint or seclusion to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others is of the same gravity as other interventions that require the physician's or other attending practitioner's (as noted in the regulation) attention and concern.

Comment: One commenter argued for the onsite presence of the attending physician, since it would introduce someone who did not participate in the incidents leading up to the use of restraint or seclusion who may be more objective in determining whether the intervention is appropriate or whether the restraint or seclusion was imposed as a means of coercion, discipline, retaliation, or convenience.

Response: Including such a requirement would be unnecessarily burdensome. The regulation requires that the attending physician be notified as soon as possible if a restraint or seclusion has not been ordered by the attending physician. The attending physician has a vested interest in determining whether the intervention is appropriate since the physician is ultimately responsible for oversight of the patient's care. If the attending physician believes that the intervention is not needed, he or she may instruct staff to release the patient. If the attending physician wants to speak to the patient or evaluate the patient in person to gather more information, he or she can do so.

Comment: Several commenters suggested that this standard only be applied to those hospitals where deaths or other sentinel events related to restraints or seclusion have occurred.

Response: Once codified, this standard as well as the entire set of existing hospital CoPs are the requirements that all hospitals must meet to participate in the Medicare and Medicaid programs. The CoPs are minimum health and safety standards. They are intended to protect patient health and safety, and to ensure that high quality care is provided to all patients. Although the majority of hospitals are in compliance with the requirements, we cannot develop rules that only apply to some participants or a particular provider group.

Comment: One commenter asked whether any physician who performs the assessment can be any physician, or whether if it must be the patient's attending physician.

Response: As revised in this final rule, standard (e) permits a physician or other LIP, or a trained RN or PA to perform the 1-hour face-to-face evaluation of the patient. We have not specified that the evaluation must be completed by the patient's attending physician. However, if the evaluation is conducted by a trained RN or PA, the attending physician or other LIP responsible for the care of the patient must be consulted as soon as possible. The physician may determine, based on clinical need, how soon he or she should see the patient.

Comment: One hospital stated that it is the facility's responsibility to identify and provide the right number of competent staff to meet the patients' needs. The hospital opposed the one-hour provision as it has adequate, competent staff to assure patient safety and well being.

Response: Based on public comment, we have amended the 1-hour face-to-face evaluation requirement. We agree with the commenter's emphasis on the importance of adequate levels of competent staff.

Comment: One commenter suggested moving away from the requirement for an onsite physician visit, but suggested adding language requiring that, ''If the evaluation is made by telephone, a physician or LIP must personally sign, date, and note the time of the telephone order within 24 hours of the time the order was issued.''

Response: Signature and review of telephone orders arises for other types of orders, not just those involving restraint or seclusion. We see no need to establish separate requirements for how orders for these interventions would be documented.

Comment: One commenter alleged that hospitals are dodging the 1-hour requirement by releasing the patient from restraint or seclusion and starting over with a new order before reaching the 1-hour point.

Response: Ending the intervention prior to the 1-hour point does not mean that the mandated assessment and consultation are no longer necessary. These steps are still required, even if the intervention ends within one hour of initiation.

Comment: Many commenters pointed out that this provision was not in the proposed revision of the hospital CoPs.

Response: Several organizations used this argument as a basis for bringing suit against the Secretary to block implementation of this provision, but the court upheld the validity of the regulation. (See *National Association of Psychiatric Health Systems* v. *Shalala*, 120 F. Supp. 2d 33 (D.D.C. 2000).) As we stated before the court, we believe that this provision is a logical outgrowth

of the December 19, 1997 proposed rule. The court agreed with our position.

Comment: One commenter asked whether the patient has to be released from restraint or seclusion if the physician is unable to arrive within 1 hour.

Response: Since we have revised combined standard (e) to no longer require a physician's onsite visit within 1 hour, this question is no longer pertinent. However, if the face-to-face evaluation is not completed by a physician, other LIP, or a trainer RN or PA, the hospital would be out of compliance.

Comment: Several commenters were concerned that the onsite visit would not be covered by Medicare, since additional visits on the same day cannot be billed for as per the Medicare Claims Processing Internet Only Manual (IOM) pub 100–04, chapter 12, section 30.6.9B.

Response: While multiple visits in the same day by the same practitioner (or another practitioner within the same practice, with the same specialty) cannot be separately billed, practitioners should select a code that reflects all services provided during the date of service (Medicare Claim Processing Internet Only Manual (10m) Pub. 100–04, Chapter 12, section 30.6.9B).

Comment: One commenter asked that both children and adults be monitored by a physician every 15–30 minutes and that documentation be provided.

Response: We do not believe that this high degree of physician involvement is necessarily merited, practical, or reasonable in every case. Based on the patient's status and type of intervention used, more frequent monitoring by a physician, LIP or other trained staff may be necessary. The condition of the patient who is restrained or secluded must be monitored by a physician, other LIP, or trained staffed at an interval determined by hospital policy and based on assessed patient needs.

Comment: Several commenters asked whether CMS will accept a telemedicine evaluation in lieu of face-to-face evaluation.

Response: Since the requirement for face-to-face evaluation has been changed to include a trained RN or PA, there would not necessarily be any need to use telemedicine evaluation unless clinically indicated.

Telemedicine is an important developing field. We are looking at the role of telemedicine in providing healthcare. However, telemedicine is not addressed in this rule. Telemedicine will be addressed at a future date.

Comment: One commenter asked whether an advanced registered nurse practitioner can perform the 1-hour assessment.

Response: In the final rule, combined standard (e) permits an advanced registered nurse practitioner (if recognized by State law and hospital policy as having these abilities within the scope of the individual's license and consistent with individually granted clinical privileges) as being able to order the intervention as well as perform the 1-hour face-to-face evaluation.

Comment: One commenter noted that managed care reimbursement for psychiatric inpatient services is minimal, and the physician will either have to demand that the hospital pay for the physician's time or refuse to extend his or her time ''to unnecessarily observe a patient who has been safely contained by competent mental health professionals.''

Response: This final rule permits the attending physician or other attending practitioner (as noted in the rule) to determine whether and how quickly the physician's presence is merited without arbitrarily requiring it.

16. Limits for Restraint/Seclusion Orders (§ 482.13(f)(3)(ii)(D))

We stated that each written order for a physical restraint or seclusion is limited to 4 hours for adults, 2 hours for children and adolescents ages 9 to 17; or 1-hour for patients under 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.

Although a few commenters agreed with the timeframes for length of order specified in the interim final rule with comment period, the majority of comments on this requirement were from advocacy organizations wanting further restriction on the time limits and seeking clarity on who can renew the order. However, one commenter did object to the timeframes for length of order, arguing that they were not based in research and were arbitrary.

Recommendations on this provision varied and included the following:

- Limiting the timeframes for length of order to no more than one-half hour for children, 1-hour for adolescents, and 2 hours for adults.
- Making the timeframes for length of order different for seclusion and restraint use.
- Not using age as the determining criterion since it is an arbitrary factor. Patients present with a variety of clinically important indicators, such as size, weight, gender, history of abuse, disability and medical conditions that should also be used to determine the length of time a patient remains in restraint or seclusion.

Other commenters suggested that each renewal of the order should be accompanied by another face-to-face examination of the patient by the physician. A few commenters were uncertain of who would perform the assessment of the patient prior to renewing the order for the intervention. These commenters asked whether the interim final rule with comment period required physician or LIP face-to-face re-evaluation of the patient before renewal of the order.

Response: We conclude from the nature and number of comments that we did not emphasize our intent for this standard strongly enough. The regulation identifies maximum time limits on the length of each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. The physician or LIP has the discretion to write the order for a shorter length of time. The length-of-order requirement identifies critical points at which there is mandatory contact with a physician or LIP responsible for the care of the patient. In addition, the time limits do not dictate how long a patient is in restraint or seclusion. Staff should be continually assessing and monitoring the patient to ensure that the patient is released from restraint or seclusion at the earliest possible time. Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion should be discontinued. In the final rule, combined standard (e) explicitly states that the intervention must be discontinued at the earliest possible time, regardless of the length of time identified in the order. For example, if a patient's behavior responds to the intervention in 20 minutes, then the restraint or seclusion should be discontinued, even if the order was given for up to 4 hours. If restraint or seclusion is discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating the use of restraint or seclusion.

We leave to the physician's or other LIP's discretion whether an onsite assessment prior to renewing the order (for up to 4 hours, 2 hours, or 1 hour, as permitted by the regulation) is necessary. While we agree that prompt physician involvement is important, requiring face-to-face reassessment by a

physician prior to renewal of an order as proposed by the commenters would be overly burdensome. Once the physician or other LIP has assessed the patient's condition, the physician or other LIP chooses a course of action to be followed and directs staff to implement it. We believe that an RN can follow the physician's or other LIP's direction and reassess the patient. Without evidence indicating that a physician's own evaluation versus that of an RN, nurse practitioner, physician's assistant, etc.) somehow better assures patient safety, we cannot accept this suggestion. However, after 24 hours, a face-to-face assessment by a physician or other LIP must occur before a new order is written for restraints or seclusion for the violent or self-destructive patient.

We are unaware of any research or data that suggest that limiting orders to 1 hour is better than limiting them to 4 hours for adults 18 years of age or older, 2 hours for children and adolescents 9 to 17 years of age, or 1 hour for children under 9 years of age. We stress that the timeframes outlined in the regulation are maximums. The ordering practitioner has the discretion to provide an order for a shorter timeframe based on the patient's condition and factors suggested by commenters.

Comment: Some commenters were confused by the term ''renewal'' of an order. We were asked to differentiate between the original order, a renewal order, etc. One commenter stated that under policies in place before the publication of the interim final rule with comment period, continuation of a restraint order beyond the 4-hour time limit was a decision that could be delegated to an RN. The commenter asked whether this rule would require a repeat order from the physician, or whether a 4-hour continuation could be decided upon by other qualified staff, such as an RN. Some commenters supported orders being renewed in this manner for up to 24 hours without a new (physician's) order. One commenter argued that not allowing nurses to evaluate the need to continue the use of restraint or seclusion and, thus, the need to renew an order would create a burden for hospitals.

Response: Each order for restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others is limited to the maximum timeframes in the regulation before the physician or other LIP responsible for the care of the patient must be contacted again. At the end of the timeframe, if the continued use of restraint or seclusion is deemed necessary based on a patient assessment, another order is needed. These limited timeframes apply regardless of whether each order is considered a separate, distinct, original order, or whether an order is considered a continuation or renewal of the original order. Because the use of restraint or seclusion is considered an intervention that can only be authorized by the order of a physician or other LIP, it is consistent to require that the determination to continue the intervention meet this standard as well. We believe that it is reasonable to have a trained RN reassess the patient when the original order is about to expire, and then contact the physician or other LIP to obtain direction as to whether the intervention is to be continued and whether other steps are to be taken. The key is the continued medical oversight. There is no prohibition of telephone renewals. We note, however, that at the 24-hour point, if the patient is still in restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen and assessed by a physician or other LIP before a new order can be written. In the final rule, we have also specified that each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.

Comment: One commenter agreed that this provision is clinically sound and warranted. However, the commenter believed that once evaluated, the physician should have the right, based on years of clinical training and supervision and board certification, to continue seclusion or restraint with periodic nursing evaluation for 24 hours.

Response: We believe that the timeframes for length of order, as established by the regulation, are reasonable. We note that the regulatory timeframes do not mandate how long the intervention continues; they only provide check points at which the ordering practitioner, and subsequently the attending physician, must be contacted with updated information regarding the patient.

Comment: One commenter suggested that the timeframes for seclusion should be consistent with professional standards of practice, rather than being regulated by this rule.

Response: We believe the timeframes for seclusion are consistent with professional standards of practice. Seclusion should only be employed while the unsafe situation persists. Once the unsafe situation ends, the use of seclusion should be discontinued. The length-of-order requirements identify intervals at which the ordering practitioner, and subsequently the patient's attending physician, must be informed of the patient's condition so that he or she can make a decision as to how treatment should proceed.

Comment: One commenter suggested that a physician's review of the documentation of the need for restraint [for the management of violent or self-destructive behavior] should be done within 24 hours of the order being issued.

Response: A documentation review alone may not adequately protect the patient. We expect that a physician or other LIP will see the patient if the patient is still restrained or secluded at the 24-hour point. Twenty-four hours of restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others is an extreme measure which could potentially seriously harm the patient.

Comment: One commenter believed that allowing 24 hours to elapse before the physician is required to physically see and reassess the patient is too long an interval. If the patient remains extremely agitated after 12 hours in restraint or seclusion, it is evident that the intervention is not successful, and some other intervention is needed. Another commenter argued that if the patient has been restrained or secluded for 4 hours, but preferably 3, a physician consultation is necessary. The medical director needs to be called in to help chart a course of action that will get the patient out of restraint or seclusion if it is proving ineffective.

Response: We agree with the commenter's concern that a patient's continued agitation may indicate a need to consider another course of treatment. However, the reason for the use of restraint or seclusion is to protect the patient or others from harm. The use of these interventions must not end efforts to treat the underlying cause of the behavior; nor is it expected that treatment will come to a complete halt. We expect that the use of restraint or seclusion will only last while the unsafe situation persists. Certainly, trained staff should work with the patient toward release as quickly as possible and use other interventions to de-escalate the crisis behavior.

17. Simultaneous Use of Restraint and Seclusion (§ 482.13(f)(4))

We stated that restraint and seclusion may not be used simultaneously unless

the patient is—(1) continually monitored face-to-face by an assigned staff member; or (2) continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

Comment: One commenter questioned whether our intent is that a patient who has been medicated and placed in seclusion must be continually monitored.

Response: The regulation only requires continual monitoring when restraint and seclusion are used simultaneously. If the use of a drug meets the definition of a restraint, and the patient is simultaneously placed in seclusion, all the requirements related to the simultaneous use of restraint and seclusion apply, including the requirement for continual monitoring.

Comment: One commenter asked for definition of the word ''staff.'' Another commenter asked for more detail regarding the type of monitoring and the level of expertise of the monitors. One commenter argued that children should be monitored by a person who is trained to interact and counsel.

Response: The word ''staff,'' as used in the regulation, has the standard definition found in any dictionary and includes anyone employed by the hospital directly or under a contract. Staff who monitor the patient face-to-face should be trained not only in restraint and seclusion techniques, but also in how to monitor physical and emotional status (taking vital signs, checking physical well-being, working with the patient to help the patient regain self-control, recognizing when the emergency situation has abated and the interventions (either one or both) can be ended). The components of continual monitoring must be determined by staff based on hospital policy, an individualized patient assessment, and the intervention used. Standard (f) specifies the criteria CMS will apply to staff to ascertain whether they have been ''trained''within the meaning of our regulation.

Comment: Some commenters stated that the rule does not explain why restraint and seclusion would be used simultaneously and argued that restraint and seclusion should not be used simultaneously. Some commenters asked to have simultaneous restraint and seclusion banned. These commenters voiced their belief that there is no clinical justification for subjecting a patient to both restraint and seclusion at the same time, other than for convenience of staff, for discipline, coercion, or retaliation. If simultaneous use continues to be permitted, these commenters suggest that patients should be constantly monitored by staff that is in the room or right outside the seclusion room, but in direct visual sight.

Response: Although simultaneous use of restraint and seclusion may be inappropriate in many cases, clinical situations exist where the simultaneous use of restraint and seclusion may legitimately be needed to protect the patient or others from harm. Staff must take extra care to protect the safety of the patient when more restrictive interventions are used. Restraint limits a patient's ability to move or escape from harm. Seclusion of a restrained patient may be necessary to protect a patient from possible abuse, assault or self injury during the intervention. For example, a patient is restrained alone in a room to maintain the patient's privacy. Shielding the patient from contact with others may be more humane and supportive of personal dignity than permitting everyone on the unit to witness what is happening to the patient. In this situation, it may be necessary to lock the door and seclude the patient if a staff member is not assigned to sit with the patient one on one in order to protect the patient.

When the simultaneous use of restraint and seclusion is employed, we would expect to see adequate documentation that justifies the decision for simultaneous use as well as vigilance in continuously monitoring the patient so that the patient's care needs are met. We would expect that the simultaneous use of restraint or seclusion be discontinued at the earliest possible time, regardless of the length of time identified in the order.

We do not agree with the commenters' assertions that these uses necessarily constitute patient abuse. However, there are risks associated with the simultaneous use of restraint and seclusion. Therefore in this final rule, we clarify that all requirements specified under standard (e) apply in the simultaneous use of restraint and seclusion, which is not permitted unless the patient is continually monitored face-to-face by an assigned, trained staff member, or continually monitored by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient. The hospital is responsible for providing the level of monitoring and frequency of reassessment that will protect the patient's safety.

Comment: One commenter questioned whether the use of a restraint is considered to be seclusion when the restraint prevents the patient from leaving the room. The commenter further queried whether a patient restrained in a seclusion room with the door open and unlocked would be considered to be in seclusion, and whether a patient restrained in the patient's room would be ''in seclusion.''

Response: In a situation where the patient is being restrained by a technique or device that interferes with the patient's mobility, the fact that the patient is confined in a room is a secondary effect. This situation is not equivalent to the use of seclusion. It is important to examine what would happen if the restraint were removed—if the patient would be free to leave the room if the restraint were removed, the patient is not being secluded. Conversely, if the restraint were removed and the door is locked or the staff otherwise physically prevent the patient from leaving the room, then the patient is being secluded.

18. Use of Video and Audio Monitoring

The use of video and audio monitoring met with mixed response. However, overall, the commenters viewed it negatively. Consumer advocates tended to see it as inappropriately depriving the patient of human contact when such contact would be beneficial to help the patient regain self-control, and as not assuring that the patient's physical and psychiatric status are adequately monitored.

Comment: One commenter stated that audio/video monitoring would be ''particularly odious to an individual already trussed up, tied down, and left alone.'' The use of video and audio equipment further alienates a patient who may be craving attention and engaging in the only behavior that will bring about human contact.

Another commenter argued that there is no substitute for face-to-face monitoring with periodic checks of patient's vital signs. The commenter recounted two separate instances where patients died while in restraints and seclusion. In both instances, the paramedics were unable to ventilate the patients because they were unable to place a tube down the throat of the patient. The onset of rigor mortis demonstrated that these patients had been dead for several hours before hospital staff discovered them and called the paramedics. The nursing logs for both patients indicated that the patients had been checked every 15 minutes. In these instances, ''checked'' meant looked at through a window into the seclusion room.

Some commenters argued that audio and video monitoring is costly and would result in financial burden to the hospitals. One commenter explained

that his hospital does not have the financial resources to hire additional nurses or nurse aides to perform one-to-one monitoring, nor does it have the resources to buy video systems for monitoring. Another commenter characterized electronic monitoring as costly and invasive of privacy.

A commenter argued that face-to-face monitoring only increases patient agitation and that both face-to-face and video/audio monitoring confirm the misperceptions of psychotic patients who are paranoid or delusional.

Other commenters did not object to alternative methods for monitoring, but had suggestions about requiring both. One commenter asked that we permit audio monitoring, but not require it. Another commenter suggested that we reconsider the need for audio monitoring if video monitoring is in place.

One commenter believed that video monitoring and taping was appropriate to ensure proper patient monitoring and quality control; however, this commenter believed that the regulations should also require staff to be in the patient's room. One commenter recommended ongoing audio/video monitoring to protect patient safety.

Another commenter asked for a more prescriptive definition of ''close proximity.'' The commenter understood that the intent of requiring staff to be in close proximity is to assure that hospital staff could quickly reach a patient should a safety issue arise.

Response: We agree that audio and video monitoring are not substitutes for the therapeutic intervention that should be occurring to help the patient regain self-control or for the level of monitoring necessary to assure that the patient is safe and that the patient's care needs are met. The use of video and audio monitoring equipment does not eliminate the need for other therapeutic interventions or frequent assessment of the patient's needs and status. For one patient, continual monitoring face-to-face by an assigned staff member may be appropriate and necessary. For another patient, the continual presence of an assigned staff member may cause the patient to become more agitated. In this situation, continual monitoring by trained staff using both video and audio equipment with periodic in-room monitoring may be more appropriate. In either situation, vigilant monitoring is necessary to protect the patient from harm, and ensure that the intervention is discontinued at the earliest possible time.

The hospital is responsible for providing the level of monitoring and frequency of reassessment that will protect the patient's safety. Continual monitoring cannot happen solely from outside the seclusion room. Staff must enter the seclusion room in order to—(1) monitor a patient's vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, etc., and assess and re-evaluate the patient; (2) provide for nutritional needs; range of motion, and elimination needs; and (3) provide other necessary therapeutic interventions and patient care. In response to comments, we have therefore revised combined standard (e) to clarify that all requirements specified under standard (e) apply in the simultaneous use of restraint and seclusion.

In response to comments that requested that we reconsider requiring both video and audio monitoring, we believe that neither video nor audio monitoring alone adequately protect patient safety when restraint and seclusion are used simultaneously. We do not require video and audio monitoring; instead, it is one method the facility can use to monitor its patients.

In response to the request for a more prescriptive definition of ''close proximity,'' the intent is to ensure that staff is immediately available to intervene and render appropriate interventions to meet the patient's needs. However, based on the number of possible unit configurations, we believe an outcome-oriented requirement is more appropriate than a more prescriptive one.

Comment: One commenter suggested that the regulations should specify that under no circumstances should a restrained patient be left unattended, as a patient in restraint is vulnerable to attack or mistreatment from others.

Response: Including such a requirement would be unnecessarily burdensome. As discussed earlier, we agree that a patient is more vulnerable to possible abuse, assault, or self injury during a more restrictive intervention. We expect staff to take extra care to protect the safety of the patient when more restrictive interventions are used. Regardless of the intervention used, the hospital is responsible for providing the level of monitoring and frequency of assessment necessary to protect the patient's safety. We believe hospitals should have the flexibility to provide the level of monitoring and frequency of assessment necessary to protect the patient's safety based on hospital policy and an individualized patient assessment.

Comment: Due to nationwide staff shortages, one commenter stated that his facility would be unable to meet the requirement.

Response: As one commenter offered earlier, it is the hospital's responsibility to assure that it has adequate staff available to meet the patients' needs. Given the acuity of a patient in restraint and seclusion simultaneously, we believe that heightened monitoring and intervention are merited.

Comment: One commenter stated that the requirement for face-to-face monitoring places staff at higher risk for injury.

Response: We believe that the required training elements within this regulation will promote staff awareness and expertise in handling potentially hazardous situations.

Comment: One commenter suggested that a better approach for increasing physician oversight and involvement would be to require a log of restraint use to be kept by the hospital, along with quarterly reports generated for local peer review organizations to track restraint and seclusion use. Patterns of excessive use would emerge more readily than they would otherwise under the current requirements.

Several commenters suggested requiring a restraint/seclusion log, and included elements that should be part of this log, such as the time initiated, discontinued, time physician was contacted, documentation of physical exams, etc. Additionally, other commenters believed that quality improvement efforts could more appropriately address the concerns regarding patient safety and quality of care.

Response: We agree. Although not mandated in this rule, we expect a hospital will address, as part of its quality assessment and performance improvement (QAPI) program, patient safety and quality of care issues. We also believe that this sort of tracking and monitoring may be appropriate as part of a hospital's QAPI program. However, including such a requirement would be unnecessarily burdensome. Hospitals should have the flexibility to identify and monitor the quality indicators that are most critical to the patient population(s) that they serve.

Comment: One commenter questioned how face-to-face monitoring should be documented.

Response: The regulation does not specify how face-to-face monitoring will be documented. This should be addressed by hospital policy.

19. Reporting of Death(s) Related to Restraint/Seclusion (§ 482.13(f)(7))

We stated that the hospital must report to CMS any death that occurs

while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

Comment: Several commenters noted that all deaths are routinely reported to State authorities.

Response: As noted earlier in this preamble, while there may be local mechanisms for reporting deaths, there is, at present, no nationwide system for reporting these deaths. We have estimated that the total number of deaths related to the use of restraint and seclusion in hospitals will be less than 10 per year. Therefore, given that the average number of reports per hospital is one or less, we do not believe that it is burdensome to ask that the hospital notify the CMS regional office if a patient dies while in restraint or seclusion, or where it is reasonable to assume that restraint or seclusion contributed directly or indirectly to the patient's death.

Comment: One commenter who supported the provision as written opposed requiring more detailed reporting and expressed concern about routine reporting to the Protection and Advocacy organizations (P&As). (Providing the P&As with information was mentioned in the preamble of the interim final rule with comment period.) Some commenters echoed this concern, expressing serious reservations about CMS's ability to maintain the confidentiality of the sensitive information provided in accordance with the new rule. These commenters did not believe that information provided to the P&As would be protected from disclosure or legal discovery. One commenter asked whether CMS would maintain the confidentiality of the information, or share it with outside entities.

Those commenters who opposed sharing the information with other entities argued that forcing hospitals to report injuries and the circumstances around them would in many cases require release of information that hospitals gather through their own peer review activities. Almost all 50 States protect information gathered in peer review and other quality internal improvement processes from discovery by lawyers. One commenter referred to *Bredice* v. *Doctor's Hospital, Inc.* (50 FRD 249 (D.D.C. 1970)), citing it as a case in which the court found that it was in the overwhelming public interest to maintain the confidentiality of the minutes and reports of medical staff meetings during which doctors critically analyze the hospital's medical care. The commenter argued that self-critical analysis privilege is now judicially recognized as a result of this case.

In contrast, a core of commenters from the public and the patient advocacy community supported sharing this information with the P&As, stressing the importance of partnering between CMS and P&As. These commenters encouraged a mandatory, detailed system of reporting to the P&As to ensure comprehensive investigations of incidents where patients die or are injured during restraint or seclusion use.

Response: Since the publication of the interim final rule with comment period, we have implemented a process for restraint or seclusion death reporting. We centrally track reports of death from restraints or seclusion occurring in hospitals. We use this information to: Authorize onsite investigations and complaint surveys of these hospitals, in accordance with the current complaint investigation process; and to inform the Federally-mandated P&A entity in the respective State or territory. P&A programs are congressionally authorized (in accordance with 42 U.S.C. 10801 et seq.) to access facilities and to investigate abuse and neglect complaints.

Comment: One commenter asked what information must be provided by the hospital and the timeframe within which the hospital must report the information to CMS. Some commenters proposed introducing timeframes for reporting, such as contacting the CMS regional office within 4 days of a patient death and the P&A within an additional 3 days. The commenters who supported such timeframes cited proposed national legislation, The Children's Health Act of 2000 (the CHA). The commenters who asked for definite timeframes stated that delays in reporting compromise the ability to investigate effectively (staff may leave, medical/documentary evidence may be lost or concealed, and potentially deadly practices continue). Other commenters suggested that CMS require reporting to the P&A within 24 hours of an incident.

Response: The CHA was signed into law on October 17, 2000 (Pub. L. 106–310). Section 592 of the CHA establishes minimum death reporting requirements. This final rule conforms to these requirements. We have revised our requirements to specify that the hospital report each death to the CMS regional office by telephone no later than the close of business the next business day following knowledge of the patient's death. This information will be relayed to CMS central office and the State survey agency, inasmuch as it acts as a direct agent of CMS. Our central office maintains a database to compile information related to deaths associated with seclusion or restraint.

Comment: Some commenters suggested that the regulation excuses hospitals from revealing many deaths precipitated by the misuse of restraint or seclusion by allowing the hospital to make the determination of whether a patient's death is reasonably assumed to have resulted from restraint or seclusion. These commenters strongly believed that providers tend to dismiss restraint-related deaths as ''unfortunate isolated incidents,'' not the manifestation of individual abuse or systemic failures, and that hospitals can rationalize that deaths were due to a patient's underlying condition or ''natural causes.'' Several commenters cited an example of the death of a young man who suffered a severe asthma attack soon after fighting with another patient and being restrained. According to the commenters, the death was ruled to be due to natural causes, even though the medical examiner found that the stress of the fight and restraint triggered the attack. Some commenters indicated that a complicating issue is that death may occur after a patient has been restrained or secluded in an originating facility, and is then transferred to another facility. The receiving facility may be unaware of what has transpired at the originating facility and may not report the death.

To address this issue, these commenters suggested that at a minimum, CMS specify that any deaths that occur within one week of restraint or seclusion use be assumed to be the result of restraint or seclusion. Optimally, however, these commenters argued for reporting all deaths of patients with a psychiatric diagnosis or mental retardation. The commenters stated that in this way, CMS could remove the subjectivity currently permitted by allowing the hospital to make a determination that the death is ''reasonably assumed'' to be a result of restraint or seclusion use.

These commenters also stated that a requirement for reporting the deaths of all patients with a mental retardation or psychiatric diagnosis would also permit CMS and the P&As to capture deaths that occurred post-transfer, as a result of restraint and seclusion practices at another facility.

Response: We have revised the reporting requirements. The hospital must report to CMS each death that occurs while a patient is in restraint or in seclusion or both at the hospital; and, each death known to the hospital that occurs within 1 week after restraint

(whether physical restraint or drugs used as a restraint) or seclusion, in cases in which it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. We have also clarified the meaning of ''reasonable to assume.'' As a result, ''reasonable to assume'' includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or deaths related to chest compression, restriction of breathing, or asphyxiation. In addition, we have moved the reporting requirements from standard (f) and created a separate standard (standard (g)) that addresses these requirements. This was done to clarify that all deaths associated with the use of seclusion or restraint or both must be reported. The reporting requirements in standard (g) are applicable to restraint and seclusion use.

We are not adopting the commenter's suggestion that all deaths of patients with a psychiatric or mental retardation diagnosis be reported to CMS; nor will we assume that all deaths that occur within 1 week of the use of restraint or seclusion are the result of restraint or seclusion.

Comment: A commenter stated that the reporting process is severely deficient because inadequate information would be provided to CMS and the P&As. The commenter suggested specific elements that should be reported, including—

- Identity of deceased/injured patient;
- Patient's age;
- Identity of patient's guardian, if applicable;
- Identification of next of kin, in cases involving patient death;
- Date of death/injury;
- Patient's home address;
- Medications patient was taking/other medical services provided;
- Cause and circumstances of death/injury;
- Whether/by whom death/injury is being investigated; and
- Identity of person making report.

Some commenters believed that the report submitted to CMS should be standardized and in writing.

Response: We agree that the suggested elements should be reported. However, to allow some flexibility for hospitals, we are not specifying these elements in the regulation text. In the final rule, standard (g), we have specified that each death referenced in this section must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. In addition, we have added a requirement that staff must document in the patient's medical record the date and time the death was reported to CMS.

Comment: One commenter suggested replacing the word ''assume'' with ''suspicion or belief.''

Response: We have retained use of the word ''assume'' and added language to clarify the meaning of ''reasonable to assume.''

Comment: One commenter indicated that the accrediting organization should also receive this information as deaths would be ''sentinel events'' under JCAHO policy.

Response: We currently inform the hospital's accrediting organization when we receive a death report from a hospital. In addition, hospitals should report deaths to their accrediting organization in accordance with their accreditation standards. JCAHO instituted a sentinel events reporting policy (effective October 31, 1998) that encourages hospitals to voluntarily report such occurrences within 7 days of the incident.

Comment: One commenter opposed the reporting requirement, stating that there is no need to increase the number of people involved with the monitoring and/or investigating patient deaths. Another commenter echoed this sentiment, noting that this requirement is duplicative of JCAHO's sentinel event reporting requirement, and that we should simply share data with the JCAHO instead.

In contrast, a private psychiatric health system agreed with this provision, saying it makes good sense. Many commenters supported this provision, although they suggested measures that they believed would strengthen it, such as requiring that serious injuries be reported and specifying lists of elements to be provided to CMS.

Response: Section 592 of the CHA mandates death reporting and this final rule incorporates/addresses these requirements. These requirements address gaps in existing reporting systems that inhibit the ability to conduct meaningful analysis of trends and target problems. JCAHO's system is voluntary, not mandatory, and 20 percent of the hospitals that participate in Medicare and Medicaid are not JCAHO accredited. To adequately track deaths, mandatory reporting is needed by all hospitals.

We believe that injury reporting is beyond the scope of the CHA; and therefore, we are not incorporating injury reporting provisions in this final rule. However, we would expect that serious injuries related to the use of restraint or seclusion would be monitored through the hospital's QAPI program.

Comment: Several commenters suggested that reporting should include not only deaths of patients, but injuries to staff during the restraint or seclusion procedure.

Response: We do not require reporting of staff injuries associated with the use of seclusion or restraint. However, hospitals may establish their own systems for tracking such information.

Comment: One commenter suggested requiring hospitals to report the number of seclusion or restraint occurrences; the total number of patients secluded or restrained; the average number of hours per occurrence; and, the average number of hours in seclusion or restraint per patient. The commenter also recommended that we protect patient privacy by withholding of identifying information but otherwise reporting demographic data.

Response: We believe that the burden of such an approach would have the opposite effect; that is, it would most likely result in hospital under-reporting of patients in restraint or seclusion. However, although not mandated in this rule, we expect that a hospital will address utilization of restraint and seclusion as part of their QAPI program. Regarding the recommendation to this information is withheld identifying information, required to investigate or otherwise follow-up on a reported death, if necessary.

Comment: Some commenters believed that serious injuries, both physical and psychological, must be reported to be proactive and to prevent deaths. These commenters realized that there may be some additional burden on hospitals, but believed that burden could be minimized by limiting reports to more severe types of injuries. One commenter asked that if we do add injury reporting, that it be limited to injuries that require medical attention.

Some commenters offered a general argument that the P&As would be a better entity than CMS to receive the information and investigate the incidents. For example, commenters stated that the P&As have trained investigators who are already a part of the Department of Health and Human Services. Commenters also stated that the P&As need to be involved to adequately perform the necessary investigations.

In contrast, several commenters questioned why the P&As should be provided this information, since they have no authority to sanction a hospital and are not able to act as CMS's agent. The commenters stated that this

provision would expose the provider to two possible investigations without any clear and convincing rationale.

Response: We are not adding any injury reporting requirement in this rule. Aside from the issue of hospital burden and potential disagreement on what constitutes a reportable event, a fundamental problem in requiring injury reporting for this setting is the administrative burden on the program itself. Many commenters seemed to acknowledge this limitation, in that they used it as an argument for the need for increased P&A involvement. So, these commenters may argue, even if CMS cannot administratively handle injury reporting, this information could be routed to the P&As for investigation or made available to the public.

We believe that this points to a misperception of the roles of the various agencies. A P&A cannot act as our agent. There is no statutory connection between CMS and the P&As, as there is between CMS and the State survey agencies. The P&A cannot take an enforcement action on our behalf. While we support the role of the P&As, and we believe that a coordinated effort between agencies is appropriate, we also believe that the roles should not blur into each other. We have a distinct interest in the health and safety of patients, which is shared by the P&As. However, we also have a statutorily-governed relationship with the providers of services. That relationship is built on the expectation of confidentiality. We need information from the hospitals inasmuch as we evaluate whether they are meeting the standards for care we have set.

Comment: Mental health advocacy groups and P&A organizations requested that the name, address, phone number, and brief description of services provided by the P&A be required to be posted in each hospital.

Response: We believe requiring that this information be posted would be unnecessarily burdensome. Hospitals are already required to provide patients with contact information if the patient wishes to file a grievance.

Comment: One commenter stated that if serious injury or death occurs, that event needs to be recorded and an independent auditor needs to investigate the incident. The auditor should be clinically oriented, not of an administrative background.

Response: We only require that deaths be reported. Upon receipt of the information, we can initiate an independent investigation of the death. We are not requiring that hospitals report serious injuries, but this type of information could be reviewed while surveyors are onsite. In addition, we will not require that the hospital hire an independent auditor to investigate deaths and serious injuries.

Comment: One commenter charged that the reporting requirement is not consistent with initiatives to create a government that works better and costs less.

Response: We disagree. We do not believe that the revised reporting requirements are overly burdensome. Furthermore, the reporting system serves as an outcome indicator that can be used to target our investigational efforts.

Comment: One P&A supported the reporting of serious injuries, but argued for added resources for P&As so that meaningful and prompt investigations can occur.

Response: We agree with the importance of P&A investigations. However, we do not allocate funding for the P&A programs.

Comment: One commenter indicated that it is burdensome for a hospital to have to review charts on all patient deaths to determine if restraints or seclusion were used with the patient. The commenter questioned whether only Medicare and Medicaid beneficiary deaths need to be reported, or if all patient deaths related to restraint or seclusion must be reported.

Response: The CoPs apply to all patients in a Medicare- and Medicaid-participating hospital, not just Medicare/Medicaid beneficiaries. Therefore, all patient deaths associated with the use of restraint or seclusion or both must be reported. We do not view this as particularly burdensome since these deaths should be infrequent.

Comment: A commenter stated that the regulation does not discuss a penalty for failure to report.

Response: Noncompliance with this requirement, as with any of the others in these standards, constitutes a violation of the CoPs that would potentially be subject to termination of the hospital provider agreement as described at 42 CFR 489.53.

IV. Provisions of the Final Rule

For reasons specified in section III of the preamble to this final rule, we are codifying the Patients' Rights CoP within the current hospital CoPs under Subpart B—Administration at § 482.13. The eight standards specified in this final rule establish minimum protections and rights for patients. Any changes that have been made to clarify or strengthen the provisions that appeared in the interim final rule with comment period are noted in the following description of the provisions.

The first standard, ''Notice of Rights,'' requires the patient or the patient's representative, as permitted by State law, to be informed of the patient's rights prior to furnishing or discontinuing care whenever possible. The standard also requires that the hospital have a grievance process, that the patient be informed of whom to contact to file a grievance, and that the process include specific elements. This standard has not been revised; and therefore, is being finalized without change.

The second standard, ''Exercise of Rights,'' provides the patient the right to participate in the development and implementation of his or her plan of care, and to request or refuse treatment. This standard supports the patient's right to make decisions regarding his or her care and to formulate advance directives and have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.102 (Requirements for providers). This standard also supports the patient's right to have a family member or representative of his or her choice and his or her physician notified promptly of the patient's admission to the hospital. This standard has not been revised; and therefore is being finalized without change.

The third standard, ''Privacy and Safety,'' which includes the right to personal privacy, to receive care in a safe setting, and to be free from all forms of abuse or harassment. This standard has not been revised; and therefore is being finalized without change.

The fourth standard, ''Confidentiality of Patient Records,'' provides the patient's right to the confidentiality of his or her records, and to access those records. This standard has not been revised; and therefore is being finalized without change.

The fifth standard, ''Restraint or seclusion,'' differs both in content and in application from the standard presented in the interim final rule with comment period. We have revised and combined the requirements contained in standards (e) and (f) in the interim final rule into a single, combined standard in the final rule. The final, combined standard (e) applies to the use of restraint, the use of seclusion, as well as the simultaneous use of restraint and seclusion regardless of patient location.

The revised, combined standard (e) states that all patients have the right to be free from physical or mental abuse, and corporal punishment. It retains the patient's right to be free from restraint or seclusion, of any form, imposed by staff as a means of coercion, discipline,

convenience, or retaliation. It also states that restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, staff or others and must be discontinued at the earliest possible time.

A significant change from the interim final rule with comment period to this final rule is that standard (e) provides a revised definition of ''restraint.'' In the final rule, we adopted the restraint definition contained in the CHA. A restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. The final rule also clarifies that a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). The seclusion definition contained in the interim final rule with comment period has been retained with minor content revisions. Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Standard (e) also clarifies that seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

All of the requirements contained in the current standard (e) ''Restraint for acute medical and surgical care'' are also contained in the current standard (f) ''Seclusion and restraint for behavior management.'' These requirements have been moved to the combined standard (e) in the final rule. The more stringent requirements contained in the current standard (f), but not in the current standard (e) have also been moved to the combined standard (e) in the final rule. These more stringent requirements are: Time limits on the length of each order, and the 1-hour face-to-face evaluation. The final rule clarifies that these two requirements only apply when restraint or seclusion are used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Requirements for the simultaneous use of restraint and seclusion have also been retained in the final rule.

Standard (e) retains the following requirements: Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm; the type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient or others from harm; and, the use of restraint or seclusion must be in accordance with a written modification to the patient's plan of care, and implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

Standard (e) retains and clarifies the requirement that use of a restraint or seclusion must be in accordance with the order of a physician or other LIP who is responsible for the care of the patient as specified under § 482.12(c) and is authorized to order restraint or seclusion by hospital policy in accordance with State law. The standard also requires that the restraint or seclusion order never be written as a standing order or on an as needed basis (PRN), and that the attending physician must be consulted as soon as possible if restraint or seclusion is not ordered by the patient's attending physician. Standard (e) also sets limits on the length of each order for restraint or seclusion used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others based on the age of the patient, and states that the order may only be renewed in accordance with these limits for up to a total of 24 hours unless superseded by State law that is more restrictive. After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a physician or other LIP (if allowed by State law) must see and assess the patient. Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy. Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

Further, standard (e) specifies that the condition of the patient who is restrained or secluded must be monitored by a physician, other LIP or by trained staff at an interval determined by hospital policy. The criteria for staff to be considered ''trained'' are specified under § 482.13(f). In addition, physician and other LIP training requirements must be specified in hospital policy. At a minimum, physicians and other LIPs authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

A significant change from the interim final rule with comment period to this final rule is that standard (e) has been revised to expand the type of practitioners permitted to conduct the 1-hour face-to-face evaluation. When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a physician or other LIP, or a RN or PA trained in accordance with the requirements specified under § 482.13(f), must see the patient face-to-face within 1-hour after the initiation of the intervention. This practitioner must evaluate the patient's immediate situation, the patient's reaction to the intervention, the patient's medical and behavioral condition, and the need to continue or terminate the restraint or seclusion. As specified at § 482.13(e)(13), State law (by statute or regulation) regarding the 1-hour face-to-face evaluation may be more restrictive than these requirements. If the 1-hour face-to-face evaluation is conducted by a trained RN or PA, the attending physician or other LIP who is responsible for the care of the patient as specified under § 482.12(c) must be consulted as soon as possible after completion of the evaluation.

Standard (e) clarifies requirements related to the simultaneous use of restraint and seclusion. All requirements specified under standard (e) apply in the simultaneous use of restraint and seclusion, which is not permitted unless the patient is continually monitored face-to-face by an assigned, trained staff member, or continually monitored by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

Finally, standard (e) has been amended to specify elements of documentation. When restraint or seclusion is used, there must be documentation in the patient's medical record of the following: The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the

immediate physical safety of the patient, a staff member, or others; alternatives or other less restrictive interventions attempted (as applicable); the patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and, the patient's response to the intervention(s) used, including the rationale for continued use of the intervention. When restraint or seclusion is used for violent or self-destructive behavior, documentation must also include findings from the 1-hour face-to-face assessment.

Standard (f) is a new standard that addresses staff training requirements. A patient has a right to the safe implementation of restraint or seclusion by trained staff. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion before performing any of these actions, as part of orientation, and subsequently on a periodic basis consistent with hospital policy.

In addition, standard (f) states that the hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require restraint or seclusion;
- The use of non-physical intervention skills;
- Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition;
- The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
- Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary;
- Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation; and,
- The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

Standard (g) is a new standard that addresses reporting requirements for deaths associated with the use of restraint or seclusion. The hospital must report to CMS each death that: occurs while a patient is in restraint or in seclusion at the hospital; occurs within 24 hours after the patient has been removed from restraint or seclusion; and, each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. For the purposes of this regulation, ''reasonable to assume'' includes, but is not limited to deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation. Each death referenced in this section must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. Staff must document in the patient's medical record the date and time the death was reported to CMS. Although we have modified some of the provisions to address public comments, these modifications do not lessen protections afforded patients who are restrained or secluded.

V. 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.

Section 482.13 of this document contains information collection requirements; however, these information collection requirements are currently approved under OMB control number 0938–0328, ''Hospital Conditions of Participation'' with a current expiration date of January 31, 2008.

This document makes changes to the requirements in the following paragraphs within § 482.13 that contain information collection requirements. In this final rule, we have combined the requirements that were set forth in the interim final rule under standard § 482.13(e) Standard: Restraint or Seclusion used in the provision of acute medical, pre and post surgical care and § 482.13(f) Standard: Seclusion and restraint for management of violent, self destructive or aggressive behavior into a single standard, § 482.13(e) Standard: Restraint and seclusion. This change is designed to address restraint and seclusion use regardless of the treatment setting in which it occurs.

Section 482.13(e) Standard: Restraint or Seclusion

Although we believe many hospitals are already complying with the requirements in this standard through usual and customary practices, the revisions, reformatting, and additions to the existing regulatory text may result in increased burden. However, we believe this increased burden should be offset by reduced burden upon the physicians and LIPs since the need to assess the patient within 1-hour of the initiation of restraint or seclusion can be performed by other qualified LIPS as well.

Section 482.13(f) Standard: Restraint or Seclusion: Staff Training Requirements

As we have discussed in greater detail in sections III. and IV. of the preamble to this final rule, revisions have been made to the proposed § 482.13(e). Paragraph (e)(15) has been added to address the documentation requirements when restraint and seclusion are used simultaneously. We believe the majority of hospitals already maintain such documentation. Therefore, the burden associated with this requirement will not impose undue hardship on most hospitals. We believe that compliance with these standards constitutes a usual and customary business practice and the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Section 482.13(g) Standard: Death Reporting Requirements

The requirements contained in this section were previously contained in paragraph (f)(7) of this section and are currently approved under OMB control number 0938–0328. See section VI. of the preamble to this final rule for a summary of the estimated burden hours associated with this section.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer. Fax (202) 395–6974.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act (the Act), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule revises the restraints and seclusion provisions of the Patients' Rights CoP that were published in the July 2, 1999 interim final rule with comment period. The CoPs are the basic health and safety requirements that a hospital must meet in order to participate in the Medicare program. This rule will implement regulations that are intended to reduce the use of restraint and seclusion, eliminate the potential for adverse outcomes when restraint, seclusion or both are implemented, and minimize the burden associated with compliance with the rule. While it is not possible at this point to determine definitively the additional costs to the Medicare program resulting from this rule, we estimate that the impact will be below $100 million; and therefore, we have determined that this final rule is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government jurisdictions. Individuals and States are not included in the definition of small entity. We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural facilities. In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. That 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 since superseded by ''core based statistical areas'' and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $120 million. This rule has no impact on the expenditures of State, local, or tribal governments, and the impact on the private sector is estimated to be less than $120 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Thus rule will not have any effect on State and local governments.

In the December 19, 1997 **Federal Register**, we issued a proposed rule that detailed our plans to revise all of the hospital CoPs which emphasized lessening Federal regulation to eliminate unnecessary structural and process requirements, focus on outcomes of care, allow greater flexibility to hospitals and practitioners to meet quality standards, and place a stronger emphasis on quality assessment and performance improvement. The proposed rule indicated our intent to include a new Patients' Rights CoP for hospitals that contained rights not addressed in the then current CoPs. We solicited comments on the Patients' Rights CoP and received strong support for its establishment from the public, mental health advocacy groups, media, and the Congress. These groups and individuals expressed serious concern about improper care of patients in the hospital setting, particularly with regard to the use of seclusion and restraint.

On July 2, 1999, we issued an interim final rule with comment period that set forth requirements supporting and protecting patients' rights in the hospital setting. It included four standards that were finalized to ensure minimum protections of each patient's physical and emotional health and safety. These standards address each patient's right to: Notification of his or her rights; the exercise of his or her rights in regard to his or her care; privacy and safety; and confidentiality of patient's records.

Additionally, this interim final rule specifically addressed the right to be free from the use of seclusion and restraint and included various requirements to protect the patient when use of these interventions is necessary.

B. Anticipated Effects

1. Effects on Providers

We anticipate the impact of these finalized standards will vary widely among hospitals. However, we do not have the benefit of several key pieces of information. For example, we do not have reliable data on the prevalence of restraint and seclusion use, data on the volume of staff in hospitals, or data on the varying levels and qualifications of hospital staff who may be involved in restraint and seclusion use. Given these and a variety of other factors, it would be unfair to calculate an estimate based on the average of the limited available data. In another example, with respect to training, this rule will have significantly less impact on a hospital that already has a proactive training program in place and has significantly reduced its restraint and seclusion use than it will in a hospital that has not independently taken such an approach.

Factors such as size, services rendered, staffing, and patient populations vary as well. An additional consideration was noted when one caller who telephoned for clarification on the provisions of the interim final rule with comment period complained that some hospitals specifically screen out patients with potentially violent,

self-destructive behavior, so that this population is diverted to State systems, in turn, resulting in these State systems potentially bearing the brunt of this burden. We are hesitant to make impact estimates in this final rule that may not account for these and other unforeseen variations. Thus, we reserve the right to provide estimates when feasible. Below we discuss the anticipated effects on providers of the standards related to restraints and seclusion.

a. Section 482.13(e) Standard: Restraint or Seclusion

Standard 482.13(e), previously entitled ''Restraint for acute medical and surgical care'' in the interim final rule with comment period, is now entitled ''Restraint or seclusion'' in this final rule. The existing regulation sets out the patient's rights in the event he or she is restrained or secluded, and limits when and by whom restraint or seclusion can be implemented. We have combined the existing standards 482.13(e) and 482.13(f) for clarity since it is our goal to have the use of restraint or seclusion reduced in all settings of the hospital. The revisions, reformatting, and additions to the existing regulatory language will not result in additional impact upon hospitals associated with their efforts to comply with this regulation. Instead, since we have provided more clarity in the definition of a restraint with respect to medical and surgical services, burdens on hospitals should decrease.

In previous § 482.13(e)(3)(B), we stated the patient's ''treating'' physician be consulted in the event of restraint or seclusion. However, based on comments we have revised the requirement at § 482.13(e)(7) to reflect the need to consult the ''attending'' physician instead of the ''treating'' physician as soon as possible if the attending physician did not order the restraint or seclusion.

We have revised and expanded § 482.13(e)(4) to specify, at § 482.13(e)(10), that a physician, other licensed independent practitioner or trained staff meet the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy. We also recognize there will be some impact associated with performing patient assessment and monitoring. However, we view patient assessment and monitoring as a standard component of patient care.

Section 482.13(f)(3)(ii)(c), now § 482.13(e)(7), clarifies that the ''attending'' physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion. Although this may minimally increase burden to hospitals, we believe it is a best practice for patient safety.

We have added elements at § 482.13(e)(15) that monitoring must occur face-to-face by trained staff or by using both video and audio equipment, when there is simultaneous use of restraint and seclusion. We have added elements at § 482.13(e)(16) regarding the documentation that must be included in the patient's medical record when the patient is restrained or secluded, including the 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior, the patient's behavior and intervention used, alternatives or other less restrictive interventions attempted (as applicable), the patient's condition or symptom(s) that warranted restraint or seclusion use, and the patient's response to the use of the restraint or seclusion intervention, including the need for continued use of restraint or seclusion. We do not believe additional burdens are imposed by this requirement since it is a routine and customary practice to document the circumstances surrounding such an event for comprehensiveness of patient care.

In the interim final rule with comment period at § 482.13(f)(3)(ii)(c), we required that the physician or other LIP must see and evaluate the patient's need for restraint or seclusion within 1-hour after the initiation of restraint or seclusion. This 1-hour on-site physician or LIP evaluation was the most controversial provision of the interim final rule with comment period.

Limited data has been gathered in the industry to date regarding the prevalence of restraint and seclusion use. However, among the limited data that is available, it reflects the use of restraint or seclusion for behavior management only per the current requirement at 482.13(f).

For example, based on information provided to us by the National Association of Psychiatric Health Systems (NAPHS), fifty NAPHS members supplied data for the cost of complying with the CMS requirements that a physician or LIP evaluate a patient face-to-face within 1 hour of the initiation of restraint or seclusion. The data that was supplied combined: (1) The cost of maintaining a physician or LIP on call to be available in case there is an event of a restraint or seclusion and (2) the cost of having a physician or LIP come to the facility to evaluate a patient within 1 hour when a restraint or seclusion episode occurs. The average cost was $80,789 per facility per year.

The NAPHS further discussed that there are approximately 250 freestanding specialty hospitals in the United States. This number does not include the approximately 1,400 behavioral health units of general hospitals or government (state and county) psychiatric specialty hospitals. The 1 hour rule applies to all these facilities.

An average NAPHS member hospital is a 60–80 bed community-based specialty hospital. The NAPHS stated the average total budget of such facilities is approximately $10-$15 million hence the NAPHS views this $80,000 to be a very significant portion of its operating budget.

We heard from many hospitals that this requirement was impossible to fulfill because of the lack of available personnel, geographic challenges, and the high costs associated with maintaining this degree of coverage. This was particularly noted among rural hospitals. Furthermore, these commenters stated that a required onsite visit is costly with no demonstrable benefit in many cases.

We determined that the heightened degree of intervention and restriction of who can perform this assessment was excessive and would not be feasible in many rural or remote areas. In response to industry concerns, we have expanded who may perform the 1-hour face-to-face evaluation. Conversely, some commenters requested on-site mandatory physician presence within half an hour of initiation of restraint or seclusion. Again, we believe this would be too burdensome for hospitals in rural or remote areas to comply.

Thus, we anticipate the expansion of who may perform the 1-hour face-to-face evaluation will be less burdensome to hospitals. We believe the training required by this rule will equip staff with appropriate skills for handling escalating or aggressive patient behavior and should reduce overall use of restraints. However, we are aware that the facility's size, progress in reducing the use of restraint or seclusion, and other characteristics will have a varying impact upon each facility's performance of this requirement.

Again, the NAPHS stated their respondents reported it took an estimated 30 minutes to 1 hour to document all the specific elements required by CMS after a restraint or seclusion episode. This included several elements unique to the rule such as notifying the attending physician if the restraint was ordered by someone other than the patient's attending physician.

Thus, our burden estimate is based on a median timeframe (that is, 45 minutes) that we believe it takes to complete the required documentation in the patient's medical record. However, since we are unable to estimate the prevalence of restraint and seclusion, we can not apply this estimate to assess the associated burden across behavioral health and medical surgical settings.

b. Section 482.13(f) Standard: Staff Training Requirements

Standard 482.13(f), previously entitled ''Restraint or seclusion: Seclusion and restraint for behavior management,'' has been revised to read ''Staff training requirements.'' This standard will specifically address the requirements that have been significantly changed or are new regarding staff training.

In section 482.13(f) Standard: Staff training requirements. Staff training requirements have been expanded to include various training specifications. While we have tried to minimize the burden which will be placed on hospitals in order to meet this requirement, we believe it is important for the provision of safe and effective restraint or seclusion use.

We require that before staff apply restraints, implement seclusion, perform associated monitoring and assessment of the restrained or secluded patient, or provide care for a restrained or secluded patient, the staff must be trained and able to demonstrate competency in the performance of these actions. We have revised the staff training requirements to address the following broad areas: Training intervals, training contents, trainer requirements, and trainer documentation.

When developing this final rule, we considered public comments regarding the impact associated with the requirement that all staff with direct patient contact be trained in the use of restraint or seclusion. Some argued that this broad requirement would entail training dietary, administrative, housekeeping, and other types of nonprofessional staff who are not direct care providers and not involved in the application or use of restraint or seclusion. To reduce burden and create a more reasonable requirement while assuring patient safety, we have mandated that only those staff who are involved in the application of restraint or seclusion or performing associated monitoring and assessment of, or providing care for restrained or secluded patients have this training. While we expect physicians and LIPs to be trained in the proper use of restraint or seclusion, we do not expect that they will be trained with the other hospital staff. Thus, we have not included physicians and LIPs in the burden associated with these requirements. Instead, we require the remaining hospital staff who have direct contact with patients must be trained in restraint or seclusion use.

We also considered commenters'suggestions that training be provided by a nationally-recognized training program, such as the Crisis Training Institute. Others asked that we provide a list of criteria to be covered in this training. In this final rule, we have specified broad topics to be covered in training, and have not required that staff be trained by an outside organization. We believe that in-house training may be more economical than sending staff off-site for instruction. However, hospitals would still have the option of sending either selected or all staff to outside training if they believe that this is warranted.

Thus, we have based our burden estimate on having the actual number of trainers attend such training from an outside organization one time. We believe that most facilities would, in turn, have these trained individuals function as program developers and trainers of the appropriate hospital staff. We believe in most instances this professional will be a registered nurse. Thus, we used $38.88 as the nursing hourly rate in this estimate.

Train-the trainer programs are the way many facilities provide staff instruction. The four day instructor certification program given by the Crisis Prevention Institute (CPI, INC.) costs $1,200 dollars in tuition plus travel, lodging, and participant salary (*http://www.crisisprevention.com*).

We estimate, on average, that roundtrip travel for each nurse will cost approximately $400 to cover the need for either local or distant travel, lodging for each nurse will costs approximately $120 per night × 3 nights, and the meals and incidental expenses (M&IE) will be approximately $50 per day depending upon the location within the designated state. Thus, we anticipate the cost to train one nurse per the 6,200 hospitals to be $1,200 for the course, an estimated $400 airfare based on location, $360 for 3 days lodging, $150 for 3 days M&IE, $112.50 for partial day M&IE, and $1,244.16 for the nurse's salarysat $38.88 per hour × 8 hours per day × 4 days. These expenses would total $466.66 per nurse per hospital. If all 6,200 hospitals were to send one nurse to such training, the total cost for the 6,200 hospitals would be $21,493,292.00.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Off-site training of the trainer:		
Cost of course × 1 nurse		$1,200.00
Airfare × 1 nurse		400.00
Lodging × 1 nurse		360.00
M&IE × 1 nurse		262.50
Salary for 1 nurse × $38.88 per hr. × 8 hrs. day × 4 days each for a one time training	32	1,244.16
Total for 1 nurse per hospital × 6,200 hospitals	198,400	21,493,292.00

To be responsive to requests for more detail regarding our expectations and to assure staff competency, we have described the content to be covered during training. Given that most facilities already have some type of training program, as noted in many comments from hospitals, we believe that these requirements will only serve to refine existing programs, not mandate new ones. The current JCAHO standards which apply to approximately 80 percent of the Medicare- and Medicaid-participating hospitals address staff training and competence with respect to the use of restraint or seclusion at PC.12.30. The current JCAHO standard which applies to the hospital leadership's approach to the use of restraint for acute medical and surgical (non-psychiatric) care at PC.11.10 refers to staff orientation and education. In effect, these JCAHO standards already require training of this kind for staff involved with the application of restraint or seclusion. Thus, there may be some initial cost for revising

programs' materials to incorporate the elements specified in the regulation.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Developing a new training program (20% of hospitals = 6,200 ÷ 20% = 1,240):		
1 clinical trainer @ $38.88 hr. × 40 hrs. on average one-time × 1,240 hospitals	49,600	$1,928,448.00
Total	49,600	1,928,448.00

Note: Salary data used in this estimate is based on the salary estimates reported on-line at *http://www.salary* com. Estimates based on median annual salary ($80,867.00 including benefits) for a Staff nurse-RN divided by 2,080 hours per year worked by a full-time employed Staff RN.

We require that each individual who will potentially be involved in restraint and seclusion of a patient have training in the proper techniques. According to the National Association of Psychiatric Health Systems (NAPHS), initial training in de-escalation techniques, restraint and seclusion policies and procedures, and restraint and seclusion techniques range from 7 to 16 hours of staff and instructor time.

Using data from the American Hospital Association's (AHA) 2004 Annual Survey, the average number of total full-time and part-time clinical employees per hospital are 248 and 113 respectively. Clinical employees include physicians and dentists, medical and dental residents and interns, other trainees, registered nurses, licensed practical (vocational Nurses), and nursing assistants. While we recognize this does not include clinical staff in such areas as rehabilitation services, this total of 361 persons per hospital should provide an estimate on which to base this analysis. We realize that some hospitals will have more or less employees in which to train.

Additionally, the CMS' OSCAR data, reveals the average number of beds per hospital is 160. We estimate that an average size hospital may have 361 staff persons who will require this training.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Attendance in the training program:		
1 clinical trainer @ $38.88 hr. × 8 hrs. × 6,200 hospitals	49,600	$1,928,448.00
361 trainees × 16 hours per hospital × 6,200 hospitals	17,905,600	.....
Total	17,955,200	1,928,448.00

We require that each individual will receive annual updates to the training and that the annual training will also be documented. Again, according to NAPHS, annual updates are about 7 hours of staff and instructor time per each employee who has direct patient contact. Again, an average size hospital has 361 employees who have direct patient contact that must be trained in de-escalation techniques.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Annual updates in the training program:		
1 clinical trainer @ $.38.88 hr. × 4 hrs. on average annually × 6,200 hospitals	24,800	964,224.00
361 trainees × 4 hours per hospital × 6,200 hospitals	8,952,800	.....
Total	8,977,600	964,224.00

Additionally, we required recordkeeping for documenting in each trained individual's personnel record that he or she has successfully completed training as discussed in Section V. of the preamble to this final rule. As noted there, we believe that such records are kept by the hospital in the normal course of business. Therefore, we do not believe that these requirements would have a significant economic impact on hospitals.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Documenting attendance in the training program:		
1 clinical trainer @ $38.88 hr. × 5 minutes on average × 361 trainees annually × 6,200 hospitals	179,056	6,691,697.20
Total	179,056	6,961,697.20

Finally, we require that each hospital revise its training program annually as needed. We estimate this task to take approximately 4 hours annually per hospitals.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Revising the training program:		
1 clinical trainer @ $38.88 hr. × 4 hours per average size hospital × 6,200 hospitals	24,800	964,224.00
Total	24,800	964,224.00

c. Section 482.13(g) Standard: Death Reporting Requirements

This requirement, previously an element in the interim final rule with comment period, has been revised to be a separate standard. In revising this to form a separate standard, we have made it applicable to all deaths associated with the use of restraint or seclusion throughout the hospital. We have added the requirements at § 482.13(g)(1)(i) that a hospital must report to CMS each death that occurs while a patient is in restraint or seclusion at the hospital, at § 482.13(g)(1)(ii) each death that occurs within 24 hours after the patient has been removed from restraint or seclusion, and at § 482.13(g)(1)(iii) that the hospital must report each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that the use of restraint seclusion contributed directly or indirectly to a patient's death.

At § 482.13(g)(2) and § 481.13(g)(3), we require that each death referenced in this section must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. We believe that the number of deaths related to restraint or seclusion use are still under-reported. In October 1998, the *Hartford Courant* cited the results of a study that identified 142 deaths from seclusion and restraint use in behavioral health treatment facilities over the past 10 years. Since the Patients Rights CoP became effective in 1999, the annual total of patient deaths related to restraint and seclusion use has been reported to CMS as follows: 1999 (14), 2000 (34), 2001 (22), 2002 (19), 2003 (17), 2004 (24), 2005 (30), and 2006 (5) year-to-date respectively as of June 19, 2006. These numbers include deaths from seclusion or restraint use in behavioral health settings not the medical-surgical settings in the hospital.

Although our goal is to reduce the utilization of restraint or seclusion and associated deaths, we are aware that the actual number of deaths from seclusion and restraint use may increase due to the increased reporting requirements of deaths due to seclusion and restraint use in all treatment settings in the hospital. Thus, we anticipate there will be burden associated with this requirement due to the increased number of deaths that will be reported by the various units within the hospital. For the purposes of calculating burden, we are assuming the number of deaths based on current levels and are not considering the reduction in the number of deaths we expect to result from this regulation.

Given this historical data, we believe the number of reports certainly should average less than one per hospital per year (that is, the total number of deaths in 8 years (165) divided by the total number of hospitals 6,200 divided by 8 years equals .0033). Thus, we believe the impact associated with this provision (that is, making a telephone call and filling in a written form to report a death to the CMS) to be negligible.

We estimate that one clerical person would report the death to CMS and document the death in the patient's medical record. The burden associated with the completion of this task would be .25 (15 minutes divided by 60 minutes in one hour) × an average of 20 occurrences per year throughout the 6,200 hospitals, .25 × 20 = 5 hours. The estimated cost associated would be 5 hours × $.31 (that is, $18.88 hour divided by 60minutes per hour × 15 minutes = 4.71 × 20 occurrences per year = $94.20 annually).

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Reporting death to CMS and documenting in medical record:		
1 clerical person @ $18.88 hr. × 15 min. × average of 20 occurrences in hospital annually	5	$94.20
Total	5	94.20

Note: Salary data used in this estimate is based on salary estimates reported on-line at *http://www.salary* com. Estimates based on median annual salary ($39,190.00 including benefits) for an admitting clerk divided by 2,080 hours per year worked by a full-time employed admitting clerk.

2. Effect on Beneficiaries

The implementation of the Patients Rights CoP will serve to protect not only Medicare and Medicaid beneficiaries but all patients receiving care in all Medicare-participating hospitals (that is, short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug), including small rural hospitals. With the finalization of standards a–g of the Patient's Rights CoP, we forsee better protection regarding notification of the patient's rights, exercise of the patient's rights with regard to his or her care, privacy and safety, confidentiality of the patient's records, and restraint and seclusion use. Thus, all patients will benefit from the hospital's focus on patients' rights. Through these protections, patient care can be delivered in an atmosphere of respect for an individual patient's comfort, dignity, and privacy. We also believe that implementation of this final rule will lead to a reduction in the numbers of restraint or seclusion related injuries and deaths in hospitals.

3. Effect on Medicare and Medicaid Programs

Given that hospitals have been required to comply with the regulations at § 482.13(a) through § 482.13(f) since 1999, we do not expect the implementation of the finalized Patients' Rights provisions to generate significant cost to the Medicare or Medicaid programs. We do not believe there will be any additional costs to the survey and certification program as compliance with this CoP will either be reviewed through a routine, nonaccredited hospital survey,

validation survey or as part of the existing complaint survey process for hospitals.

C. Alternatives Considered

We originally considered developing one set of very general requirements regulating restraint or seclusion use in all hospitals for all situations. However, based on public comments and recent concerns about restraint or seclusion use for behavior management situations, we concluded that one set of requirements did not afford patients with adequate protections. In addition, we noted that JCAHO has more prescriptive standards for behavioral health care accreditation than for hospital accreditation.

We considered recognizing only physicians as the individuals able to order restraints or seclusion. However, in recognizing that other types of practitioners provide a great deal of care in rural and frontier areas, we did not adopt that approach.

We considered keeping standards e and f separate as originally proposed. However, due to public comment we found it to be more prudent to address the use of restraint or seclusion in either medical-surgical or behavioral treatment contexts in a single standard.

We considered finalizing the training section as proposed. In turn, we planned to let hospitals establish, implement, and monitor their own training programs. However, industry concerns were the impetus for providing further direction regarding training. Additionally, we considered mandating training for physicians and other LIPs; however, the industry believed this was too prescriptive.

Regarding the timeframes in which a patient must be evaluated if restraint or seclusion is used to manage violent or self-destructive behavior, we considered more restrictive options including adopting the Pennsylvania Office of Mental Health policy that requires an onsite evaluation by a physician within half an hour of initiation of the intervention. However, we rejected this idea on the basis that it is unrealistic for rural areas because of geographical barriers and practitioner shortages, cost (as noted by commenters).

We considered adopting more restrictive requirements for the maximum time frames for the length of an order for restraint or seclusion. However, since there was no supporting literature or studies, we decided to adopt the approach and timeframes developed and articulated by JCAHO for its hospital accreditation and behavioral health care accreditation programs. These standards were developed by experts from the health care field and represent consensus on the approach and time frames for uses of seclusion or restraints. In addition, approximately 80 percent of the Medicare- and Medicaid-participating hospitals are already subject to these requirements through accreditation. Therefore, we believe it is reasonable to adopt requirements similar to those of JCAHO.

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

List of Subjects in 42 CFR Part 482

Grants programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the interim rule amending 42 CFR chapter IV published on July 2, 1999 **Federal Register** (64 FR 36070) is adopted as final with the following changes:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

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

■ 2. Section 482.13 is revised to read as follows:

§ 482.13 Condition of participation: Patient's rights.

A hospital must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* (1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(c) *Standard: Privacy and safety.* (1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of his or her clinical records.

(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a

means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) *Definitions.* (i) A *restraint* is—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) *Seclusion* is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The use of restraint or seclusion must be—

(i) In accordance with a written modification to the patient's plan of care; and

(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

(5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

(6) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

(7) The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(8) Unless superseded by State law that is more restrictive—

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older;

(B) 2 hours for children and adolescents 9 to 17 years of age; or

(C) 1 hour for children under 9 years of age; and

(ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.

(iii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.

(9) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

(10) The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.

(11) Physician and other licensed independent practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

(12) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention—

(i) By a—

(A) Physician or other licensed independent practitioner; or

(B) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.

(ii) To evaluate—

(A) The patient's immediate situation;

(B) The patient's reaction to the intervention;

(C) The patient's medical and behavioral condition; and

(D) The need to continue or terminate the restraint or seclusion.

(13) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of this section.

(14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) as soon as possible after the completion of the 1-hour face-to-face evaluation.

(15) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—

(i) Face-to-face by an assigned, trained staff member; or

(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

(16) When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

(i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;

(ii) A description of the patient's behavior and the intervention used;

(iii) Alternatives or other less restrictive interventions attempted (as applicable);

(iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and

(v) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) *Training intervals.* Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion—

(i) Before performing any of the actions specified in this paragraph;

(ii) As part of orientation; and

(iii) Subsequently on a periodic basis consistent with hospital policy.

(2) *Training content.* The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.

(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(4) *Training documentation.* The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(g) *Standard: Death reporting requirements:* Hospitals must report deaths associated with the use of seclusion or restraint.

(1) The hospital must report the following information to CMS:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.

(3) Staff must document in the patient's medical record the date and time the death was reported to CMS.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

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

Dated: December 14, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 16, 2006.

Michael O. Leavitt,

Secretary.

[FR Doc. 06–9559 Filed 12–7–06; 8:45 am]

BILLING CODE 4120–01–P

Federal Register

Friday,
December 8, 2006

Part V

Department of Labor

Mine Safety and Health Administration

30 CFR Parts 3, 48, 50, and 75
Emergency Mine Evacuation; Final Rule

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 3, 48, 50, 75

RIN 1219–AB46

Emergency Mine Evacuation

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: The Mine Safety and Health Administration (MSHA) is issuing this final rule to revise the Agency's Emergency Temporary Standard (ETS), which addresses standards in the Code of Federal Regulations (CFR), title 30, parts 48, 50, and 75. The final rule includes requirements for increased availability and storage of self-contained self-rescue devices (SCSRs); improved emergency evacuation drills and self-contained self-rescue device training; and the installation and maintenance of lifelines in underground coal mines. In addition, the final rule requires immediate accident notification applicable to all mines. The requirements provide an improved, integrated approach to emergency evacuation training and emergency preparedness. This final rule does not reduce protections afforded miners under existing standards.

DATES: *Effective Date:* This rule is effective December 8, 2006.

Compliance Dates:

§§ 48.3 and 75.1502—The operator shall submit a revised training plan and a revised program of instruction to the appropriate District Manager for approval no later than February 6, 2007, and conduct training within 30 days of plan approval.

§ 75.1504—The operator shall complete the initial quarterly emergency mine evacuation training and drill no later than March 31, 2007.

§ 75.1504(c)(3)—The operator shall place purchase orders for realistic SCSR training units or devices within 30 days of notification by MSHA that the units are available, and conduct this component of expectations training within 60 days of receipt of the units. MSHA will notify mine operators of the availability of realistic SCSR training units by publishing a notice in the **Federal Register**.

§§ 75.1714–6 and 75.1714–7—The operator shall provide emergency tethers and handheld, multi-gas detectors no later than February 6, 2007.

§ 75.1714–8—The operator shall complete the self-contained self-rescue (SCSR) device inventory no later than March 31, 2007.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director, Office of Standards, Regulations, and Variances, MSHA, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939. Ms. Silvey can be reached at *silvey.patricia@dol.gov* (internet e-mail), 202–693–9440 (voice), or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Introduction

The outline of this final rule is as follows:

I. Introduction
- A. Background of the Final Rule
- B. General Discussion of the Final Rule

II. Section-By-Section Analysis
- A. Part 48—Training and Retraining of Miners
- B. Part 50—Notification, Investigation, Reports and Records of Accidents, Injuries, Illnesses, Employment, and Coal Production in Mines
- C. Part 75—Mandatory Safety Standards—Underground Coal Mines

III. Derivation and Distribution Tables

IV. Executive Order 12866
- A. Population-at-Risk
- B. Compliance Costs
- C. Benefits

V. Feasibility

VI. Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act (SBREFA)
- A. Definition of a Small Mine
- B. Factual Basis for Certification

VII. Paperwork Reduction Act of 1995
- A. Summary
- B. Procedural Details

VIII. Other Regulatory Considerations
- A. The Unfunded Mandates Reform Act of 1995
- B. The Treasury and General Government Appropriations Act of 1999: Assessment of Federal Regulations and Policies on Families
- C. Executive Order 12630: Government Actions and Interference With Constitutionally Protected Property Rights
- D. Executive Order 12988: Civil Justice Reform
- E. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
- F. Executive Order 13132: Federalism
- G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
- H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
- I. Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking

IX. Final Rule Text

A. Background of the Final Rule

In developing the final rule, MSHA considered accident and injury data, research studies and data, implementation and enforcement experience, and the written comments and hearing testimony on the Emergency Temporary Standard (ETS), as well as provisions of the Mine Improvement and New Emergency Response Act of 2006 (Pub. L. 109–236) (MINER Act).

1. Emergency Temporary Standard

MSHA issued an ETS on March 9, 2006 (71 FR 12252) in accordance with Section 101(b) of the Federal Mine Safety and Health Act of 1977 (Mine Act). Mine emergencies in underground coal mines, particularly the accidents at the Sago and Aracoma Alma mines in January 2006, led MSHA to conclude that a more integrated approach to mine emergency response and evacuation was necessary. In issuing the ETS, MSHA acted to protect miners from a grave danger associated with mine emergencies and evacuations. In accordance with the Mine Act, the ETS served as the proposed rule, and was effective immediately upon publication. This final rule addresses standards and issues in the ETS.

The ETS included requirements for underground coal mine operators to: provide additional self-contained self-rescue devices (SCSRs) for persons working underground; conduct improved SCSR training and more realistic evacuation drills; and install and maintain lifelines in both escapeways. The ETS also required all mine operators to immediately notify MSHA of accidents within 15 minutes.

MSHA solicited public comments on the ETS and held four public hearings. These hearings took place on: April 24, 2006, in Lakewood, Colorado; April 26, 2006, in Lexington, Kentucky; April 28, 2006, in Arlington, Virginia; and May 9, 2006, in Charleston, West Virginia (71 FR 15028). The public comment period, scheduled to close on May 30, 2006, was extended to June 29, 2006 (71 FR 29785), in response to a request from the public and to allow the public additional time to respond to the 17 questions and other issues raised in the ETS and in MSHA's opening statement at the public hearings. Comments and public hearing transcripts are available on MSHA's website at *www.msha.gov.* MSHA considered all relevant comments when developing this final rule.

2. The Mine Improvement and New Emergency Response Act of 2006

Responding to the Sago and Aracoma Alma mine tragedies, Congress enacted the MINER Act, which was signed by the President on June 15, 2006. The MINER Act amended the Mine Act and, among other things, included provisions

that addressed some of the same requirements as the ETS. The MINER Act included requirements for SCSR storage, training, lifelines, and accident notification.

MSHA issued Program Policy Letter (PPL) No. P06–V–8 on July 21, 2006, PPL No. P06–V–9 on August 4, 2006, and PPL No. P06–V–10 on October 24, 2006, providing guidance to the mining industry for implementing Emergency Response Plans in accordance with Section 2 of the MINER Act. In the final rule, MSHA reconciles the ETS with applicable provisions of the MINER Act.

3. Timeline for Implementation of the Final Rule

MSHA provides mine operators additional time to comply with various provisions of this final rule. The mine operator may have to revise training, emergency evacuation, or firefighting plans; train miners in new and revised provisions; determine the locations for SCSR storage; purchase and install equipment, as applicable; or compile SCSR inventories. Because of ETS and MINER Act requirements, operators will already be in compliance with many of the provisions in this final.

Underground coal mine operators must submit a revised training plan for part 48 and a revised program of instruction for § 75.1502 to the relevant MSHA District Manager for approval no later than February 6, 2007. The operator must train in accordance with the revised program under 30 CFR 75.1502 within 30 days of plan approval. Any new or revised training plan and program must incorporate new and revised requirements, even if the equipment necessary to conduct the training is not yet available. The final rule allows operators until February 6, 2007, to obtain tethers and hand-held, multi-gas detectors.

The final rule also allows operators until March 31, 2007 (the first quarter of 2007) to complete the mine emergency evacuation training and drill required by § 75.1504 and the SCSR inventory required by § 75.1714–8. The final rule does not include a specific compliance date for one component of ''expectations'' training required by § 75.1504(c) because realistic SCSR training units, or devices that provide the sensation of SCSR airflow resistance and heat, are not yet available for purchase. The final rule requires the mine operator to have a purchase order for these realistic SCSR training units within 30 days of notification by MSHA that the units are available. The mine operator must complete training on breathing through a realistic SCSR training unit or equivalent device within 60 days of receipt of the training units.

MSHA will accept, as good faith evidence of compliance with the final rule, purchase orders for: SCSR training units and mouthpieces (§ 75.1504); additional SCSRs (§ 75.1714–4); tethers (§ 75.1714–6); and handheld multi-gas detectors (§ 75.1714–7). The Agency will also accept contracts with a training facility to provide SCSR ''expectations'' training [§ 75.1504(c)] as good faith evidence of compliance with the final rule.

B. General Discussion of the Final Rule

The final rule helps assure that miners, mine operators, and MSHA will be able to respond quickly and effectively in the event of an emergency. It includes requirements for mine operators to provide increased capability for mine emergency response and evacuation and covers SCSR availability and storage; training and drills; lifelines, tethers, and multi-gas detectors; and accident notification.

1. Self-Contained Self-Rescue Devices (SCSRs)

Explosions and mine fires are an ever-present threat in an underground coal mine and can present a grave potential hazard to underground coal miners due to toxic atmospheres and limited visibility. Contaminated air can contain volatile hydrocarbons, chlorine, hydrogen cyanide, isocyanates, oxides of nitrogen, and oxides of sulfur. These contaminants are more complex and potentially more harmful than carbon monoxide and carbon dioxide, the ordinary combustion products of coal fires.

SCSRs are closed-circuit breathing devices containing or producing an independent supply of oxygen, enabling miners to breathe in the presence of hazardous or life-threatening contaminants in the mine atmosphere. SCSRs allow miners to escape from mine fires, explosions, and other incidents where an irrespirable mine atmosphere is present. Since 1980, MSHA has required that each person working in an underground coal mine have immediate access to an SCSR.

The final rule adds requirements to assure that SCSRs are maintained in good condition and are accessible to all underground miners. The final rule also includes requirements to assure that miners know when and how to use SCSRs effectively.

2. Effective Mine Emergency Training and Response

The best technology, equipment, and emergency supplies are of little use if they are not used effectively or at all. Emergencies can cause disorientation and panic. The appropriate response in a mine emergency can be vital to survival. Training is critical to instilling discipline, confidence, and skill necessary to successfully escape and survive an emergency. The final rule requires more comprehensive training and realistic mine emergency evacuation training and drills to help assure that underground coal miners can respond quickly and appropriately to life threatening mine emergencies.

3. Continuous Directional Lifelines and Tethers

MSHA intends that miners, not required to respond to a mine emergency, evacuate the mine as quickly as possible. In this final rule, MSHA reiterates that, in the event of a mine emergency, the first line of defense is to evacuate the mine. To assist miners in evacuating the mine under conditions of panic and poor visibility, the final rule requires mine operators to provide both continuous directional lifelines and tethers. Continuous, directional lifelines are required to be installed and maintained in both the primary and alternate escapeways to guide miners to a mine exit. Tethers are required to be stored at inby storage locations and on mantrips so that members of a mine crew can link together while evacuating the mine.

4. Notifying MSHA of Accidents

In emergencies, where delay in responding can mean the difference between life and death, immediate notification leads to the mobilization of an effective mine emergency response. Immediate notification activates MSHA emergency response efforts, which can be critical in saving lives, stabilizing the situation, and preserving the accident scene. Immediate notification also promotes Agency assistance of the mine's first responder efforts. In other situations, it allows for a range of appropriate Agency responses depending on the circumstances. It alerts MSHA to trends or warning signals that can trigger a special inspection, an investigation, or targeted enforcement. This communication also encourages operators and miners to work with MSHA to develop procedures that prevent incidents from resulting in more hazardous situations, ultimately leading to disasters.

II. Section-By-Section Analysis

This final rule adds new requirements in 30 CFR parts 48, 50, and 75. In addition, this final rule makes non-substantive conforming amendments to

30 CFR part 3 to reflect changed numbering of standards and to display additional OMB control numbers under the Paperwork Reduction Act of 1995.

A. Part 48—Training and Retraining of Miners

The final rule makes several changes to the training standards in 30 CFR part 48. It modifies SCSR donning procedures by removing the option allowing underground coal miners to simulate the insertion of the mouthpiece while explaining this task.

Commenters were concerned that ETS training requirements applied only to underground coal mines. They stated that underground metal and nonmetal mines face the same evacuation needs as coal mines when a fire, explosion, or gas or water inundation occurs underground. Commenters expressed concern that MSHA was making a substantive change to the training courses in §§ 48.5(b)(5) and 48.6(b)(5) by referencing 30 CFR 57.11053 (escape and evacuation plans applicable to metal and nonmetal mines). Another commenter expressed concern that the ETS was ambiguous with respect to some provisions in 30 CFR part 48. This commenter asked MSHA to clarify that the changes to part 48 apply only to underground coal mines.

The training provisions in the ETS applied only to underground coal mines, and not to metal and nonmetal mines. Similarly, the training provisions in this final rule apply only to underground coal mines, and not to metal and nonmetal mines. Although the final rule retains the reference to 30 CFR 57.11053, it makes no change to the training requirement for metal and nonmetal evacuation procedures. Changes to metal and nonmetal emergency evacuation procedures in 30 CFR part 57 are beyond the scope of this final rule.

Some commenters were concerned that, by adding new or expanded requirements, new miner and annual refresher training would become more overloaded. These commenters recommended that MSHA remove mine emergency training requirements from part 48 and consolidate them in part 75. These commenters stated that consolidating mine emergency evacuation training requirements in part 75 would emphasize the importance of this training.

In response to commenters' concerns, the final rule transfers to part 75, part 48 annual refresher training requirements on self-rescue devices and on mine maps, escapeways, emergency evacuation, and firefighting, and integrates them with mine emergency evacuation training and drill requirements. By providing underground coal miners with an integrated, more realistic training experience quarterly, this final rule will increase training effectiveness. Because this training now will be conducted under part 75, the time that was previously allotted for it, in the 8 hours of annual refresher training required under part 48, can be used for other health and safety subjects.

Under the final rule, independent contractors who do not receive this training under part 75 will continue to receive it under part 48. For these workers, this training will continue to count toward part 48 training requirements.

1. Section 48.3 Training Plans

This final rule modifies § 48.3(p) to require each operator of an underground coal mine, who is required to submit a revised program of instruction for 30 CFR 75.1502, to also submit a revised training plan under part 48. Consistent with MSHA's past practice, to minimize administrative burdens, the Agency will provide coal mine operators with a training plan addendum to address the change made in SCSR donning procedures requiring insertion of the mouthpiece. Underground coal mine operators can attach the addendum to their approved training plan in lieu of resubmitting the entire part 48 training plan for approval.

2. Sections 48.5(b)(2), 48.6(b)(12), 48.8(b)(8), and 48.11(a)(4) Self-Rescue and Respiratory Devices

The final rule retains the ETS requirements for self-rescue and respiratory device training, including instruction and demonstration in the use, care, and maintenance of self-rescue and respiratory devices used at the mine. The ETS standards required hands-on training in SCSR donning procedures, including a requirement that the miner insert the mouthpiece or simulate this task while explaining proper insertion, and a requirement for hands-on training in transferring from a ''self-rescue device to an SCSR.'' The final rule revises the existing standard and removes the option allowing miners to simulate inserting the mouthpiece while explaining proper insertion. The final rule also clarifies MSHA's intent that transferring from a ''self-rescue device to an SCSR'' applies to all applicable self-rescue devices at the mine.

Under the final rule, after receiving new or experienced miner training, underground coal miners will receive SCSR donning and transferring training under part 75, as part of the emergency mine evacuation training and drills, rather than under part 48 annual refresher training. Independent contractors who do not participate in mine emergency evacuation drills conducted under part 75 must continue to receive SCSR donning and transferring training under § 48.8, annual refresher training, and § 48.11, hazard training.

The existing standards emphasize that proficiency in donning the SCSR is essential for a miner to successfully escape the mine during a mine emergency. The MINER Act further underscores this by requiring SCSR ''training for each miner in proper procedures for donning self-rescuers, switching from one unit to another, and ensuring a proper fit.'' MSHA experience and data show that a simulation of inserting the SCSR mouthpiece does not adequately provide the miner with the necessary skills to obtain a proper fit of the mouthpiece. Benefits supporting actual insertion of the mouthpiece include the miner's experience of a proper fit of the mouthpiece and the sensation of resistance breathing. This aspect of SCSR training is more effective when taught and learned in a safe environment, rather than in an emergency evacuation situation.

Some commenters pointed out that insertion of the mouthpiece is a motor skill that requires practice to develop proficiency, and that simulation does not really provide this type of training. Several commenters supported training that included actual insertion of the mouthpiece using a training mouthpiece. One suggested that an economical disposable mouthpiece be developed for use in ''expectations'' training. Referencing his company's participation in Bureau of Mines' research studies in the early 1980's, one commenter stated that miners at his mine were each provided with their own mouthpiece and corrugated hose, which would simulate breathing resistance and function as a personal training unit. One SCSR manufacturer makes a mouthpiece that not only simulates the breathing resistance of their SCSR, but is easily removable from the SCSR training unit. As pointed out by one commenter, these portable mouthpieces could be purchased for each employee, which would alleviate any hygienic concerns.

The mining public has expressed concern over sharing a training mouthpiece even after it is cleaned and disinfected. Some miners have resisted using these devices, stating that the sanitizing methods may not be effective.

In ''Cleaning, Disinfecting, and Sterilizing Self-Contained Self-Rescuer Mouthpiece Assemblies Used in Hands-On Training,'' [1] the Bureau of Mines describes some procedures for disinfecting mouthpieces. MSHA understands that insertion of the mouthpiece may cause some anxiety in miners; however, with proper cleaning and disinfecting, or personal mouthpieces, miners' anxiety should be minimized. Cleaning and disinfecting shared mouthpieces and providing disposable or personal mouthpieces are acceptable for training.

One commenter pointed out that—

> Information on the correct procedures [for transferring SCSR units] is not provided by the manufacturer, especially from one manufacturer's unit to another. Also, no instructions are available to transfer from a chemical generating oxygen unit to a compressed oxygen type unit or vice-versa.

MSHA has developed training materials to assist mine operators and certified instructors in providing training on transferring between all applicable SCSRs. MSHA will make training materials available to mine operators and post them on the Agency's Web site.

3. Section 48.8(b)(4) Roof or Ground Control, Ventilation, Emergency Evacuation and Firefighting Plans

The final rule makes a conforming amendment to § 48.8(b)(4) to clarify that underground coal miners who receive quarterly training on emergency evacuation and firefighting plans in effect at the mine, as part of the emergency mine evacuation training and drills under § 75.1504, are not required to receive this training as part of their annual refresher training.

4. Sections 48.5(e) and 48.6(f) Participation in Evacuation Drills

This final rule removes §§ 48.5(e) and 48.6(f). These paragraphs in the ETS had been added to require new or newly employed experienced coal miners to participate in the next escapeway or evacuation drill. The final rule consolidates and expands the escapeway and evacuation drill requirements for underground coal mines under § 75.1504 and transfers the requirement for newly hired miners to participate in the next evacuation drill to § 75.1504(a)(1). The initial drill requirements in §§ 48.5(e) and 48.6(f) are no longer needed.

5. Section 48.11(a)(4) Hazard Training

This final rule retains the existing requirement for hands-on training in donning an SCSR and transferring from one self-rescue device to an SCSR. The final rule revises the ETS requirement to clarify MSHA's intent that hands-on training in transferring is between all applicable self-rescue devices at the mine. This final rule also revises the SCSR donning protocol to require insertion of the mouthpiece. Section II.A.2. of this preamble discusses this change.

Some commenters stated that the requirements for hands-on training in donning and transferring all types of SCSRs used at the mine is unnecessary for non-mining personnel. They suggest that non-mining personnel, such as visitors and vendors, can receive adequate training via demonstration or video review of the use of an SCSR. Some suggested limited training on a designated unit. Others stated that—

> * * * with regard to hazard training, we recommend clearly providing the operators the flexibility to accept form 5023 [*sic*] documentation of applicable, up-to-date SCSR training in lieu of hands-on training for non-mine employees * * *.

Commenters stated that training non-mining personnel on donning multiple types of SCSRs would be counterproductive and that training on transferring between all self-rescue devices at the mine would be overwhelming and provide little benefit, especially for visitors. Commenters pointed out that these persons are accompanied at all times by an experienced miner who could assist them in the unlikely event of a mine emergency requiring the use of an SCSR.

MSHA's experience and data suggest that all persons underground must be provided practical, hands-on experience in donning and transferring an SCSR. The final rule requires hands-on SCSR donning and transferring training for visitors, short-term workers, or independent contractors not regularly exposed to mine hazards under § 48.11, hazard training, rather than under § 75.1504. If the mine uses only one type of SCSR, these persons must be trained to don and transfer only that one type. If visitors, short-term workers, or independent contractors are going into the mine past an SCSR storage location that contains a different type SCSR than the one carried, these persons must be trained to don and transfer between both types of SCSRs before going underground. Training in transferring from one SCSR to another SCSR will provide them with skill needed to transfer to and don another SCSR. Even though accompanied by an experienced miner, at a minimum, visitors must be prepared to independently, quickly, and correctly don and transfer an SCSR. MSHA agrees that SCSR training for visitors, short-term workers, or independent contractors unfamiliar with mining could be confusing and that they may not always retain all the steps required to don and transfer. If these persons are involved in a mine emergency, direct assistance or instruction may be impossible. The better prepared these persons, however, the better their chance for donning the SCSR correctly during the first few critical minutes of a mine emergency.

B. Part 50—Notification, Investigation, Reports and Records of Accidents, Injuries, Illnesses, Employment, and Coal Production in Mines

Notifying MSHA of accidents must be a priority of the mine operator. Any unnecessary delay can result in loss of life or other harmful consequences. The final rule retains the requirement in the ETS that mine operators notify MSHA of all accidents immediately and within 15 minutes. The final rule also revises the definition for two types of reportable accidents, ''fire'' and ''entrapment.''

On January 2, 2006, the operator of the Sago Mine delayed notifying MSHA of the explosion for more than 2 hours. MSHA issued the ETS with the 15-minute immediate notification requirement, effective March 9, 2006. Subsequently, when the explosion at the Darby Mine occurred on May 20, 2006, the operator alerted MSHA within 5 minutes of being aware of the explosion. This allowed MSHA to immediately initiate a rescue response.

1. Section 50.2(h) Definition of Accident

The final rule amends the definition for two types of reportable accidents.

a. Section 50.2(h)(3): Accident Definition for Entrapment. Under the ETS and the previous standard, ''accident'' included ''[a]n entrapment of an individual for more than thirty minutes.'' Section 5(a) of the MINER Act amends Section 103(j) of the Mine Act pertaining to the reporting of accidents to include an ''entrapment of an individual at the mine which has a reasonable potential to cause death.'' Thus, to conform with the MINER Act, the final rule amends the definition of ''accident'' under § 50.2(h)(3) to include such entrapments.

In using the ''reasonable potential to cause death'' basis for injuries and entrapments, the MINER Act and the final rule retain an element of judgment. This ''reasonable potential'' language also appeared under the ETS and the prior standard in relation to injuries. According to the Federal Mine Safety and Health Review Commission (Commission), the operator's decision as

[1] NIOSH, Information Circular IC 9236, 1989.

to what constitutes a ''reasonable potential to cause death'' ''cannot be made upon the basis of clinical or hypertechnical opinions as to a miner's chance of survival.'' The judgment is based on what a reasonable person would discern under the circumstances, particularly when ''[t]he decision to call MSHA must be made in a matter of minutes after a serious accident.'' [See *Cougar Coal*, 25 FMSHRC 513 at 521 (September 5, 2003)]. Based on MSHA experience and common medical knowledge, some types of ''injuries which have a reasonable potential to cause death'' include concussions, cases requiring cardio-pulmonary resuscitation (CPR), limb amputations, major upper body blunt force trauma, and cases of intermittent or extended unconsciousness. These injuries can result from various indicative events, including an irrespirable atmosphere or ignitable gas, compromised ventilation controls, and roof instability.

b. Section 50.2(h)(6): Accident Definition for Mine Fires. Mine fires have been an ongoing Agency concern. Underground fires can lead to catastrophic consequences under certain conditions. The prior standard required operators to report fires not extinguished within 30 minutes of discovery. Almost all fires occurring in underground mines are extinguished within 30 minutes of discovery. Many of those fires, however, have the potential to cause injury or death, particularly if the underlying causes are not addressed. Knowing the locations of these fires can help miners, mine operators, and MSHA identify problem areas requiring corrective action.

In the ETS, MSHA solicited comment on § 50.2(h)(6). MSHA was concerned that some fires extinguished within 30 minutes, such as fires occurring in the same place, can signal a serious or potentially serious hazard. MSHA specifically asked whether the definition should be revised to cover all unplanned underground mine fires, or fires of particular types, duration, or locations.

Some commenters supported retaining the existing definition. They said that the 30-minute cut-off is adequate and clear, and there is no compelling reason to change it. They said that fires extinguished in a shorter period of time include many fires that do not present any significant hazard. They said that reporting all fires would be burdensome and involve an unnecessary use of resources. A log was suggested to alleviate the reporting burden.

Other commenters, however, said that the definition should be broadened to include all unplanned underground mine fires. These commenters pointed out that fires can be devastating to a mine and the miners. They said that it should not be left up to mine operators to decide how long it takes to extinguish a fire. They said that fires are seriously under-reported. They also said that if fires remain unreported, then the mine operator is less likely to eliminate the source of the problem. Another commenter urged MSHA to consider the issue of belt flammability stating that belt fires ''require escape in many instances.''

The final rule retains the existing requirement for reporting fires for surface mines and surface areas of underground mines. Surface fires do not involve the hazard potential that underground fires present in a confined environment. For unplanned underground fires, the final rule expands the definition of accident to include all fires not extinguished within 10 minutes of discovery.

We agree with a commenter who, basing the comment on experience in the Pittsburgh seam, said that 30 minutes is ''entirely too long,'' because a fire that's been burning for 30 minutes can be ''totally out of control.'' Similarly, belt fires that include open flame, smoldering coal, smoking belts, or hot glowing rollers, can be hard to control. MSHA experience and data include a number of belt fires, among them the Alma Aracoma fire on January 19, 2006, that could not be contained by the miners at the scene. MSHA expects that the increased reporting of unplanned underground fires, including belt fires, will help focus attention on problems that need to be identified and corrected before developing into an uncontrollable fire.

The requirement to report all underground fires not extinguished within 10 minutes of discovery will address those fires requiring activation of the fire-fighting plan and evacuation of miners. Based on Agency experience and data, MSHA determined that 10 minutes is a reasonable time for attempting to extinguish a fire and to notify the surface. In an underground environment, if miners attempt to fight the fire for 30 minutes and are unsuccessful, the fire will probably become uncontrollable. The revised reporting requirement will result in earlier plan activation as miners will more quickly notify supervisors who can call in firefighting crews while the other miners get out of harm's way. The final rule's requirement to report fires not extinguished within 10 minutes targets fires that can jeopardize safety while excluding minor, nuisance events.

2. Section 50.10 Immediate Notification

The final rule retains the requirement in the ETS that mine operators notify MSHA immediately of all reportable accidents. Immediate notification is defined as ''at once without delay and within 15 minutes.'' It is significant to note, however, that the higher penalties, for failing to ''provide timely notification'' to MSHA, apply only to those accidents that are specified in Section 5(a) of the MINER Act. These are accidents that involve ''the death of an individual at the mine, or an injury or entrapment of an individual at the mine which has a reasonable potential to cause death.'' The final rule, like the MINER Act, does not include any exceptions to the 15-minute notification provision.

a. Notifying MSHA within 15 Minutes. Before the ETS, the standard required operators to contact MSHA ''immediately'' if an accident occurred. The ETS required that all accidents be reported at once without delay and within 15 minutes, with an exception for lost communications. While many commenters said they supported the goal of notification, they opposed the 15-minute requirement. Commenters said that 15 minutes passes too fast, is too short, and does not allow for the gathering of sufficient information. Instead of 15 minutes, commenters suggested 30 minutes and an hour or more as alternatives.

Other commenters suggested that MSHA eliminate any specified time requirement and revert back to the general pre-ETS ''immediately contact'' standard. They said it was flexible, acknowledged those situations where operators ''did the best they could,'' and allowed for ''wiggle room.'' Commenters noted that about 90 percent of the accidents reported to MSHA in 2005 were ''unplanned roof falls at or above the anchorage point, and damage to hoisting equipment,'' and did not involve an injury to a miner. These commenters stated that the 15-minute requirement should not apply in those non-emergency cases, and that MSHA could be overwhelmed with reporting and false alarms. Other commenters stated that the 15-minute requirement should not apply in situations in which the operator had to perform rescue or life-saving actions.

Other commenters supported the 15-minute requirement for all accidents. They said that MSHA can best decide what to do with the information it gets. They said the problem is one of under-reporting accidents, not over-reporting. These commenters said that delays in

reporting accidents, like the delay in reporting the Sago accident, are unacceptable. The commenters also said that requiring notification within 15 minutes actually aids operators by removing uncertainty concerning when to notify MSHA.

As mentioned above, the MINER Act was signed into law on June 15, 2006. Several comments suggested retaining the 15-minute requirement for only the accidents specified in the MINER Act. In addition, commenters suggested limiting that requirement to underground coal mines or including a life saving exception. Other comments, however, supported the 15-minute reporting requirement in the ETS. One commenter said that the sooner individuals with expertise arrive at the scene ''the better the chances for a successful outcome.''

MSHA's experience with implementation of the ETS indicates that the 15-minute requirement for reporting all accidents is working. The operator's reporting of the Darby explosion serves as an example of how timely reporting can result in effective mobilization of emergency response resources. Operators of varying mine sizes and types have been able to meet the 15-minute requirement under the ETS. Some operators may have had to alter their response procedures to ensure quicker notification.

Timely reporting can be crucial in emergency, life-threatening situations to activate effective emergency response and rescue. Not only can this be vital to the saving of lives, but it can be instrumental to having expert Agency personnel at the scene with authority to assure that the accident site remains undisturbed and preserved for investigation into causes. For remote operations, it enables MSHA to quickly communicate with local rescue and emergency services. While many reported accidents do not involve an injury or are non-emergencies, they may be near misses or signify a trend or problem that left uncorrected can be extremely hazardous. Fires, explosions, and gas and water inundations are of special concern.

In making the decision to retain the notification requirement in the ETS, MSHA considered the dynamic nature of the mining industry. The mining environment is ever-changing; there is always the threat of new hazards or dangers. The reporting of roof falls, unplanned explosions, haulage accidents, or unstable conditions at impoundments, for example, may necessitate critical, pro-active corrective actions and the need for emergency response assistance. The demand for many mining commodities is accelerating. Production growth can push mining into depths with more structural instability. As the chance for encountering older underground works and strata increases, so does the potential for gas and water inundation.

Based on MSHA's experience under the ETS, ''within 15 minutes'' provides adequate time for operators to notify MSHA with sufficient information. For example, the mine operator often knows the general character of an event, such as an explosion or inundation, and can report it under the 15-minute requirement before knowing whether a person has been injured or killed or whether the event is life threatening. MSHA's experience and data reveal that reportable accidents are not common. The 15-minute requirement poses no significant increased burden on the mining industry while providing improved protection for miners.

A number of commenters stated that having to notify MSHA within 15 minutes could interfere with the operator's rescue efforts and calling 911. They said that operators should not be expected to divert from life saving and emergency activities to phone MSHA. This can arise particularly with small operators who may need to engage any and all available personnel to respond to an emergency. They said there should be an exception for those life saving and emergency activities in addition to the exception for loss of communications.

Other commenters, however, disputed the need for any exception. One commenter pointed out that loss of communications in a mine is an indicator of a problem, and the mine operator ''must be required to contact MSHA with the information available to him within the mandatory time frame.'' Some commenters objected to saying that the 15-minute notification requirement could interfere with rescue or life saving. They said operators can anticipate problems in their emergency plans. Moreover, the commenters said that operators can use cell phones, blackberries, or other communication devices, which they readily use to make other calls in emergency situations. One commenter stated that ''[A]ny operator who cannot initiate onsite emergency efforts and call the regulatory agency should not be in the mining business.''

The final rule, like the MINER Act, does not include any exceptions to the 15-minute notification provision, including one for loss of communications. As noted above, some commenters sought an exception for life saving, or for directing rescue efforts. If a situation were to arise involving extenuating circumstances, such as an operator having to choose between saving someone's life and notifying MSHA, enforcement discretion would take those circumstances into account. MSHA does not expect that an operator who has to make a decision between rendering life-saving assistance and calling MSHA would be penalized for providing that assistance.

Pointing out that the ETS addressed events in underground coal mines, a few commenters said that the 15-minute notification provision should apply only to underground coal or other underground mines. Other commenters said that MSHA activation of a response team does not usually occur for accidents at surface operations. Consistent with the MINER Act, the final rule does not limit the notification provision to underground mines. Accidents and deaths occur at all types of mines. Surface mines, for example, over the years have suffered numerous fires; serious haulage, equipment, and explosives accidents; electrocutions; highwall failures; explosions; and impoundment failures. Prompt notification focuses MSHA, operators, and miners on problem areas. Even where MSHA does not activate an emergency response, the Agency conducts an investigation. Prompt notification enables MSHA to secure an accident site, preserving vital evidence that can otherwise be easily lost. In addition, prompt notification provides MSHA with data to accurately determine trends and means of prevention.

There also was comment on what triggers the 15-minute period. Some commenters said that the MINER Act should be followed literally with one commenter stating that the 15-minute period should commence once the operator ''realizes'' an accident has occurred. While the MINER Act uses ''realizes,'' that commenter conceded that there is ''some ambiguity'' in the term.

Consistent with current case law and interpretation of the notification provision, the final rule alternatively uses the clarifying terms ''once the mine operator knows or should know,'' based on the judgment of a reasonable person. MSHA acknowledges that the operator needs time to determine whether an accident has occurred in the first place. As stated in the preamble to the ETS, the Federal Mine Safety and Health Review Commission (FMSHRC) interpreted the notification standard to allow reasonable time for the operator to make that determination. MSHA recognizes that an operator may not know instantly when an accident occurs, but emphasizes that the operator

must make that determination promptly, consistent with the underlying purpose of the standard. Thus, an operator, like any reasonable person under the circumstances, is held to know or realize that an accident has occurred.

The final rule retains the ETS terms ''at once and without delay,'' which highlight that reporting must be done promptly. Though a commenter said that these terms are synonyms and should be deleted, the terms are dictionary references used by the Commission in defining and emphasizing what is intended by ''immediately.'' [See *Consolidation Coal*, 11 FMSHRC 1935 at 1938 (October 31, 1989).] ''Immediately'' is to be understood ''in light of the [notification] regulation's command of prompt, vigorous action.''

b. Method of Notification. Many commenters stated that the method of contacting MSHA needed to be improved and streamlined. In the ETS and prior standard, operators were directed to first contact the appropriate MSHA District Office and, failing that, to use a 1–800 number to an MSHA headquarters answering service. Commenters said that this system was often inefficient and time consuming, taking a number of phone calls to accomplish notification. Many commenters advocated a nationwide call center, staffed by knowledgeable persons, where the mine operator could place one call to take care of notification. Other suggestions included a District system of emergency phone numbers with staff coverage 24 hours a day, 7 days per week, or a one-call system to voice mail.

MSHA agrees that the system for contacting the Agency needed to be improved. MSHA has acquired a nationwide call system; thus, the final rule eliminates the requirement that mine operators first notify the appropriate District Office. MSHA has set up an improved system that provides a person to answer calls 24 hours per day, 7 days per week. The final rule lists the toll-free number, which is the same number mine operators currently use for notification purposes. Once the mine operator calls the toll-free service, notification is achieved.

C. Part 75—Mandatory Safety Standards—Underground Coal Mines

This final rule does not address §§ 75.350(b)(7), 75.380(n), and 75.383(c), which were deleted in the ETS. The final rule also makes organizational changes and adds paragraph headings and numbers to make specific requirements easier to find and understand, to clarify existing provisions, and to accommodate new and transferred provisions. These non-substantive revisions do not reduce protection for miners.

1. Sections 75.380 and 75.381 Lifelines in Escapeways

The final rule retains ETS requirements §§ 75.380(d)(7) and 75.381(c)(5) that provide for the use of directional lifelines in both the primary and alternate escapeways for underground bituminous, lignite, and anthracite coal mines. The final rule requires that a continuous, directional lifeline be installed and maintained in each escapeway. The lifeline must: be marked with a reflective material every 25 feet; be located in a manner that allows miners to use it effectively to escape; have tactile directional indicators signifying the direction of escape placed at intervals not exceeding 100 feet; and be attached to and mark the location of stored SCSRs. The final rule also adds a requirement that lifelines be made of flame-resistant material upon replacement, and that all lifelines be flame-resistant no later than June 15, 2009, to conform with Section 2 of the MINER Act.

A directional lifeline is generally a rope made of durable material, although the final rule, like the ETS allows an equivalent device, such as a pipe or handrail. Some commenters stated that a track or belt structure could be considered an equivalent device. MSHA has clarified in this final rule that a lifeline must provide tactile feedback to indicate the direction of escape. In an emergency, visibility may be limited and render devices, such as a track or belt structure, ineffective as a means of indicating direction. MSHA is concerned that the mine operator will be unable to attach tactile directional indicators, which are resistant to physical damage, to a track or belt structure. Because tactile directional indicators on a track or belt structure are likely to be damaged during normal mining activities, MSHA does not believe that a track or belt structure would provide safety equivalent to a lifeline and considers them to be unreliable and impractical. In addition, MSHA is concerned that a conveyor belt structure used as a lifeline presents a significant potential hazard to escaping miners, unless the belts are both de-energized and locked-out. Further, a track used as a lifeline would require escaping miners to crawl to use the tactile indicators on the track.

a. Continuous Lifeline. The final rule, §§ 75.380(d)(7)(i) and 75.381(c)(5)(i), requires that durable, continuous lifelines be installed and maintained in both escapeways leading from the working sections or areas where mechanized mining equipment is being installed or removed. The lifelines must be continuous throughout the entire length of each escapeway to the surface escape drift opening, to the escape shaft or slope facilities to the surface, or to the surface, as applicable.

Most commenters supported the installation of lifelines in escapeways. Other commenters expressed concerns that the installation of a lifeline in escapeways where mechanized mining equipment regularly travels could result not only in damage to the lifeline, but a damaged lifeline could become a potential hazard to personnel. MSHA agrees that care needs to be taken when lifelines are installed in escapeways that are also used as travelways for mechanized mining equipment. Installation techniques are available that will permit lifelines to be protected from damage from mobile equipment while still being readily available to miners during emergencies. These provisions remain unchanged from the ETS.

b. Flame-Resistant and Reflective. The final rule, §§ 75.380(d)(7)(ii) and 75.381(c)(5)(ii), adds new requirements that lifelines be flame-resistant upon replacement of existing lifelines; but in no case later than June 15, 2009. This requirement was added to respond to comments and to conform the final rule with Section 2 of the MINER Act.

Many commenters stated that lifelines should be made of flame-resistant material and some suggested that MSHA require lifelines to be flame-resistant. MSHA agrees that flame-resistant lifelines provide an added degree of protection for miners and the final rule requires that lifelines be ''Flame-resistant in accordance with the requirements of part 18 of this chapter upon replacement of existing lifelines; but in no case later than June 15, 2009.'' The flame-resistant requirements contained in part 18 are currently applied to other materials used in mining, such as conveyor belt, hose conduit, and packing gland materials. MSHA has determined that the Agency's requirements for flame-resistant materials are also appropriate for lifelines used in underground coal mines. MSHA anticipates that lifeline manufacturers will be able to meet the flame-resistant requirement under part 18 and will submit products for approval prior to the time specified in the final rule.

The final rule, §§ 75.380(d)(7)(iii) and 75.381(c)(5)(iii), requires that lifelines be marked with a reflective material every 25 feet, so that miners can locate

the lifeline using their cap lamps in low-visibility conditions, such as when smoke is present. No comments were received on these provisions and they remain unchanged from the ETS.

c. Lifeline Accessibility. The final rule, §§ 75.380(d)(7)(iv) and 75.381(c)(5)(iv), requires that lifelines be positioned so that miners can use them effectively to escape. Proper positioning of the lifeline regarding height, accessibility, and location as determined by mining conditions improves the ability of miners to effectively use lifelines to escape during emergency situations. No comments were received on this provision and it remains unchanged from the ETS.

d. Tactile Indicators. The final rule, §§ 75.380(d)(7)(v) and 75.381(c)(5)(v), requires that lifelines contain tactile indicators signifying the direction and route of escape, placed at intervals not to exceed 100 feet. In the public hearings, MSHA asked whether ''direction indicators on lifelines [should] be standardized.'' MSHA also asked whether ''the point end of the cone [should] be toward the face?'' Most commenters supported standardization of directional indicators. This provision in the final rule is changed from the ETS to include a new requirement that ''[w]hen cones are used as directional indicators, they shall be installed so that the tapered section points inby.'' This new requirement is consistent with NIOSH's recommendation [2] and supported by commenters.

The final rule, §§ 75.380(d)(7)(vi) and 75.381(c)(5)(vi), requires that lifelines be ''securely attached to and marked to provide tactile feedback indicating the location of any SCSR storage locations in the escapeways.'' When visibility is restricted during an emergency, tactile feedback is necessary to guide miners to exit the mine and would also be necessary to locate additional SCSR storage along the escapeway. For this reason, the final rule clarifies that the indicator on the lifeline for locating additional SCSRs be tactile.

2. Section 75.383 Escapeway Maps and Drills

This final rule transfers existing requirements from § 75.383(a) to a new § 75.1505 and combines § 75.383(b) and ETS § 75.1502(c) into a new, improved and expanded § 75.1504. Therefore, § 75.383 is no longer necessary and the final rule removes it.

Section 75.383(b)(1) required all miners to participate in a practice drill every 90 days; but, the miners only had to travel a portion of the escapeways. On the other hand, the drills in § 75.383(b)(2) and (3) required a supervisor and two miners to travel the entire escapeway every 6 weeks. In addition, § 75.383(b)(2) and (3) required the operator to rotate miners for these 6-week drills, so that all miners participated, and to alternate escapeways, so that the escapeways from all sections were traveled to the surface or to the exits at the bottom of the shaft or slope. MSHA has determined that requiring all miners to travel an entire escapeway each quarter provides increased safety for miners and eliminates the need for the 6-week drill requirement.

In the opening statement at the public hearings, MSHA stated the Agency's intent to incorporate the drill requirements in § 75.383 with the emergency evacuation drill requirements in ETS § 75.1502(c) and solicited comments on this approach to emergency evacuation drills. Commenters generally supported the elimination of the § 75.383 escapeway drills. In response, the final rule incorporates requirements from § 75.383(b) into § 75.1504 and expands these requirements. These expanded requirements make escapeway drills more realistic and, therefore, more effective.

3. Section 75.1502 Mine Emergency Evacuation and Firefighting Program of Instruction

Final rule § 75.1502 contains the requirements for a written plan for conducting the training and drills required under §§ 75.1503, 75.1504, and 75.1505. In general, the training plan provisions in ETS § 75.1502(a) become § 75.1502; the firefighting provisions in § 75.1502(b) become § 75.1503; the evacuation training and drill requirements in ETS § 75.1502(c) become § 75.1504; and the mine and escapeway map requirements in § 75.383(a) become § 75.1505. Almost all of the requirements in § 75.1502 are derived from existing requirements. The final rule conforms the program of instruction in § 75.1502 with the requirements added to the quarterly training and drills and annual expectations training in § 75.1504.

Commenters were concerned that the ETS had not included miners or miners' representatives in the process for developing emergency mine evacuation training and drills. MSHA anticipates that mine operators will work with miners in developing the program of instruction and implementing the mine emergency evacuation training and drills.

a. Introduction to § 75.1502. The final rule retains introductory language from ETS § 75.1502(a); adjusts the frequency of training and drills from every 90 days to quarterly; defines the quarter based on a calendar year; and includes new implementing language. This new implementing language requires that operators submit a revised program of instruction to MSHA for approval by February 6, 2007, and initiate the revised training within 30 days of plan approval.

In the final rule, MSHA adjusts the frequency of training and drills from every 90 days to quarterly in response to comments and to provide flexibility. MSHA recognizes that some training is more appropriately given in a classroom or a simulated mining environment. Added flexibility in scheduling will allow operators time to give all miners this critical training and drills quarterly. An operator may find it more convenient to schedule training and drills over several days or weeks depending on the availability of instructors, training equipment, or facilities.

Under the final rule, operators will have the flexibility to conduct quarterly mine emergency evacuation training and drills, either the first, second, or third month of the quarter. The month in which a miner completes mine emergency evacuation training and drills, in effect, becomes that miner's ''anniversary'' month for this quarterly training. For example, a miner receiving quarterly mine emergency training and drills in January, the first month of the first quarter, is required to complete the second quarterly training no later than the end of April, the first month of the second quarter. If a miner completes the training before that miner's anniversary month, then the month the training and drills were completed establishes a new anniversary month for subsequent training and drills. This is consistent with MSHA policy for part 48 annual refresher training.

Commenters suggested that the requirement for emergency evacuation drills be changed from every 90 days to quarterly. One commenter suggested that training during a specific month each quarter would allow for more effective scheduling of people and resources. Another commenter stated that switching to quarterly training would make it easier to schedule training in a timely manner if the miner misses a drill. This commenter stated that, if a miner is off, more flexibility allows the operator time to schedule makeup training and still be in compliance.

[2] NIOSH, IC 9481, p. 9, 2005.

The final rule's change in mine emergency evacuation training and drills from every 90 days to quarterly increases flexibility, makes recordkeeping easier, and better ensures that all miners participate quarterly.

b. Section 75.1502(a) and (b): Program Approval and New or Revised Provisions. The final rule §§ 75.1502(a) and (b) retain the requirements in ETS § 75.1502(a)(3). Like the ETS, the final rule requires the operator to submit a program of instruction, and any revisions, for approval to the District Manager of the Coal Mine Safety and Health district in which the mine is located. Before implementing any new or revised approved plan provision, the operator must instruct miners in the changes.

c. Section 75.1502(c): Instruction Plan Contents. The final rule has consolidated the requirements for mine emergency evacuation training and drills from 30 CFR 48.8 and part 75 in the instruction plan under final § 75.1502. Contents of the instruction plan include: Mine and escapeway maps; evacuation and firefighting plans; locations of abandoned areas, escapeways, exits, and routes of travel to the surface; and the location and use of firefighting and fire suppression equipment and materials. Although MSHA considers consolidation of these requirements to be an administrative change, it improves an operator's ability to provide more comprehensive and effective evacuation training and drills.

The final rule retains the existing requirements from ETS § 75.1502(a)(1); includes evacuation-related training requirements from § 48.8; enhances the scenario training; and requires annual expectations training. Like the ETS, the final rule requires operators to develop scenarios for mine emergencies, including fires, explosions, and gas or water inundations, and to develop best options for evacuation under each type of emergency. Under the final rule, scenarios must include conditions in the mine or circumstances that require immediate donning of self-rescue devices. In response to questions, the final rule clarifies that scenarios must also include a discussion of options and a decision as to the best option in each situation.

To ensure that the scenarios address the various conditions that miners may encounter in the event of an emergency, the final rule, § 75.1502(c)(2)(ii), includes more examples. It clarifies that the scenarios must include, as applicable, instruction in locating and using continuous directional lifelines, tethers, and doors; traversing undercasts or overcasts; and switching escapeways. MSHA includes this requirement to emphasize the importance of using scenarios to conduct mine emergency evacuation drills so that miners will be familiarized with emergency equipment, including conditions that may be encountered in escaping the mine.

The final rule retains and combines the requirements of ETS § 75.1502(a)(1)(v) and (vi) in § 75.1502(c)(3). This provision requires training on the operation of fire suppression equipment and the location and use of firefighting equipment and materials. These requirements are unchanged from the ETS.

ETS § 75.1502(a)(1)(vii) required training on the location of escapeways, exits, and routes of travel to the surface, including the location [and use] of continuous directional lifelines or equivalent devices. The final rule retains this requirement in § 75.1502(c)(4) and transfers training on the use of lifelines to evacuation scenarios in § 75.1502(c)(2)(ii).

ETS § 75.1502(a)(1)(viii) required that the instruction plan include training on the locations, quantity, types, and use of stored SCSRs, if applicable. The final rule retains this requirement in § 75.1502(c)(5). This provision will help assure that miners receive appropriate donning and transfer training on all applicable SCSRs.

Annual refresher training in § 48.8(b)(4) requires a review of the mine map; the escapeway system; the escape, firefighting, and emergency evacuation plans in effect at the mine; and the location of abandoned areas. The final rule transfers this training requirement to § 75.1502(c)(6) for underground coal miners. Miners who receive this training as part of their quarterly drills under 30 CFR 75.1504(b)(4) are not required to take it under part 48. The Agency transferred this provision so that emergency evacuation training and drills would be consolidated in part 75.

Final rule § 75.1502(c)(7) includes a new provision requiring operators to describe how miners will receive annual expectations training, which is an integral component of mine emergency evacuation training. This new provision complements the integrated approach to training as reflected in the mine emergency evacuation drill requirement in final § 75.1504.

MSHA addresses commenters' concerns about § 75.1502 Mine Emergency Evacuation and Firefighting Program of Instruction in § 75.1504 Mine Emergency Evacuation Training and Drills, which addresses the implementation of this program of instruction.

d. Section 75.1502(d): Instructors. Final rule § 75.1502(d) retains unchanged ETS § 75.1502(a)(2) that requires operators to designate persons with the appropriate abilities, training, knowledge, or experience to provide training and conduct mine emergency evacuation drills in his or her area of expertise. The final rule also retains the ETS requirement that persons conducting SCSR donning and transferring training must be able to effectively train and evaluate whether miners can successfully don the SCSR and transfer between all applicable SCSR devices.

MSHA experience and NIOSH research [3] indicate that, in an emergency, effectively trained miners are more likely to recall needed knowledge and skills. NIOSH recognizes that a key component of effective training is the instructor's ability to communicate their knowledge and skills to others and to evaluate performance. Further, NIOSH states that good trainers must have extensive knowledge or competence in the task or job they are teaching. There were no comments on this provision.

4. Section 75.1503 Use of Fire Suppression Equipment

The final rule transfers the requirements for use of fire suppression equipment from § 75.1502(b) to new § 75.1503. It is administrative and makes no substantive change to the existing requirements.

5. Section 75.1504 Mine Emergency Evacuation Training and Drills

The mine operator's approved program of instruction, in § 75.1502, contains requirements that the miner must experience in the § 75.1504 training and drills. This final rule renumbers and revises ETS § 75.1502(c) as final § 75.1504. It also removes ETS § 75.1502(c)(4) that had allowed evacuation drills to satisfy escapeway drill requirements in § 75.383. Because there are no longer any escapeways drills under § 75.383, § 75.1502(c)(4) is no longer necessary.

The ETS enhanced the requirements for evacuation training and drills by requiring that these drills be more than a simulation. The final rule retains and further enhances evacuation drill requirements by integrating mine emergency training from § 48.8 and § 75.383 into § 75.1504.

a. Introduction to § 75.1504. In the introductory text to § 75.1504, the final

[3] NIOSH, ''Strategies for Improving Miners' Training,'' *Information Circular IC 9463*, DHHS (NIOSH) Publication No. 2002–156, September 2002.

rule incorporates the existing introductory language from ETS § 75.1502(c). The final rule requires all miners to participate in the training and drills. This includes independent contractors who must participate in the quarterly drill when it is being conducted in the section or working place where they are located.

b. Section 75.1504(a) Schedule of Training and Drills. As discussed previously, the final rule provides mine operators flexibility in completing drills on a quarterly basis. This change provides a reasonable, defined period of time to complete drills and allows for adjustments to accommodate work schedules or conflicts.

As stated in the ETS, MSHA recognizes that regular and frequent participation in emergency evacuation training and drills reinforces the miner's knowledge and skill necessary to respond effectively in a mine emergency. Frequent drills lessen disorientation, stress, and panic that may cause miners to hesitate in making critical decisions or to make poor decisions. For this reason, the final rule retains the requirement that all miners participate in evacuation training and drills, and includes a new requirement for annual expectations training under paragraph (c).

In § 75.1504(a)(1), the final rule requires that a newly hired miner, who has not participated in an evacuation training and drill at that mine within the previous 3 months, must participate in the next applicable drill. This provision provides flexibility to the mine operator by allowing up to 3 months for newly hired miners to complete the quarterly mine emergency training and drill. This requirement is transferred from §§ 48.5(e) and 48.6(f).

In new § 75.1504(a)(2), the final rule requires that a section or outby foreman travel both escapeways in their entirety prior to assuming duties on the section or outby work location.

In the opening statement at the public hearings, MSHA asked if section bosses should travel both escapeways in their entirety prior to assuming duties on that section. Several commenters said that a foreman should not be required to travel both escapeways in their entirety. Commenters generally agreed that a foreman should travel those portions of both escapeways that the foreman has not traveled within the previous 3 months. In fact, one commenter stated that this requirement makes good practical sense and that all supervisors should be familiar with the escapeways prior to assuming their responsibilities.

MSHA agrees that a foreman needs to have traveled both escapeways prior to assuming duties on the section. A foreman is responsible for training miners in escapeway drills and must have the training, knowledge, or experience to conduct these drills. Also, the foreman is in a leadership position and, in the event of an emergency, is entrusted with the responsibility for leading miners out of the mine safely. To do this, the foreman must have the necessary skills, including complete familiarity with both the primary and alternate escapeways. MSHA experience is that a well-trained foreman can instill confidence in miners and gain their trust. The final rule, accordingly, requires a foreman to travel both escapeways prior to assuming duties on the section. This includes walking portions as necessary and to focus on unique and lifesaving features.

c. Section 75.1504(b) Content of Drills. Final rule § 75.1504(b) retains and clarifies ETS § 75.1502(c)(2) requirements for a comprehensive, realistic mine emergency evacuation drill, and incorporates escapeway drill requirements from § 75.383(b)(1).

(i) Section 75.1504(b)(1) Hands-On SCSR Training. Before going underground, all persons must be able to demonstrate proficiency in donning and transferring of SCSRs used in that mine. After initial training under 30 CFR part 48, the miner continues to receive ''hands-on'' training for donning and transferring of self-rescue devices as part of the quarterly mine emergency evacuation training and drills.

If an emergency arises, many miners may have to escape through long and difficult underground escapeways containing irrespirable air. MSHA has identified problems related to skill degradation in the use of SCSRs in mine emergencies. In a series of studies from 1990 through 1993, the U.S. Bureau of Mines, University of Kentucky, and MSHA researchers measured skills degradation. In one study, the proficiency rate for donning an SCSR dropped about 80 percent in follow-up evaluations conducted about 90 days after training. MSHA recognizes that with any nonroutine task, such as donning and transferring of SCSRs, knowledge and skill diminish rapidly. SCSR donning is a motor skill and research indicates that reinforcing motor skills, through more frequent training, will substantially reduce motor-skill degradation. In another study [4] researchers concluded that ''companies should adopt a hands-on training protocol that allows them to integrate SCSR donning practice into other workplace routines such as fire [drills].''

The ETS reflected MSHA's conviction that more frequent and effective SCSR training is necessary. Based on skills degradation research [5] supporting additional SCSR training, and past experience where improved training might have made a difference in an escape, final rule § 75.1504(b)(1) retains the ETS requirement for ''hands-on'' training in the complete donning and transferring of each type of SCSR used at the mine.

To assure that miners can obtain a proper fit of the SCSR mouthpiece, the final rule changes the requirement in § 75.1504(b)(1)(ii) from ''inserting the mouthpiece or simulating this task while explaining proper insertion of the mouthpiece'' to ''inserting the mouthpiece.'' MSHA is concerned that without actually physically inserting the mouthpiece, a miner may not gain the skills to effectively and properly perform this action. This change is consistent with language in the MINER Act that requires all operators to develop ''an emergency response plan'' for ''ensuring a proper fit'' of an SCSR.

(ii) Section 75.1504(b)(2) Comprehensive SCSR Training. MSHA is concerned that some miners may not have been receiving adequate emphasis on three important instructions for using an SCSR. Even though much of this information is included in existing training courses and manufacturers' instructions, the final rule includes these instructions to emphasize their importance. This requirement poses no additional burden on mine operators.

In § 75.1504(b)(2)(i), the final rule emphasizes the importance of recognizing when the SCSR is not functioning properly and demonstrating how to initiate and reinitiate the starting sequence. MSHA is concerned that miners may not be able to recognize when an SCSR is functioning properly. This may have caused miners to remove their SCSRs prematurely, thinking that the device was not working when breathing became difficult. Also, miners need the skills and knowledge to initiate (cold start) an SCSR if it fails to start automatically after the starting sequence is initiated.

In § 75.1504(b)(2)(ii), the final rule requires that the SCSR training emphasize the importance of not removing the mouthpiece until the miner is out of the mine. MSHA is concerned that miners may remove their mouthpiece before reaching fresh air or to communicate. Even though a miner may believe that the air is breathable

[4] The U.S. Bureau of Mines (Vaught *et al.*, 1993).

[5] *Ibid.*

because it appears clear and there is no smoke, the mine air may contain high levels of toxic gases or have insufficient oxygen to sustain life.

In § 75.1504(b)(2)(iii), the final rule requires operators to instruct miners about the effects of over-breathing the capability of the SCSR. SCSRs produce oxygen at a specific flow rate. Rapid and deep breathing (over-breathing) caused by panic or physical exertion can potentially create more demand for oxygen than an SCSR can supply. Like all other respiratory devices, SCSRs are more effective when the miner is better trained to understand their capabilities and to use them properly.

(iii) Section 75.1504(b)(3) Realistic Training and Drills. In § 75.1504(b)(3), the final rule retains and clarifies ETS § 75.1502(c)(2) requiring a comprehensive, realistic mine emergency evacuation drill and integrates the escapeway drill requirements from § 75.383(b).

NIOSH studies [6] relating to stress and its effect on behavior during an emergency noted that miners who had more experience or training also tended to report less stress during the exercise. MSHA agrees with the NIOSH assessment that miners will be better prepared to react more effectively if they are more familiar with and have a better appreciation of the requirements for evacuating the mine. By traveling both escapeways in their entirety and practicing using the other required evacuation tools, miners will gain confidence and a better understanding of the time and effort required to evacuate the mine successfully in an actual emergency.

Scenarios. In § 75.1504(b)(3), the final rule enhances the requirement for a realistic mine emergency evacuation drill by specifying that the drill must be initiated based on one of the approved mine emergency scenarios from the Mine Emergency Evacuation and Firefighting Program of Instruction. To ensure that the four major scenarios (fire, explosion, gas or water inundation) are covered each year, § 75.1504(b)(3)(i) requires that a different scenario be used each quarter. Although ETS § 75.1502(a)(1) included a requirement for scenarios, it did not state specifically that these scenarios were to be used for conducting the evacuation drills.

In the opening statement at the public hearings, MSHA stated that it intended that scenarios required by the Approved Program of Instruction would be used to start and to conduct the mine emergency evacuation drills. Commenters generally supported the concept of using mine-specific scenarios to conduct mine emergency evacuation drills. One commenter recognized the importance of providing ''* * * training scenarios that simulate the actual experience.'' Another commenter said that operators should routinely update and change the scenarios to ensure that they are an adequate learning tool.

MSHA agrees with commenters that a variety of scenarios provide miners with a better, more realistic and effective drill. Depending on the conditions at the mine, the mine operator may need to develop more than one scenario for each type of mine emergency. The final rule does not limit the mine operators' choices of scenarios, but rather includes a requirement that scenarios require a discussion of options and a decision as to the best option for evacuation in each scenario.

Traveling Escapeways. The final rule, like the ETS, requires miners to travel the primary or alternate escapeway to the surface or exits at the bottom of a shaft or slope, physically locating continuous, directional lifelines or equivalent devices, tethers, and stored SCSRs, as part of their quarterly evacuation drill. To ensure that miners are familiar with both escapeways, the final rule retains the requirement that the drill be conducted in a different escapeway than the previous quarterly drill. Traveling both escapeways provides miners with a more realistic experience of unique escapeway conditions they may encounter in evacuating the mine, including uneven terrain, ladders, doors, airlocks, and overcasts. Hands-on experience with these conditions helps assure that the miner can successfully escape the mine in an actual emergency. Under the final rule, travel can be by any means of conveyance, including mantrips, mobile equipment, or walking.

The ETS required the mine operator to have miners travel the escapeways and physically locate the lifelines and stored SCSRs. MSHA stated that miners should be able to safely evacuate a mine without the use of mechanized transportation. In both the preamble and MSHA's opening statement at the public hearings, MSHA requested comments about whether miners should be required to walk the escapeway rather than use mechanized transportation during the drills.

Most commenters expressed concern about the safety and usefulness of requiring miners to walk the escapeways. Commenters acknowledged the value of physically using lifelines, finding SCSR storage locations, and traversing unique or difficult portions of the escapeways; but, considered walking an entire escapeway to be unnecessary. These commenters were concerned that requiring miners to walk the escapeway each quarter would be counterproductive, and urged the Agency to allow miners to walk the escapeways in segments. Many commenters expressed concern that walking an escapeway would expose miners unnecessarily to increased risk of injury, especially the aging workforce. These commenters pointed out that a few injuries during an actual emergency are acceptable; but, they are not acceptable during a drill.

MSHA received several comments that addressed underground mine firefighting drills (§ 75.383). Commenters acknowledged that miners walked the escapeways under existing § 75.383(b) drills and were concerned that, in combining the escapeway and evacuation drills, miners would be required to walk an escapeway every 90 days.

MSHA considered commenters' concerns and agrees that walking each escapeway in its entirety is not necessary to provide the miner a realistic experience of evacuating the mine. Furthermore, MSHA agrees that requiring all miners to walk entire escapeways may expose miners unnecessarily to physical strain. An evacuation may involve a combination of travel modes, including both mechanized transportation and walking. MSHA encourages rapid evacuation of all miners in an emergency. In most cases, this will involve the use of mechanized transportation. The unique characteristics of the escapeways, conditions caused by the emergency, or required training such as physically locating lifelines and SCSRs, however, may prevent the use of mechanized transportation. Walking may be necessary in those circumstances. In response to commenters' concerns, the final rule includes a performance-based requirement that miners travel the escapeway, including traversing or negotiating specific portions and switching escapeways, as applicable. This means that miners will walk certain portions to complete the required training, such as in physically locating and practicing the use of lifelines.

(iv) Section 75.1504(b)(4) Review of Emergency Escapeway Maps and Plans. Final rule § 75.1504(b)(4) combines requirements for a review of the mine and escapeway maps, the firefighting plan, and the mine emergency evacuation plan in effect at the mine

[6] NIOSH. ''Judgment and Decision-Making under Stress: An Overview for Emergency Managers,'' (Kowalski and Vaught, YEAR).

[from existing §§ 48.8(b)(4), 75.383(b)(4), and 75.1502(a)]. In § 75.1504(b)(4)(i), the final rule requires the operator to inform miners of the locations of fire doors, check curtains, changes in the routes of travel, and plans for diverting smoke from escapeways. In § 75.1504(b)(4)(ii), the final rule requires that, in reviewing maps and plans, the operator train miners in locating abandoned areas, escapeways, exits, and routes of travel to the surface, including the location of continuous directional lifelines or equivalent devices. This training complements § 75.1504(b)(3) by having miners learn to locate on the mine map the key items that they must physically use or locate during the realistic escapeway drill.

(v) Section 75.1504(b)(5) Firefighting Training. Final rule § 75.1504(b)(5) combines requirements for training miners on the operation of the fire suppression equipment available in the mine and the location and use of firefighting equipment and materials [from ETS § 75.1502(a)(1)(v) and (vi)]. This paragraph contains no new requirements.

(d) Section 75.1504(c) Annual Expectations Training. Section 75.1504(c) is a new requirement that provides miners with a realistic experience of using an SCSR in an emergency situation. MSHA is concerned that miners do not always understand what to expect when using an SCSR. The SCSR expectations training requires the miner to don and transfer an SCSR in smoke, simulated smoke, or an equivalent environment. It also requires the miner to breathe through a realistic SCSR training unit or an equivalent device that provides the actual sensation of SCSR airflow resistance and heat.

In 2005, NIOSH provided a guidance document to the mining industry that identifies training techniques for increasing skill levels of miners. NIOSH concluded that training is more effective when it is both realistic and experiential.[7] Training that provides the miner with a more realistic experience of both the physical and emotional challenges that the miner may encounter in an actual life-threatening emergency is commonly referred to as ''expectations'' training. NIOSH[8] has been conducting trials with non-toxic smoke in underground mines. NIOSH notes that—

> Quality training enhances the awareness of mine fire hazards and promotes self-confidence. One of the strong points of the underground smoke training exercise was that miners felt they were better prepared for a real life situation.

While the NIOSH research was conducted in underground mines, MSHA recognizes that conducting SCSR smoke training in an active mine may be difficult, and agrees with commenters that, in most cases, this training can be provided on the surface. MSHA expects that some state agencies and private vendors will develop portable expectations training facilities that can be brought to a mine for this training.

In response to recent mine accidents requiring emergency evacuation of the mine in a toxic environment, MSHA has determined that miners need SCSR expectations training. The final rule requires this training annually. Expectations training can be used to comply with the requirements for donning and transferring the SCSR under paragraph (b)(1) as part of a mine emergency evacuation drill.

In the preamble and in the opening statement at the public hearings, MSHA asked whether it would be more instructive to conduct a more realistic drill. As an example, MSHA suggested using smoke, or a realistic mouthpiece that provides the user with the sensation of actually breathing through an SCSR. In general, the responses to this question were supportive. Commenters recognized that training is more effective when it is more realistic. One commenter said that realistic training would be more meaningful. One commenter stated that, for the best results, the drill should require the same action as if it were a real emergency. Another commenter, who had received SCSR training in smoke, said ''I want to be as sincere as possible when I tell you that this was the single most enlightening experience of my 35 years underground.'' Several commenters were concerned that conducting training in smoke would be hazardous to the miners and another was concerned that providing this training in an underground mine would be difficult. As indicated by several commenters, in most cases, this training is better when conducted on the surface in an environment that can be controlled. Commenters recommended a truck or trailer designed for this training and the possibility of developing additional simulation laboratories in the coal fields where miners could go to receive SCSR expectations training.

While some mine operators or training facilities may use actual smoke, it was never MSHA's intention to require this training to be done in actual smoke. Operators can use a non-toxic smoke, such as theatrical smoke, which is harmless. MSHA intends that this training help miners realize the burden of donning, transferring, and using an SCSR in conditions of low visibility and stress.

In § 75.1504(c)(2), the final rule requires a miner to participate in annual expectations training within one quarter of being employed at the mine. Likewise, for a miner returning to work after an absence during which the miner missed this training, the miner must receive the training within one quarter.

One issue with providing realistic SCSR training is the availability of ''live'' training units. Currently, there is only one manufacturer who has developed a prototype training unit; this unit is not yet in production. MSHA expects that, based on the requirements of this rule, other SCSR manufacturers will develop, produce, and market realistic SCSR training units. For this reason, in § 75.1504(c)(3), the final rule requires the mine operator to have a purchase order for realistic SCSR training units or devices within 30 days of notification by MSHA that the units are available. MSHA will notify mine operators of the availability of realistic SCSR training units and where to purchase them by publishing a notice in the **Federal Register**. The final rule also requires the operator to provide expectations training within 60 days of receipt of the units. MSHA will accept, as good faith evidence of compliance, purchase orders or contracts to buy realistic SCSR training units.

e. Section 75.1504(d) Certification of Drills. The final rule retains the requirement that the mine operator certify, by signature and date, that the mine emergency evacuation training and drills were held in accordance with the requirements of this section. The final rule also retains the ETS requirements that mine operators keep the certifications for one year and make them available to authorized representatives of the Secretary and to miners' representatives.

The final rule expands the certification to include foremen traveling both escapeways prior to assuming their duties and annual expectations training for all miners. The final rule also expands the certification to require that it be made at the completion of each quarterly drill, annual expectations training, or other training. The certification must identify miners, by name, who participated in each emergency evacuation training and drill or other training. For each miner, the certification must list the content of

[7] NIOSH, ''Fire Response Preparedness for Underground Mines,'' *Informational Circular IC 9481, 2005.*

[8] NIOSH, ''Emerging Technologies: Aiding Responders in Mine Emergencies and During the Escape from Smoke-Filled Passageways,'' 2002.

the drill completed, including the escapeway traveled and scenario used.

The final rule also adds a requirement that the operator provide each miner a copy of the certificate for his or her own training when the miner requests a copy. This requirement reflects industry practice to provide the miner access to and a copy of his or her own training record at no cost to the miner.

In the opening statement at the public hearings, MSHA specifically asked whether the training record for the mine emergency evacuation training and drill should include additional information, such as a checklist. MSHA stated that the checklist could be used to itemize the successful completion of each step of the training, as outlined in the approved program of instruction. Considering the number of aspects to be addressed in each drill and the flexibility built into the various requirements, MSHA expects that mine operators would need to keep track of this training to facilitate compliance.

Commenters generally supported a checklist as an effective tool for managing and evaluating this training; however, they felt that a checklist should be optional. Commenters recognized the usefulness of a checklist to itemize the successful completion of each step of the training and for keeping track of those components of the drills that change, such as scenarios. They stated that a checklist helps assure that the training and drills include all the topics that are required by the standard. Another commenter stated that—

> When you use that checklist, if there is something people struggle with, it gives you that information. You know where to focus your efforts, particularly in between drills.

One commenter further stated that developing performance-based checklists that identify self-escape competencies would be a valuable tool to evaluate the proficiency of miners. Others stated that checklists can vary in size and complexity; that a checklist is not the only way to manage; a list of names, simply put on paper, does nothing for anyone. Another commenter stated that the energy required for maintaining these checklists could be better spent on training miners rather than dealing with another recordkeeping issue.

Although acknowledging that a checklist of activities is beneficial, one commenter was convinced that ''requiring this limited documentation is ineffective for assuring that the training was successfully performed, in whole or in part.'' This commenter said that MSHA has a responsibility beyond paperwork compliance to ensure that the training was conducted. This commenter also cited several examples of cases where the recordkeeping was kept, but the training was not completed. This commenter recommended that, to ensure that evacuation training and drills are completed, MSHA must be present to witness this activity.

In response to comments, the final rule does not include a requirement for a checklist. MSHA does recommend, however, that mine operators develop a system to help manage these drills. MSHA expects that mine operators will use some type of system, such as a checklist or other effective alternative, to track the completion of the various components of these drills for each miner, so as to assure that all miners receive the required training. The final rule lists the information to be included on the training certificate, but does not specify how the operator is to keep track of this information. To facilitate operator compliance with the drill requirements, MSHA will develop a sample checklist and make it available in the Compliance Guide for this final rule, which will be posted on MSHA's Web site at *http://www.msha.gov*.

6. Section 75.1505 Escapeway Maps [Existing § 75.383(a)]

The final rule transfers the escapeway map requirements in § 75.383(a) to § 75.1505. This change is administrative only. MSHA received no specific comments on transferring this paragraph.

7. Section 75.1714 Availability of Approved Self-Rescue Devices; Instruction in Use and Location

The final rule revises § 75.1714(b) to clarify that all persons must have SCSR donning and transferring training before going underground. This administrative change eliminates duplication of requirements and potential confusion or conflicts.

8. Sections 75.1714–2(f), 75.1714–2(g)(2), and 75.1714–4(e) Identification and Directional Signs for SCSR Storage Locations

Like the ETS, final §§ 75.1714–2(f), 75.1714–2(g)(2), and 75.1714–4(e) require signs made of reflective material to identify SCSR storage locations and to direct miners to those locations. The requirements for these signs were similar for all three provisions in the ETS; MSHA evaluated the comments accordingly.

One commenter thought the requirement for direction signs was vague ''as to where these signs should be posted.'' A more specific requirement for posting direction signs leading to an SCSR storage location would be counterproductive because the location for storing SCSRs will vary from mine to mine. Each mine operator must determine the best place for hanging these signs, considering the condition of the area surrounding the storage locations.

MSHA specifically requested comments in the ETS preamble and at the public hearings, on the appropriateness of requiring reflective signs to help locate SCSR storage locations and whether alternative methods are available for making storage locations easier to locate when conditions in the mine might obscure visibility. Many commenters agreed that reflective signs could be useful. One commenter thought that SCSR storage locations should have reflective doors, or the doors should be outlined in reflective material, so that miners could find SCSRs even if they were crawling. Some commenters pointed out that reflective signs would not be useful when thick smoke was present and that other steps would be needed, or that other options, such as strobe lights, sirens, or attaching lifelines to the SCSR storage containers, should be allowed. Other commenters thought that strobe lights were not necessary and could present an explosion hazard in the presence of methane.

While MSHA realizes that reflective signs may not be helpful in all situations, the requirement that a sign be made of a reflective material enhances miner safety by increasing the visibility of SCSR storage locations and by making them easier to locate. The reflective quality provides an advantage, such as when power is out in the mine: reflective signs allow the miner to locate an SCSR and evacuate the mine more quickly. A cap-light or outside light can reflect off the sign making it much more visible than one not made of a reflective material. For this reason, the final rule retains the requirement that signs identifying SCSR storage locations and directing miners to these storage locations be made of reflective material.

Although the ETS did not revise the words required to be displayed, MSHA received many comments requesting that MSHA allow signs to use the term ''SCSRs'' instead of ''SELF-RESCUER'' or ''SELF-RESCUERS.'' One commenter stated that MSHA was being too prescriptive in requiring such specific wording. These commenters stated that the term ''SCSRs'' is used industry-wide.

The terms required to be displayed on the signs predated the ETS: § 75.1714–2(f) required the signs to say ''SELF-

RESCUER'' or ''SELF-RESCUERS'' and § 75.1714–2(g)(2) required the signs to say ''SELF-RESCUERS.'' The purpose for requiring signs to display specific terms is to maintain consistency throughout the underground coal mining industry. Requiring consistent wording enhances safety by helping to ensure that, in an emergency situation, a miner will be able to readily identify where SCSRs are stored, even when the miner works at a different mine. MSHA agrees with commenters that ''SCSR'' is a commonly used term; therefore, the final rule permits the use of either term, ''SCSRs'' or ''SELF-RESCUERS,'' to indicate the location of stored SCSRs.

Final § 75.1714–2(f) inserts a provision inadvertently omitted from former § 75.1714–2(f) when the ETS was published. That requirement read, ''If a SCSR is not carried out of the mine at the end of a miner's shift, the place of storage must be approved by the District Manager.'' Since the requirement was inadvertently omitted, the ETS did not discuss it. MSHA received no comments on the omission. Therefore, this final rule adds the omitted portion of former § 75.1714–2(f).

9. Section 75.1714–4 Additional Self-Contained Self-Rescuers

Final § 75.1714–4 addresses the need to provide and store additional SCSRs that will offer protection for the maximum number of people in the mine if an emergency occurs. The final rule revises the ETS requirements for additional SCSRs and the location of stored SCSRs. Changes to this section include: revised methods for determining SCSR storage locations in each escapeway and for miners who do not have a fixed work location; and, removing the requirement to provide an outby storage plan. The final rule also makes non-substantive editorial changes.

a. Additional SCSRs in Work Places. Final § 75.1714–4(a) retains the ETS requirement that mine operators provide all persons with an additional SCSR at their underground work locations. Section 2 of the MINER Act reiterated the ETS requirement. MSHA revised the ETS to clarify requirements for providing additional SCSRs to persons who do not work at a fixed location by adding § 75.1714–4(a)(2).

Specifically, MSHA was concerned that persons who work alone in various parts of the mine, i.e., pumpers and examiners, could not carry an extra SCSR with them and generally did not have access to an additional SCSR. For this reason, in the preamble and its opening statement at the public hearings, MSHA requested comment on how SCSR storage locations could be made readily accessible to persons with no fixed work location, such as pumpers, outby crews, and examiners working underground.

Some commenters stated that the SCSR storage locations should be figured on a mine-by-mine basis due to the different mine conditions and situations. Other commenters suggested that these locations should be addressed in the outby SCSR storage plan. Another commenter suggested using the time-distance tables in MSHA's Program Policy Manual (PPM), Volume 5, § 75.1714–2, ''Self-Rescue Devices; Use and Location Requirements,'' for pumpers and examiners; outby crews, such as belt maintenance and supply personnel; and others who are similarly situated.

MSHA considered these comments and adds a requirement in final § 75.1714–4(a)(2) that the mine operator store additional SCSRs along the normal travel routes for pumpers, examiners, and other persons who do not have a fixed work location. These SCSRs must be stored at a distance no greater than the average miner could walk in 30 minutes. The final rule uses the 30 minute SCSR storage location spacing to be consistent with the MINER Act requirement for escapeways. The distance between SCSR storage locations must be determined by using one of the methods found under paragraph (c)(2) of this section.

b. Additional SCSRs on Mantrips. Final § 75.1714–4(b) retains the requirement from the ETS that all persons using a mantrip or mobile equipment to enter or exit the mine have an additional SCSR, which provides protection for one-hour or longer, available from portal to portal. At many mines, persons use mantrips or mobile equipment, such as scoops, ramcars, or pick-up trucks, to enter or exit the mine and travel to and from their working station. A mine accident or emergency that requires evacuation could occur while crews are traveling. If miners traveling on mantrips or mobile equipment are using filter self-rescuers they must be provided with two SCSRs, each of which provides protection for a period of one hour or longer. If SCSRs with a capacity of less than one hour are worn by miners, the additional SCSR required by § 75.1714–4(b) may be stored along the escapeway at intervals that are readily accessible to the miners.

Mine operators may use additional SCSRs stored on the mantrip or mobile equipment to comply with § 75.1714–4(a) for persons either at a fixed work location or a non-fixed location, if the mantrip stays on the section or near the work location. If the mantrip leaves the section or the work location, the operator can comply with § 75.1714–4(a) by removing the SCSRs from the mantrip and keeping them on the section or near the work location.

One commenter strongly agreed with the requirement to have additional SCSRs available on the mantrip or mobile equipment, and stated that the explanation made ''great sense.'' Another commenter stated that some MSHA districts were misinterpreting the requirement in that they were requiring the mine operator to supply two SCSRs per employee on the personnel carrier if a one-hour belt-wearable unit was not employed. Another commenter believed that this requirement limits the option of wearing a unit smaller than a one-hour unit for ergonomic reasons. The commenter stated that the provision should permit each personnel carrier to store one hour of oxygen for each person traveling on that vehicle provided that the travel distance to exit the mine on the vehicle's normal route is no further than an average miner can walk in 30 minutes.

MSHA has considered these comments and the final rule retains the ETS requirement that an additional SCSR be available to all miners traveling on mantrips or mobile equipment. All miners are required to have two SCSRs available to them while using mechanized transportation to or from their work locations.

c. Additional SCSRs in Escapeways. Final § 75.1714–4(c) retains the ETS requirement that the mine operator store additional SCSRs in the required escapeways when each person underground cannot safely evacuate the mine within 30 minutes. MSHA has changed this provision to be consistent with the MINER Act by specifying that the spacing between SCSR storage locations in each required escapeway be no greater than the distance an average miner can walk in 30 minutes. As discussed later in the preamble, the final rule provides two methods for determining spacing.

(i) Additional SCSRs. Final § 75.1714–4(c)(1) retains the ETS requirement that each SCSR storage location in the required escapeways contain at least one SCSR, which provides protection for a period of one hour or longer, for every person who will be inby that location.

(ii) Spacing of Stored SCSRs. ETS § 75.1714–4(c) required the mine operator to submit an outby SCSR storage plan to the appropriate District Manager for approval. The final rule eliminates the requirement for an outby

SCSR storage plan because it will be addressed in the Emergency Response Plan required by Section 2(b) of the MINER Act.

Final § 75.1714–4(c)(2) provides two methods for determining the 30-minute spacing of SCSRs storage locations in escapeways. The first method, found in final § 75.1714–4(c)(2)(i), requires the mine operator to calculate the spacing based on a sample of typical miners walking a selected length of each escapeway. A sample of typical miners is a cross-section of the population of all miners who would have to evacuate the mine and use the SCSRS stored in the escapeways. In general, operators using this option must use a sample that includes miners of various ages, weights, levels of physical fitness, and smoking habits; and a selected portion of the escapeway that reflects entry height, slope, and underfoot conditions representative of the entire escapeway.

The second method, found in final § 75.1714–4(c)(2)(ii), requires a mine operator to use a table that specifies maximum SCSR storage location spacing based on average entry height, except escapeways with grades over 5 percent. This table is based on statistical data collected from the MSHA–NIOSH study from 1997.[9]

(iii) Comments on Performance-Based Approach to Spacing of SCSR Storage Locations. The ETS included a ''heart-rate method'' as an option for determining SCSR storage location spacing. Many commenters stated that they were ''very concerned about this suggested method,'' and did ''not believe it is practical, effective or reliable to expect those working underground to determine a 'worst case scenario.' '' These commenters stated that the heart rate method required a judgment about which miner appears to be the slowest to evacuate. These commenters also stated that the slowest miner could change from day to day, depending on the employees available, whether someone was injured, or even whether one miner did not feel well on a particular day. Some commenters were concerned that requiring the miner to participate in the ''heart-rate'' test would be hazardous to the miner's health.

Although some commenters favored the ''heart-rate method,'' commenters generally opposed solely using this method, but supported a performance-based approach. One commenter supported the heart rate method, but also suggested a combination of methods. This commenter stated that the age and size of a miner (factors of the heart rate method) could be combined with the 2,500 to 5,000 foot requirements (escapeway intervals posed in the ETS based on the average entry height), with storage being located at the shorter distance. Other commenters stated that escapeway conditions vary; yet timed walks can provide necessary information to determine the distance between SCSR storage locations. One of these commenters stated that it was hard to imagine one standard that would work for every mine. One commenter stated that, for mine operators who do not want to conduct performance testing, prescriptive standards could be allowed as an alternative. One commenter suggested the actual capacity of the SCSR be used to determine the distances between SCSR storage locations, rather than the unit's certified capacity.

In response to comments, final rule § 75.1714–4(c)(2)(i) includes an option that allows the mine operator to calculate the distance between SCSR storage locations by using the average distance walked in 30 minutes over a typical length of each escapeway by a sample of typical miners. Because the MINER Act requires SCSR storage locations in escapeways to be no further than the average miner could walk in 30 minutes, MSHA has eliminated the ''worst case'' scenario as a requirement.

(iv) Comments on Prescriptive Spacing of SCSR Storage Locations. Many commenters were in favor of a prescriptive approach to determining spacing for SCSR storage locations. Commenters encouraged MSHA to set an objective standard to achieve uniformity throughout the industry. One commenter stated that MSHA should use a design type standard as the maximum required distance, and allow mine operators to use performance testing to decrease the distance of the storage locations. Another commenter stated that MSHA, NIOSH, and miners' representatives should determine, through studies, the specific distances between SCSR storage locations. This commenter opposed permitting different distances under storage plans because plans become ''unwieldy'' and the operator ''can't keep monitoring them constantly.'' This commenter stated further that mine operators do not need flexibility.

Some commenters suggested that MSHA incorporate the height/distance chart in MSHA's Program Policy Manual (PPM), Volume 5, § 75.1714–2, ''Self-Rescue Devices; Use and Location Requirements,'' into this final rule. Commenters stated that the chart has been used to convert travel time to distance and could be used for that purpose in the final rule. Other commenters stated that the West Virginia chart, which was originally developed by MSHA, should be the standard used. Some commenters stated that this issue was made moot by the new MINER Act, which states that the self rescuer distances are based on the distance that an average miner can travel in 30 minutes.

Some commenters, however, stated that a prescriptive standard would not be appropriate because it is uniform across all mines and mining conditions, regardless of differences. One commenter stated that prescriptive standards of this sort are inherently inaccurate and fail to take account of numerous relevant variables, such as seam height, or other unique mine characteristics, as well as the physical condition of the miners involved in evacuations. The commenter quoted MSHA's compliance guide (Volume 2, at Q. 26), in which MSHA stated that such uniform specifications ''do not take into account the slope of the escapeway, travel conditions, or the age of the escaping miner.''

In response to comments and to retain flexibility, MSHA developed a table that provides maximum distances for spacing SCSR storage locations in § 75.1714–4(c)(2).

(d) Additional SCSRs in Hardened Rooms. The final rule adds an alternative in § 75.1714–4(d) to allow mine operators to store SCSRs between adjacent escapeways in a hardened room.

MSHA asked, in its opening statement at the public hearings, if there were circumstances under which it would be appropriate to share SCSRs between adjacent escapeways in a hardened room or ''safe haven'' that is constructed using permanent seal techniques. Several comments were received that were both for and against this alternative. Some commenters preferred to store one SCSR per miner in a structure between adjacent escapeways that was accessible through doors from either escapeway.

MSHA has considered these comments and determined that allowing one SCSR per miner to be stored between adjacent escapeways, which would serve both escapeways, can provide improved protection for miners if certain conditions are met. The SCSR storage location must be secured against damage from explosions in either escapeway. Requiring that the hardened room be designed and constructed to the same explosion force criteria as seals can provide greater protection than

[9] MSHA–NIOSH study, ''The Oxygen Cost of a Mine Escape'' (Kovac, Kravitz, and Rehak, 1997).

SCSR storage arrangements in escapeways.

The final rule also requires that the hardened room contain an independent source of air. At this time, MSHA has reviewed several alternatives for providing independent, positive pressure ventilation from the surface to a hardened room. Some of these alternatives include: (1) A vertical bore hole from the surface; (2) directionally drilled holes and suitable piping within the mine; or (3) a robust insulated compressed air distribution system.

These hardened rooms would provide a smoke-free environment for transferring SCSRs and communicating with the surface and with other miners. This would facilitate SCSR transfer and miners' successful evacuation. The agency expects that, on balance, hardened rooms would not usually be a less costly alternative. MSHA does believe that this alternative would provide for improved safety. If an operator intends to use a hardened room for SCSR storage between escapeways, the location and construction parameters must first be included in the mine's ventilation plan approved by the District Manager.

e. Storage Location Accessibility. Final § 75.1714–4(e) retains the ETS requirement that all SCSRs be stored according to manufacturers' instructions in locations that are conspicuous and readily accessible by each person in the mine. Manufacturers' instructions are included in the documentation for all SCSRs submitted to MSHA and NIOSH for approval under 42 CFR part 84. Additionally, the instructions are included with all SCSRs from each manufacturer.

The first ETS Compliance Guide, *Training Questions for Emergency Mine Evacuation,* contains guidance on how to make the storage location conspicuous. This requirement minimizes the time it takes a miner to locate an SCSR when it is needed following an accident or emergency. An SCSR conspicuously stored or readily accessible could make the difference between the success or failure of an emergency mine evacuation.

The manufacturer's instructions for a specific type of SCSR include a shake test, to check the integrity of the internal SCSR chemical beds, for SCSRs not transported or carried by the miner. Several commenters requested that MSHA eliminate the shake test. Because the shake test is included in the instructions for maintaining the reliability of the SCSR and is included as a condition of its approval, failure to conduct the shake test would invalidate the SCSR approval under 42 CFR part 84. As such, MSHA has no authority to eliminate this requirement. The final rule requires inspections and tests of SCSRs to be implemented according to the manufacturer's instructions. For certain SCSRs, this includes a shake test every 90 days.

10. Section 75.1714–5 Map Locations of Self-Contained Self-Rescuers

Final § 75.1714–5 retains the requirement for the mine operator to mark the SCSR storage locations on the § 75.1505 (formerly § 75.383) posted mine escapeway map and on the § 75.1200 mine map. Mine maps help assure that all persons are aware of the storage locations of all SCSRs in the mine and the § 75.1200 mine map is used for mine rescue response.

11. Section 75.1714–6 Emergency Tethers

Final § 75.1714–6 is a new requirement and addresses MSHA's concern that miners not become separated when escaping from a smoke-filled environment. Tethers are durable ropes or equivalent material designed to permit members of a mine crew to link together while evacuating the mine during an emergency. The final rule requires that at least one tether, of sufficient length to link together members of a mine crew, be placed with the additional SCSRs stored at fixed underground work locations and on mobile equipment used to enter or exit the mine. If the mining conditions require miners to walk out of the mine, tethers will help keep individual miners from becoming separated from the crew. Tethers, however, do not have to be stored with the additional SCSRs for pumpers, examiners, and other persons who generally work alone.

In the ETS preamble and in the opening statement at the hearings, MSHA requested comments on whether miners should have the ability to tether themselves together during escape through smoke-filled environments. MSHA also asked for input regarding storage, method of attachment, and placement of tethers. Commenters generally supported a requirement that tethers be made available for miners to use, but did not want MSHA to require their use. Commenters expressed a variety of opinions as to where tethers should be stored. Some stated that tethers should be stored at the beginning of the lifelines. Commenters did not support prescriptive requirements for tether construction. They believed that this should be left to the discretion of the mine operator.

MSHA agrees that specific requirements for the length, method of attachment, and other details of construction should be left for the mine operator to address based on the specific needs and conditions of the mine. In response to commenters' concerns, the final rule provides miners with the capability of tethering together, but does not require miners to use them.

12. Section 75.1714–7 Multi-Gas Detectors

Final § 75.1714–7 is a new requirement and addresses MSHA's concern that miners make a more informed decision about when to don an SCSR. This section requires that the operator provide an MSHA-approved, handheld, multi-gas detector, which can measure methane, oxygen, and carbon monoxide, to each group of miners and to each miner working alone; that at least one miner in each group be a *qualified person* under § 75.150; and that each miner working alone be trained to use the detectors to take gas readings and to interpret the readings. In addition, the detector must be maintained and calibrated as specified in existing § 75.320.

During the ETS hearings, MSHA asked for comment on whether mine operators should be required to provide miners with handheld, multi-gas detectors in connection with MSHA's request for comment about when miners should don their SCSRs. MSHA was concerned that during a mine emergency, a miner might have difficulty determining when to don an SCSR. A toxic gas or reduced oxygen levels can be colorless and odorless; often, these potentially fatal hazards are undetectable without the use of a gas or air-quality detector. MSHA is requiring approved, handheld, multi-gas detectors to enable miners to measure critical mine gases during an emergency.

MSHA received a variety of comments on this issue. One commenter stated that MSHA should immediately mandate this requirement. Multiple commenters stated that this requirement would be burdensome to comply with for each person, but thought that it would be a good idea for section crews and other groups. One commenter thought that the requirement was a good one, but was concerned about monthly calibration for that amount of equipment. This commenter also expressed concern about miners needing training to use the multi-gas detectors. Commenters suggested that a patch that changed color or some other indicator of harmful levels of carbon monoxide would be helpful.

While personal monitors or badges may assist in the decision to don an SCSR, no product of this type is

currently approved by MSHA for use in underground coal mines. A multi-gas detector is a viable alternative. MSHA-approved, multi-gas detectors can simplify measuring gasses because separate detectors for each gas would have different operating instructions and calibration procedures requiring additional burden. Generally, this requirement can be satisfied by units that are already in use in the coal mines. Existing standards require that tests be made for excess methane, oxygen deficiency, and carbon monoxide, and that a qualified person take these measurements.

MSHA received many comments on the issue of when miners should don SCSRs. Commenters stated that individuals working alone could be instructed to don an SCSR when smoke was encountered. Several commenters thought that MSHA should allow more than one way to comply with the requirement of when miners should don an SCSR. These commenters suggested that donning occur as follows: When smoke is visible; if elevated carbon monoxide is detected; if low oxygen is detected; if directed by the supervisor; or if the mine-wide Atmospheric Monitoring System, coupled with an effective communication system, advised the miner of the need to don. Commenters acknowledged the benefit of donning an SCSR at the first sign of fire, but also acknowledged the benefit of ''knowing'' the atmosphere to make an informed decision.

MSHA has considered these comments, and includes final § 75.1714–7 in response to them. MSHA agrees that miners should don SCSRs when any of the conditions suggested by the commenters exist or if miners experience any other emergency situation where they feel that they may need respiratory protection. A handheld, multi-gas detector that can measure methane, oxygen, and carbon monoxide will enable miners to measure critical mine gases during an emergency and increase their chances of survival. Miners in a group can warn each other and help each other if one loses consciousness. A miner working alone also needs a multi-gas detector to help determine when to don an SCSR. Without the multi-gas detector, by the time a miner working alone realizes that carbon monoxide levels are high or oxygen levels are low, the miner may be unable to don an SCSR. In fact, it is possible for the miner to lose consciousness without ever realizing that the air is irrespirable.

13. Section 75.1714–8 Reporting SCSR Inventory and Malfunctions; Retention of SCSRs

Final § 75.1714–8 addresses new reporting requirements in response to MSHA's concern that the Agency did not always learn of problems associated with SCSRs, or did not learn of them in a timely manner. In addition, often, when MSHA was able to identify a problem, MSHA had difficulty in locating affected SCSRs for recalls. This final rule includes requirements for maintaining and reporting an inventory of all SCSRs at the mine, reporting problems with SCSRs, and retaining defective SCSRs for possible investigation.

a. Inventory Requirements. In new § 75.1714–8(a), the final rule requires a mine operator to provide MSHA with a complete inventory of all SCSRs at each mine. Operators must submit the inventory within the first quarter of 2007 for existing mines and within 3 months of beginning operation for new mines. Final § 75.1714–8(a)(1) requires that the inventory include the mine name, MSHA mine identification number, mine location, and, for each SCSR, the manufacturer, the model type, the date of manufacture, and the serial number. Final § 75.1714–8(a)(2) requires the mine operator to update the inventory. The operator must report a change to MSHA within the quarter that the change occurred. This requirement keeps the database current and assists the mine operator in complying with 30 CFR § 75.1714–3. Also, consistent with other sections of this final rule, this provision specifies calendar quarters for reporting, *i.e.*, Jan–Mar, Apr–Jun, Jul–Sep, and Oct–Dec.

In the past, MSHA has discovered problems with all brands of SCSRs. Sometimes, these problems were related to specific production runs that generated unique serial numbers for the SCSRs. Sometimes, the problems affected SCSRs from one manufacturer. During past recalls, MSHA had problems locating outdated or nonworking SCSRs. MSHA inspectors had to travel to each mine to examine each SCSR to make sure all affected devices were actually removed from service. With the ETS and the MINER Act requiring a significant number of additional SCSRs, a centralized database can facilitate the identification of problem SCSRs. MSHA can then expeditiously inform the affected mine operator and ensure that these SCSRs are removed from service before miners attempt to use them in a mine emergency.

b. Reporting Problems and Malfunctions. New § 75.1714–8(b) requires mine operators to report SCSR defects, performance problems, and malfunctions to MSHA. The report must include a detailed description of the problem and the inventory data required under § 75.1714–8(a)(1). The purpose of this reporting requirement is to help assure that MSHA is notified of problems associated with SCSRs in a timely manner, thus facilitating MSHA's investigation of the problems. MSHA's past experience in dealing with malfunctioning SCSRs, or SCSR-related problems, demonstrates the Agency's need to be notified.

For example, a national recall of all SCSRs containing breathing tubes was conducted following an MSHA investigation of a problem. At that time, a miner used an SCSR that had a deteriorated breathing tube that failed to protect the miner. The miner suffered smoke inhalation and required emergency medical treatment. In an effort to determine whether it was an isolated problem, MSHA opened additional SCSRs at the mine and identified three more unusable units. This discovery resulted in the manufacturer recalling these breathing tubes and replacing them.

c. Retention of Reported SCSRs. New § 75.1714–8(c) requires the mine operator to retain the affected SCSR for 60 days after reporting a problem to MSHA. The purpose of this retention requirement is so that the affected SCSRs are available for examination and testing, as applicable. Preserving the SCSR is accomplished by placing it in an air-tight, sealed, plastic bag. After MSHA evaluates the problem SCSR, the Agency will make the results of the evaluation available.

d. Comments on New Reporting Requirements. In the ETS and hearings, MSHA requested comments on several reporting requirements:

- The appropriateness of requiring mine operators to report the total number of SCSRs (inventory) in use at each underground coal mine, semi-annually, to the MSHA District Manager;
- Requiring the inventory to include additional information for each SCSR, i.e., the manufacturer, the model, the date of manufacture, and the serial number;
- Requiring the mine operator to promptly report to the MSHA District Manager, in writing, all incidents where any SCSR, required by this section or existing § 75.1714, was used for an accident or emergency; and
- The reporting of all instances where an SCSR device did not function

properly and retaining the device for 90 days.

MSHA received a number of responses on the Agency's solicitation of comment on SCSR inventory. Many commenters thought that a need existed to track SCSRs because of the way companies sold and swapped SCSR units. Many commenters supported tracking the information, but stated that, while the requirement could provide useful data, they were against sending a report to MSHA. Some commenters mentioned that they would find the inventory requirement burdensome. Some commenters pointed out that neither a citation nor fine for failure to report would necessarily improve safety or the ability [of a miner] to survive an emergency. Some commenters also added that the information should be available on an information-sharing basis only. Another commenter stated that MSHA would have to allocate more resources to investigate reports and would have to provide a more efficient reporting system, such as electronic filing on the MSHA Web site.

MSHA agrees with commenters who stated that, with the increased numbers of SCSRs in the mine, an inventory system would be useful to mine operators for tracking SCSR use and location. An inventory system would facilitate mine operator's compliance with § 75.1714–3, which requires operators to track the use, maintenance, and service life of SCSRs. Also, this inventory system would assure that problem SCSRs are removed from mines expeditiously because MSHA would inform the affected mine operators.

MSHA has determined that it is necessary to create an SCSR database that is easily searchable and up-to-date to improve miner health and safety. In implementing this provision, MSHA intends to have an interactive Web site that will permit mine operators to upload inventory information electronically. For those who may not have electronic access, MSHA will accept paper copies of the inventory. MSHA will provide compliance information to mine operators to assist in meeting this requirement.

Several commenters thought that having a bar code on SCSRs would be useful. MSHA agrees that bar codes would be helpful; however, manufacturers do not currently identify SCSRs by bar code. MSHA, therefore, does not require it at this time.

MSHA received a number of comments in response to its question about the reporting of all problems of SCSR use. Commenters pointed out that this requirement would be useful to properly evaluate each model and manufacturer; that it might give an early warning of a defect; and that it would lead to developing essential information regarding the reliability of SCSRs and the effectiveness of miner training in using SCSRs. Some commenters thought that the best way for MSHA to obtain reliable statistics concerning the performance of SCSRs and to respond accordingly, would be to obtain the information on an ongoing and timely basis.

MSHA agrees with these commenters. The final rule requires mine operators to report SCSR defects, performance problems, and malfunctions to the Agency.

III. Derivation and Distribution Tables

This final rule combines, moves, and eliminates a number of requirements. The *Derivation Table* shows the source of the provisions in this final rule for requirements that are new or re-numbered. The *Distribution Table* shows the new location of existing requirements that were re-numbered or deleted.

TABLE 1.—DERIVATION OF REQUIREMENTS IN THIS FINAL RULE

Final rule section	ETS or existing sections
75.1502	75.1502(a) and (d).
75.1503	75.1502(b).
75.1504	75.383(b) and 75.1502(c).
75.1504(c)	NEW.
75.1505	75.383(a).
75.1714–4(d)	NEW.
75.1714–6	NEW.
75.1714–7	NEW.
75.1714–8	NEW.

TABLE 2.—DISTRIBUTION OF MOVED OR REMOVED SECTIONS OF ETS AND EXISTING STANDARDS

ETS or existing section	Final rule section
75.383(a)	75.1505.
75.383(b)	75.1504.
75.383(c)	DELETED.
75.1502(a)	75.1502.
75.1502(b)	75.1503.
75.1502(c)	75.1504.
75.1502(c)(4)	DELETED.
75.1502(d)	75.1502.

IV. Executive Order 12866

Executive Order (E.O.) 12866 (58 FR 51735) as amended by E.O. 13258 [Amending Executive Order 12866 on Regulatory Planning and Review (67 FR 9385)] requires that regulatory agencies assess both the costs and benefits of regulations. To comply with E.O. 12866, MSHA has prepared a Regulatory Economic Analysis (REA) for the final rule. The REA contains supporting data and explanation for the summary materials presented in sections IV–VII of this preamble, including costs and benefits, feasibility, small business impacts, and paperwork. The REA is located on MSHA's Web site at *http://www.msha.gov/REGSINFO.HTM.* A printed copy of the REA can be obtained from MSHA's Office of Standards, Regulations, and Variances.

Based on the REA, MSHA has determined that the final rule will have an annual effect of $100 million or more on the economy in the first year it is in effect. Therefore, it is an economically ''significant regulatory action'' pursuant to § 3, paragraph (f) of E.O. 12866.

A. Population-at-Risk

Using 2004 data, the final rule applies to the 634 underground coal mine operators employing 33,490 miners and 3,697 contractor workers who work underground in coal mines. Also, using 2004 data, the immediate notification provisions of the final rule apply to the entire mining industry, encompassing all 214,450 miners and 72,739 contractor workers who are employed in the 14,480 U.S. mines.

B. Compliance Costs

MSHA estimates that the final rule will result in total yearly costs (including those yearly costs that are associated with the March 9, 2006 ETS) for the underground mining industry of approximately $44.1 million at a 7% discount rate and $41.1 million at a 3% discount rate, which include the amortized value of first-year costs of about $146.9 million.[10] Of the $44.1 million yearly costs, $2.8 million will be incurred by mine operators with fewer than 20 employees; $37.0 million by mine operators with 20–500 employees; and $4.3 million by mine operators with more than 500 employees. The breakdown of the $44.1 million yearly costs by type of provision is approximately as follows: $13.7 million for training requirements; $0.5 million for lifeline requirements; $29.8 million for SCSR requirements, which includes $0.45 million for new multi-gas detector requirements; and $5,000 for accident notification requirements.

Compliance with certain cost provisions in the final rule will be achieved as a result of prior compliance with the March 9, 2006 ETS. When yearly costs that are associated with the

[10] For the rest of this section, we report cost using only the 7% discount rate results. Please see the full REA for the disaggregated results using the 3% discount rate.

March 9, 2006 ETS are subtracted from the total yearly costs noted above, the net yearly costs of the final rule are approximately $39.7 million, which include the amortized value of first-year costs of about $83.0 million. Of the $39.7 million yearly costs, $2.6 million will be incurred by mine operators with fewer than 20 employees; $33.3 million by mine operators with 20–500 employees; and $3.8 million by mine operators with more than 500 employees. The breakdown of the $39.7 million yearly costs by type of provision is approximately as follows: $13.6 million for training requirements; $0.4 million for lifeline requirements; $25.8 million for SCSR requirements; and $5,000 for accident notification requirements.

For both the total yearly cost figures and the net yearly cost figures, nearly all of the yearly costs will be borne by underground coal mine operators. A negligible amount of yearly costs (less than $3,000), having to do with accident notification requirements in Part 50, will be borne by underground metal and nonmetal mine operators. MSHA expects that the final rule will impose no additional costs on surface coal or surface metal and nonmetal mine operators.

C. Benefits

To estimate benefits, MSHA focused only on the four accidents where it is reasonable to expect that miners' lives might have been saved by the final rule. These four accidents occurred at the Wilberg Mine in 1984; at Pyro No. 9 Slope, William Station Mine in 1989; at the Sago Mine in 2006; and at the Aracoma Alma No. 1 Mine, also in 2006. In these four accidents, there were, in total, 51 fatalities and one serious injury. One of the miners at Sago Mine died in an initial explosion and would have perished even if the final rule had been in force. Also, MSHA's investigation of the 1989 accident at Pyro No. 9 Slope, William Station Mine only provided enough evidence and testimony to establish that five of the ten fatalities could have been saved if the final rule had been in force. Whether the other five miners could have been saved by the final rule is speculative.

This leaves 45 fatalities that might have been prevented if the final rule had been in force. If this final rule had been in place at the time of these accidents, the lives of most or all of these victims could have been saved. In quantitative terms, perhaps 80 percent of miners in future accidents of like character could be saved by the final rule. Multiplying 45 by 80 percent provides an estimate of 36 lives that could have been saved by the final rule.

January 1, 1983, is the starting point for the accident records in MSHA's electronic Teradata database. Starting at January 1, 1983, and ending on March 9, 2006, the date when the ETS was published, is a time span of 23.2 years. Since these four accidents occurred during this 23.2-year period, dividing 36 lives saved by 23.2 years yields an estimate of 1.55 lives saved per year. A similar calculation provides an estimate of 0.034 serious injuries prevented per year. The actual number of miners' lives saved by the final rule could be much larger.

V. Feasibility

MSHA has concluded that the requirements of the final rule are technologically and economically feasible.

The final rule contains accident notification provisions, which apply to all mines. These provisions clarify existing requirements. Although they expand existing notification requirements to cover more underground mine fires, they present no compliance difficulties. As such, they are technologically feasible.

The final rule also involves the purchase, installation, and maintenance of lifelines; SCSRs; and evacuation and SCSR training. These requirements, which only apply to underground coal mines, are generally not technology forcing and would not involve activities on the frontiers of scientific knowledge. Most SCSRs and lifelines are proven technologies long available in the marketplace and already installed and used in the underground coal mining industry. Several provisions involve newly developed technology in the areas of realistic training units and flame-resistant lifelines; however, MSHA has provided delayed effective dates to facilitate operator compliance with these provisions.

The yearly compliance costs of the final rule ($44.1 million) are equal to 0.4 percent of all revenues ($11.1 billion in 2004) for all underground coal mines. In addition, about $3,000 of yearly compliance costs are attributable to underground metal and nonmetal mines. These yearly compliance costs are equal to well less than 0.01 percent of all revenues (approximately $4.6 billion in 2004) for all underground metal and nonmetal mines. Insofar as the total compliance costs are below one percent of the estimated revenues for both underground coal and underground metal and nonmetal mines, MSHA concludes that the final rule is economically feasible for these mines.

VI. Regulatory Flexibility Act (RFA) and Small Business Regulatory Enforcement Fairness Act (SBREFA)

Pursuant to the Regulatory Flexibility Act (RFA) of 1980 as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), MSHA has analyzed the impact of the final rule on small businesses. Based on that analysis, MSHA has made a determination with respect to whether or not the Agency can certify that the final rule will not have a significant economic impact on a substantial number of small entities that are covered by this rulemaking. Unless able to certify that the final rule will not have a significant economic impact on a substantial number of small entities, MSHA must develop a final regulatory flexibility analysis.

MSHA certifies that the final rule will not have a significant economic impact on a substantial number of small entities that are covered by this rulemaking. The factual basis for this certification is presented in full in Chapter V of the REA and in summary form below.

A. Definition of a Small Mine

Under the RFA, in analyzing the impact of a rule on small entities, MSHA must use the Small Business Administration (SBA) definition for a small entity or, after consultation with the SBA Office of Advocacy, establish an alternative definition for the mining industry by publishing that definition in the **Federal Register** for notice and comment. MSHA has not taken such an action and hence is required to use the SBA definition. The SBA defines a small entity in the mining industry as an establishment with 500 or fewer employees.

MSHA has also looked at the impacts of Agency rules on a subset of mines with 500 or fewer employees—those with fewer than 20 employees, which MSHA and the mining community have traditionally referred to as ''small mines.'' These small mines differ from larger mines not only in the number of employees, but also in economies of scale in material produced, in the type and amount of production equipment, and in supply inventory. Therefore, their costs of complying with MSHA's rules and the impact of the Agency's rules on them will also tend to be different. It is for this reason that ''small mines,'' as traditionally defined by MSHA as those employing fewer than 20 workers, are of special concern to MSHA.

This analysis complies with the legal requirements of the RFA for an analysis of the impacts on ''small entities'' while continuing MSHA's traditional definition of ''small mines.'' MSHA concludes that it can certify that the final rule will not have a significant economic impact on a substantial number of small entities that are covered by this rulemaking. MSHA has determined that this is the case both for mines affected by this rulemaking with fewer than 20 employees and for mines affected by this rulemaking with 500 or fewer employees.

B. Factual Basis for Certification

MSHA's analysis of impacts on ''small entities'' begins with a ''screening'' analysis. The screening compares the estimated compliance costs of a rule for small entities in the sector affected by the rule to the estimated revenues for the affected sector. When estimated compliance costs are less than one percent of the estimated revenues, the Agency believes it is generally appropriate to conclude that there is no significant economic impact on a substantial number of small entities. When estimated compliance costs exceed one percent of revenues, it tends to indicate that further analysis may be warranted.

Surface coal and surface metal and nonmetal mines are covered in the final rule only by the immediate notification provisions. These provisions do not impose any costs on surface coal and surface metal and nonmetal mine operators and contractors. MSHA, therefore, concludes that the final rule will not have a significant economic impact on a substantial number of small entities in these mine sectors.

For underground coal mines, estimated 2004 production was 10,375,660 tons for mines that had fewer than 20 employees and 312,531,849 tons for mines that had 500 or fewer employees. Using the 2004 price of underground coal of $30.36 per ton, the 2004 underground coal revenues are estimated to be approximately $315 million for mines employing fewer than 20 employees and $9.5 billion for mines employing 500 or fewer employees. Thus, for underground coal mines with fewer than 20 employees, the estimated yearly cost of the rule as a percentage of their yearly revenues is 0.87 percent ($2.75 million/$315 million). For underground coal mines with 500 or fewer employees the estimated yearly cost of the rule as a percentage of their yearly revenues is 0.42 percent ($0.04 billion/$9.5 billion). Using either MSHA's traditional definition of a small mine (one having fewer than 20 employees) or SBA's definition of a small mine (one having 500 or fewer employees), the yearly costs of the final rule for underground coal mines will be less than 1 percent of their estimated yearly revenues.

With respect to underground metal and nonmetal mines, MSHA anticipates no yearly costs for mines that have fewer than 20 employees and less than $2,000 in yearly costs, relative to revenues of $3.7 billion in 2004, for underground metal and nonmetal mines that have 500 or fewer employees. These yearly costs of the final rule for notifying MSHA of accidents at small underground metal and nonmetal mines, therefore, will be well less than 1 percent their yearly revenues.

Whether applying MSHA's or SBA's definition of a small mine, the estimated yearly costs of the final rule will be less than 1 percent of yearly revenues and, therefore, below the level suggesting that the rule might have a significant economic impact on a substantial number of small entities. Accordingly, MSHA has certified that the final rule will not have a significant economic impact on a substantial number of small entities that are covered by the rule.

VII. Paperwork Reduction Act of 1995

A. Summary

This final rule contains information collection requirements that MSHA estimates will result in 23,920 new burden hours and approximately $1.5 million of related burden costs to mine operators and contractors in the first year that the rule is in effect. In the second year that the rule is in effect, and for every year thereafter, MSHA estimates that mine operators and contractors will incur 20,092 burden hours and approximately $1.1 million of related burden costs. The burden hours are different in the first year because some information collection requirements occur only in the first year that the rule is in effect, while other burden hours occur either every year beginning in the first year, or every year beginning in the second year that the rule is in effect.

The final rule contains information collection requirements in the following sections:

- § 48.3 Training plans; time of submission; where filed; information required; time for approval; method for disapproval; commencement of training; approval of instructors.
- § 50.10 Immediate notification.
- § 50.11 Investigation.
- § 75.1502 Mine emergency evacuation and firefighting program of instruction.
- § 75.1504 Mine emergency evacuation drills.
- § 75.1714–3 Self-rescue devices; inspection, testing, maintenance, repair and recordkeeping.
- § 75.1714–4 Additional self-contained self-rescuers.
- § 75.1714–5 Map locations of self-contained self-rescuers.
- § 75.1714–8 Reporting SCSR inventory and malfunctions; retention of SCSRs.

These requirements will be codified in title 30 of the Code of Federal Regulations. The final rule adds to the information collected under existing OMB information collections OMB 1219–0007, OMB 1219–0009, OMB 1219–0044, OMB 1219–0054, and OMB 1219–0073.

Although § 75.1714–3 is an existing provision and is not changed by the final rule, MSHA is including it in the burden estimates above because the use of additional SCSRs mandated by the final rule will increase the burden associated with inspection and recordkeeping requirements contained in this existing standard. Similarly, although § 50.11 is an existing provision that has not been changed by this final rule, the final rule has changed underground mine operators' reporting requirements concerning underground mine fires and entrapments, and this change results in an increase in the burden for § 50.11.

For a detailed explanation of how the burden hours and related costs were determined, see Chapter VII of the Regulatory Economic Analysis (REA) associated with this final rule. The REA is located on MSHA's Web site at *http://www.msha.gov/REGSINFO.HTM*. A print copy of the REA can be obtained from the Office of Standards, Regulations, and Variances at MSHA.

B. Procedural Details

The information collection package has been submitted to the Office of Management and Budget (OMB) for review under 44 U.S.C. § 3504, paragraph (h) of the Paperwork Reduction Act of 1995, as amended. A copy of the information collection package can be obtained from the Department of Labor by electronic mail request to *king.darrin@dol.gov* or by phone request to 202–693–4129.

Comments on the provisions in the information collection requirements should be sent to both the Office of Information and Regulatory Affairs of OMB and to MSHA. Comments sent to OMB should be sent to ''Attention: Desk Officer for MSHA.'' Comments sent to MSHA should be sent to the Office of Standards, Regulations, and Variances.

Addresses for both offices can be found in the Addresses section of this preamble. The regulated community is not required to respond to any collection of information unless it displays a current valid OMB control number. MSHA will publish a notice in the **Federal Register** announcing when OMB has approved the new information collection requirements.

VIII. Other Regulatory Considerations

Under the Congressional Review Act, major rules generally cannot take effect until 60 days after the rule is published in the **Federal Register**. However, section 808(2) of the Congressional Review Act states that agencies may waive this 60-day requirement for ''good cause'' and establish an earlier effective date. The Department believes that the ''good cause'' exception to the 60-day effective date requirement for major rules in the Congressional Review Act applies to this rule, because observing this requirement would be both impractical and contrary to the public interest. The Emergency Temporary Standard (ETS), which served as the basis for this final rule, was issued to address ''grave danger'' to miners. The ETS lapses on December 8, 2006. If this final rule is not effective immediately, a critical void in miner safety will be created. Therefore, DOL believes that ''good cause'' exists for waiver of the usual 60-day effective date requirement for all ''major'' rules.

A. The Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to assess the effects of federal regulatory actions on state, local, and tribal governments, and the private sector, ''other than to the extent that such regulations incorporate requirements specifically set forth in law.'' For purposes of the Unfunded Mandates Reform Act, this final rule includes a Federal mandate that will increase private sector expenditures by more than $100 million in any one year. It will not result in increased expenditures by State, local, or tribal governments; nor will it significantly or uniquely affect small governments. The Regulatory Economic Analysis provided pursuant to E.O. 12866 addresses the analytic requirements of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 et seq.).

B. The Treasury and General Government Appropriations Act of 1999: Assessment of Federal Regulations and Policies on Families

This final rule will have no affect on family well-being or stability, marital commitment, parental rights or authority, or income or poverty of families and children. Accordingly, Section 654 of the Treasury and General Government Appropriations Act of 1999 (5 U.S.C. 601 note) requires no further Agency action, analysis, or assessment.

C. Executive Order 12630: Government Actions and Interference With Constitutionally Protected Property Rights

This final rule does not implement a policy with takings implications. Accordingly, E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, requires no further Agency action or analysis.

D. Executive Order 12988: Civil Justice Reform

This final rule was written to provide a clear legal standard for affected conduct and was carefully reviewed to eliminate drafting errors and ambiguities, so as to minimize litigation and undue burden on the Federal court system. Accordingly, this final rule meets the applicable standards provided in Section 3 of E.O. 12988, Civil Justice Reform.

E. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This final rule will have no adverse impact on children. Accordingly, E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks, as amended by E.O. 13229 and 13296, requires no further Agency action or analysis.

F. Executive Order 13132: Federalism

This final rule does not have ''federalism implications'' because it will not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Accordingly, E.O. 13132, Federalism, requires no further Agency action or analysis.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This final rule does not have ''tribal implications'' because it will not ''have substantial direct effects 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.'' Accordingly, E.O. 13175, Consultation and Coordination with Indian Tribal Governments, requires no further Agency action or analysis.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This final rule has been reviewed for its impact on the supply, distribution, and use of energy because it applies to the underground coal mining sector. Insofar as this final rule will result in yearly costs of approximately $44.1 million to the underground coal mining industry, relative to annual revenues of $11.1 billion in 2004, it is not a ''significant energy action'' because it is not ''likely to have a significant adverse effect on the supply, distribution, or use of energy * * * (including a shortfall in supply, price increases, and increased use of foreign supplies).'' Accordingly, E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use, requires no further Agency action or analysis.

I. Executive Order 13272: Proper Consideration of Small Entities in Agency Rulemaking

This final rule has been thoroughly reviewed to assess and take appropriate account of its potential impact on small businesses, small governmental jurisdictions, and small organizations. MSHA has determined and certified that this final rule will not have a significant economic impact on a substantial number of small entities. Accordingly, E.O. 13272, Proper Consideration of Small Entities in Agency Rulemaking, requires no further Agency action or analysis.

List of Subjects

30 CFR Part 3

Reporting and recordkeeping requirements.

30 CFR Part 48

Education, Mine safety and health, Reporting and recordkeeping requirements.

30 CFR Part 50

Investigations, Mine safety and health, Reporting and recordkeeping requirements.

30 CFR Part 75

Communications equipment, Electric power, Emergency medical services, Explosives, Fire prevention, Mine safety and health, Reporting and recordkeeping requirements.

Dated: December 5, 2006.

Richard E. Stickler,

Assistant Secretary for Mine Safety and Health.

IX. Final Rule Text

■ For the reasons set out in the preamble and under the authority of the Mine Safety and Health Act of 1977, as amended, Chapter I of Title 30, Code of Federal Regulations, parts 3, 48, 50, and 75 are amended as follows:

PART 3—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT—[AMENDED]

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

Authority: 30 U.S.C. 957; 44 U.S.C. 3501–3520.

■ 2. Amend § 3.1 by adding entries for 30 CFR 75.1504, 75.1505, 75.1714–5, and 75.1714–8 into Table 1 to read as follows.

§ 3.1 OMB control numbers.

* * * * *

TABLE 1.—OMB CONTROL NUMBERS

30 CFR citation	OMB control No.
* * * * *	
75.1504	1219–0054
75.1505	1219–0073
* * * * *	
75.1714–5	1219–0073
75.1714–8	1219–0044
* * * * *	

PART 48—TRAINING AND RETRAINING OF MINERS

■ 3. The authority for part 48 continues to read as follows:

Authority: 30 U.S.C. 811, 825.

■ 4. Amend § 48.3 by revising paragraph (p) to read as follows:

§ 48.3 Training plans; time of submission; where filed; information required; time for approval; method for disapproval; commencement of training; approval of instructors.

* * * * *

(p) Each underground coal operator, who is required to submit a revised program of instruction for 30 CFR 75.1502, shall also submit a revised training plan under this part 48.

■ 5. Amend § 48.5 by revising paragraphs (b)(2) and (b)(5) to read as follows and by removing paragraph (e):

§ 48.5 Training of new miners; minimum courses of instruction; hours of instruction.

* * * * *

(b) * * *

(2) *Self-rescue and respiratory devices.* The course shall be given before a new miner goes underground and shall include—

(i) Instruction and demonstration in the use, care, and maintenance of self-rescue and respiratory devices used at the mine;

(ii) Hands-on training in the complete donning of all types of self-contained self-rescue devices used at the mine, which includes assuming a donning position, opening the device, activating the device, inserting the mouthpiece, and putting on the nose clip; and

(iii) Hands-on training in transferring between all applicable self-rescue devices.

* * * * *

(5) *Mine map; escapeways; emergency evacuation; barricading.* The program of instruction for mine emergency evacuation and firefighting approved by the District Manager under 30 CFR 75.1502 or the escape and evacuation plan under 30 CFR 57.11053, as applicable, shall be used for this course. The course shall include—

(i) A review of the mine map; the escapeway system; the escape, firefighting, and emergency evacuation plans in effect at the mine; and the location of abandoned areas; and

(ii) An introduction to the methods of barricading and the locations of the barricading materials, where applicable.

* * * * *

■ 6. Amend § 48.6 by revising paragraphs (b)(5) and (b)(12) to read as follows and by removing paragraph (f):

§ 48.6 Experienced miner training.

* * * * *

(b) * * *

(5) *Mine map; escapeways; emergency evacuation; barricading.* The program of instruction for mine emergency evacuation and firefighting approved by the District Manager under 30 CFR 75.1502 or the escape and evacuation plan under 30 CFR 57.11053, as applicable, shall be used for this course. The course shall include—

(i) A review of the mine map; the escapeway system; the escape, firefighting, and emergency evacuation plans in effect at the mine; and the location of abandoned areas; and

(ii) Methods of barricading and the locations of barricading materials, where applicable.

* * * * *

(12) *Self-rescue and respiratory devices.* The course shall be given before the miner goes underground and shall include—

(i) Instruction and demonstration in the use, care, and maintenance of self-rescue and respiratory devices used at the mine;

(ii) Hands-on training in the complete donning of all types of self-contained self-rescue devices used at the mine, which includes assuming a donning position, opening the device, activating the device, inserting the mouthpiece, and putting on the nose clip; and

(iii) Hands-on training in transferring between all applicable self-rescue devices.

* * * * *

■ 7. Amend § 48.8 by revising paragraphs (b)(4) and (b)(8) to read as follows:

§ 48.8 Annual refresher training of miners; minimum courses of instruction; hours of instruction.

* * * * *

(b) * * *

(4) *Roof or ground control, ventilation, emergency evacuation and firefighting plans.* The course shall include a review of roof or ground control plans in effect at the mine and the procedures for maintaining and controlling ventilation. In addition, for underground coal mines, except for miners who receive this training under 30 CFR 75.1504, the course shall include a review of the emergency evacuation and firefighting program of instruction in effect at the mine.

* * * * *

(8) *Self-rescue and respiratory devices.* The course shall include instruction and demonstration in the use, care, and maintenance of self-rescue and respiratory devices used at the mine. In addition, except for miners who receive this training under 30 CFR 75.1504, the training for self-contained self-rescue (SCSR) devices shall include:

(i) Hands-on training in the complete donning of all types of self-contained self-rescue devices used at the mine, which includes assuming a donning position, opening the device, activating the device, inserting the mouthpiece, and putting on the nose clip; and

(ii) Hands-on training in transferring between all applicable self-rescue devices.

* * * * *

■ 8. Amend § 48.11 by revising paragraphs (a)(4)(i) and (ii) to read as follows:

§ 48.11 Hazard training.

(a) * * *

(4) Use of self-rescue and respiratory devices, including:

(i) Hands-on training in the complete donning of all types of self-contained self-rescue devices used at the mine, which includes assuming a donning position, opening the device, activating the device, inserting the mouthpiece, and putting on the nose clip; and

(ii) Hands-on training in transferring between all applicable self-rescue devices; and

* * * * *

PART 50—NOTIFICATION, INVESTIGATION, REPORTS AND RECORDS OF ACCIDENTS, INJURIES, ILLNESSES, EMPLOYMENT, AND COAL PRODUCTION IN MINES—[AMENDED]

■ 9. The authority citation for part 50 is revised to read as follows:

Authority: 29 U.S.C. 557(a); 30 U.S.C. 811, 813(j), 951, 957, 961.

■ 10. Amend § 50.2 by revising paragraphs (h)(3) and (h)(6) to read as follows:

§ 50.2 Definitions.

* * * * *

(h) * * *

(3) An entrapment of an individual for more than 30 minutes or which has a reasonable potential to cause death;

* * * * *

(6) In underground mines, an unplanned fire not extinguished within 10 minutes of discovery; in surface mines and surface areas of underground mines, an unplanned fire not extinguished within 30 minutes of discovery;

* * * * *

■ 11. Revise § 50.10 to read as follows:

§ 50.10 Immediate notification.

The operator shall immediately contact MSHA at once without delay and within 15 minutes at the toll-free number, 1–800–746–1553, once the operator knows or should know that an accident has occurred.

PART 75—MANDATORY SAFETY STANDARDS—UNDERGROUND COAL MINES—[AMENDED]

■ 12. The authority citation for part 75 continues to read as follows:

Authority: 30 U.S.C. 811.

■ 13. Amend § 75.380 by revising paragraph (d)(7) to read as follows:

§ 75.380 Escapeways; bituminous and lignite mines.

* * * * *

(d) * * *

(7) Provided with a continuous, durable directional lifeline or equivalent device that shall be—

(i) Installed and maintained throughout the entire length of each escapeway as defined in paragraph (b)(1) of this section;

(ii) Flame-resistant in accordance with the requirements of part 18 of this chapter upon replacement of existing lifelines; but in no case later than June 15, 2009;

(iii) Marked with a reflective material every 25 feet;

(iv) Located in such a manner for miners to use effectively to escape;

(v) Equipped with directional indicators, signifying the route of escape, placed at intervals not exceeding 100 feet. When cones are used as directional indicators, they shall be installed so that the tapered section points inby; and

(vi) Securely attached to and marked to provide tactile feedback indicating the location of any SCSR storage locations in the escapeways.

* * * * *

■ 14. Amend § 75.381 by revising paragraph (c)(5) to read as follows:

§ 75.381 Escapeways; anthracite mines.

* * * * *

(c) * * *

(5) Provided with a continuous, durable directional lifeline or equivalent device that shall be—

(i) Installed and maintained throughout the entire length of each escapeway as defined in paragraph (b) of this section;

(ii) Flame-resistant in accordance with the requirements of part 18 of this chapter upon replacement of existing lifelines; but in no case later than June 15, 2009;

(iii) Marked with a reflective material every 25 feet;

(iv) Located in such a manner for miners to use effectively to escape;

(v) Equipped with directional indicators, signifying the route of escape, placed at intervals not exceeding 100 feet. When cones are used as directional indicators, they shall be installed so that the tapered section points inby; and

(vi) Securely attached to and marked to provide tactile feedback indicating the location of any SCSR storage locations in the escapeways.

* * * * *

§ 75.383 [Removed]

■ 15. Remove § 75.383.

■ 16. Revise § 75.1502 and add §§ 75.1503, 75.1504, and 75.1505 to read as follows:

§ 75.1502 Mine emergency evacuation and firefighting program of instruction.

Each operator of an underground coal mine shall adopt and follow a mine emergency evacuation and firefighting program that instructs all miners in the proper procedures they must follow if a mine emergency occurs.

(a) *Program approval.* The operator shall submit this program of instruction, and any revisions, for approval to the District Manager of the Coal Mine Safety and Health district in which the mine is located. Within 30 days of approval, the operator shall conduct training in accordance with the revised program.

(b) *New or revised provisions.* Before implementing any new or revised approved provision in the program of instruction, the operator shall instruct miners in the change.

(c) *Instruction plan.* The approved program shall include a specific plan designed to instruct miners on all shifts on the following:

(1) Procedures for—

(i) Evacuating the mine for mine emergencies that present an imminent danger to miners due to fire, explosion, or gas or water inundation;

(ii) Evacuating all miners not required for a mine emergency response; and

(iii) The rapid assembly and transportation of necessary miners, fire suppression equipment, and rescue apparatus to the scene of the mine emergency.

(2) The use, care, and maintenance of self-rescue devices, including hands-on training in the complete donning and transferring of all types of self-rescue devices used at the mine.

(3) Scenarios requiring a discussion of options and a decision as to the best option for evacuation under each of the various mine emergencies (fires, explosions, or gas or water inundations). These options shall include:

(i) Encountering conditions in the mine or circumstances that require immediate donning of self-rescue devices.

(ii) Using continuous directional lifelines or equivalent devices, tethers, and doors;

(iii) Traversing undercasts or overcasts;

(iv) Switching escapeways, as applicable; and

(v) Negotiating any other unique escapeway conditions.

(4) Location and use of the fire suppression and firefighting equipment and materials available in the mine.

(5) Location of the escapeways, exits, routes of travel to the surface, including the location of continuous directional lifelines or equivalent devices.

(6) Location, quantity, types, and use of stored SCSRs, as applicable.

(7) A review of the mine map; the escapeway system; the escape, firefighting, and emergency evacuation plans in effect at the mine; and the location of abandoned areas.

(8) A description of how miners will receive annual expectations training that includes practical experience in donning and transferring SCSRs in smoke, simulated smoke, or an equivalent environment and breathing through a realistic SCSR training unit or device that provides the sensation of SCSR airflow resistance and heat.

(d) *Instructors.* (1) The mine operator shall designate a person who has the ability, training, knowledge, or experience to conduct the mine emergency evacuation instruction and drills in his or her area of expertise.

(2) Persons conducting SCSR donning and transferring training shall be able to effectively train and evaluate whether miners can successfully don the SCSR and transfer to additional SCSR devices.

§ 75.1503 Use of fire suppression equipment.

In addition to the approved program of instruction required by 30 CFR 75.1502, each operator of an underground coal mine shall ensure the following.

(a) *Working section.* At least two miners in each working section on each production shift shall be proficient in the use of all fire suppression equipment available on such working section, and know the location of such fire suppression equipment.

(b) *Attended equipment.* Each operator of attended equipment specified in 30 CFR 75.1107–1(c)(1), and each miner assigned to perform job duties at the job site in the direct line of sight of attended equipment as described in 30 CFR 75.1107–1(c)(2), shall be proficient in the use of fire suppression devices installed on such attended equipment.

(c) *Maintenance shift.* The shift foreman and at least one miner for every five miners working underground on a maintenance shift shall be proficient in the use of fire suppression equipment available in the mine, and know the location of such fire suppression equipment.

§ 75.1504 Mine emergency evacuation training and drills.

Each operator of an underground coal mine shall conduct mine emergency evacuation training and drills and require all miners to participate.

(a) *Schedule of training and drills.* Each miner shall participate in a mine emergency evacuation training and drill once each quarter. Quarters shall be based on a calendar year (Jan–Mar, Apr–Jun, Jul–Sep, Oct–Dec). In addition—

(1) A newly hired miner, who has not participated in a mine emergency evacuation training and drill at the mine within the previous 3 months, shall participate in the next applicable mine emergency evacuation training and drill.

(2) Prior to assuming duties on a section or outby work location, a foreman shall travel both escapeways in their entirety.

(b) *Content of quarterly training and drill.* Each quarterly evacuation training and drill shall include the following:

(1) Hands-on training on all types of self-rescue devices used at the mine, which includes—

(i) Instruction and demonstration in the use, care, and maintenance of self-rescue devices;

(ii) The complete donning of the SCSR by assuming a donning position, opening the device, activating the device, inserting the mouthpiece, and putting on the nose clip; and

(iii) Transferring between all applicable self-rescue devices.

(2) Training that emphasizes the importance of—

(i) Recognizing when the SCSR is not functioning properly and demonstrating how to initiate and reinitiate the starting sequence;

(ii) Not removing the mouthpiece, even to communicate, until the miner reaches fresh air; and

(iii) Proper use of the SCSR by controlling breathing and physical exertion.

(3) A realistic escapeway drill that is initiated and conducted with a different approved scenario each quarter and during which each miner—

(i) Travels the primary or alternate escapeway in its entirety, alternating escapeways each quarter;

(ii) Physically locates and practices using the continuous directional lifelines or equivalent devices and tethers, and physically locates the stored SCSRs;

(iii) Traverses undercasts or overcasts and doors;

(iv) Switches escapeways, as applicable; and

(v) Negotiates any other unique escapeway conditions.

(4) A review of the mine and escapeway maps, the firefighting plan, and the mine emergency evacuation plan in effect at the mine, which shall include:

(i) Informing miners of the locations of fire doors, check curtains, changes in the routes of travel, and plans for diverting smoke from escapeways.

(ii) Locating escapeways, exits, routes of travel to the surface, and abandoned areas.

(5) Operation of the fire suppression equipment available in the mine and the location and use of firefighting equipment and materials.

(c) *Annual expectations training.* (1) Over the course of each year, each miner shall participate in expectations training that includes donning and transferring SCSRs in smoke, simulated smoke, or an equivalent environment, and breathing through a realistic SCSR training unit that provides the sensation of SCSR airflow resistance and heat.

(2) A miner shall participate in expectations training within one quarter of being employed at the mine.

(3) The mine operator shall have a purchase order for realistic SCSR training units within 30 days of notification by MSHA that the units are available. The mine operator shall provide expectations training on breathing through a realistic SCSR training unit within 60 days of receipt of the units.

(d) *Certification of training and drills.* At the completion of each training or drill required in this section, the operator shall certify by signature and date that the training or drill was held in accordance with the requirements of this section.

(1) This certification shall include the names of the miners participating in the training or drill. For each miner, this certification shall list the content of the training or drill component completed, including the escapeway traveled and scenario used, as required in paragraphs (b) and (c) of this section.

(2) Certifications shall be kept at the mine for one year.

(3) Upon request, the certifications shall be made available to an authorized representative of the Secretary and the representative of the miners.

(4) Upon request, a copy of the certification that shows his or her own training shall be provided to the participating miner.

§ 75.1505 Escapeway maps.

(a) *Content and accessibility.* An escapeway map shall show the designated escapeways from the working sections or the miners' work stations to the surface or the exits at the bottom of the shaft or slope and shall be

posted or readily accessible for all miners—

(1) In each working section;

(2) In each area where mechanized mining equipment is being installed or removed; and

(3) At a surface location of the mine where miners congregate, such as at the mine bulletin board, bathhouse, or waiting room.

(b) *Keeping maps current.* All maps shall be kept up-to-date and any change in route of travel, location of doors, or direction of airflow shall be shown on the maps by the end of the shift on which the change is made.

(c) *Informing affected miners.* Miners underground on a shift when any such change is made shall be notified immediately of the change and other affected miners shall be informed of the change before entering the underground areas of the mine.

■ 17. Amend § 75.1714 by revising paragraph (b) to read as follows:

§ 75.1714 Availability of approved self-rescue devices; instruction in use and location.

* * * * *

(b) Before any person authorized by the operator goes underground, the operator shall instruct and train such person in accordance with provisions set forth in 30 CFR part 48.

■ 18. Amend § 75.1714–2 by revising paragraphs (f) and (g)(2) to read as follows:

§ 75.1714–2 Self-rescuer devices; use and location requirements.

* * * * *

(f) If an SCSR is not carried out of the mine at the end of a miner's shift, the place of storage shall be approved by the District Manager. A sign made of reflective material with the word ''SCSRs'' or ''SELF-RESCUERS'' shall be conspicuously posted at each SCSR storage location. Direction signs made of a reflective material shall be posted leading to each storage location.

(g) * * *

(2) The one-hour canister shall be available at all times to all persons when underground in accordance with a plan submitted by the mine operator and approved by the District Manager. When the one-hour canister is placed in a storage location, a sign made of a reflective material with the word ''SCSRs'' or ''SELF-RESCUERS'' shall be conspicuously posted at each storage location. Direction signs made of a reflective material shall be posted leading to each storage location.

■ 19. Revise § 75.1714–4 to read as follows:

§ 75.1714–4 Additional self-contained self-rescuers (SCSRs).

(a) *Additional SCSRs in work places.* In addition to the requirements in §§ 75.1714, 75.1714–1, 75.1714–2, and 75.1714–3 of this part, the mine operator shall provide the following:

(1) At least one additional SCSR, which provides protection for a period of one hour or longer, for each person at a fixed underground work location.

(2) Additional SCSRs along the normal travel routes for pumpers, examiners, and other persons who do not have a fixed work location to be stored at a distance an average miner could walk in 30 minutes. The SCSR storage locations shall be determined by using one of the methods found under paragraph (c)(2) of this section.

(b) *Additional SCSRs on mantrips.* If a mantrip or mobile equipment is used to enter or exit the mine, at least one additional SCSR, which provides protection for a period of one hour or longer, shall be available for each person who uses such transportation from portal to portal.

(c) *Additional SCSRs in escapeways.* When each person underground cannot safely evacuate the mine within 30 minutes, the mine operator shall provide additional SCSRs stored in each required escapeway.

(1) Each storage location shall contain at least one SCSR, which provides protection for a period of one hour or longer, for every person who will be inby that location.

(2) Storage locations shall be spaced along each escapeway at 30-minute travel distances no greater than the distances determined by—

(i) Calculating the distance an average miner walks in 30 minutes by using the time necessary for each miner in a sample of typical miners to walk a typical length of each escapeway; or

(ii) Using the SCSR storage location spacing specified in the following table, except for escapeways with grades over 5 percent.

Average entry height	Maximum distance between SCSR storage locations (in ft.)
<40 in. (Crawl)	2,200
>40–<50 in. (Duck Walk)	3,300
>50–<65 in. (Walk Head Bent)	4,400
>65 in. (Walk Erect)	5,700

(d) *Additional SCSRs in hardened rooms.* As an alternative to providing SCSR storage locations in each escapeway, the mine operator may store SCSRs in a hardened room located between adjacent escapeways.

(1) The hardened room shall be designed and constructed to the same explosion force criteria as seals.

(2) The hardened room shall include a means to provide independent, positive pressure ventilation from the surface during an emergency.

(3) The District Manager shall approve the design and construction of hardened rooms in the ventilation plan.

(4) These SCSR storage locations shall be spaced in accordance with paragraph (c) of this section.

(e) *Storage location accessibility.* All SCSRs required under this section shall be stored according to the manufacturers' instructions, in conspicuous locations readily accessible by each person in the mine.

(f) *Storage location signs.* A sign made of reflective material with the words ''SCSRs'' or ''SELF-RESCUERS'' shall be conspicuously posted at each storage location. Direction signs made of a reflective material shall be posted leading to each storage location.

■ 20. Revise § 75.1714–5 to read as follows:

§ 75.1714–5 Map locations of self-contained self-rescuers (SCSR).

The mine operator shall indicate the locations of all stored SCSRs on the mine maps required by §§ 75.1200 and 75.1505 of this part.

■ 21. Add §§ 75.1714–6, 75.1714–7, and 75.1714–8 to read as follows:

§ 75.1714–6 Emergency tethers.

At least one tether, which is a durable rope or equivalent material designed to permit members of a mine crew to link together while evacuating the mine during an emergency, shall be provided and stored with the additional SCSRs on the fixed work location and on the mobile equipment required in §§ 75.1714–4(a)(1) and (b) of this part.

§ 75.1714–7 Multi-gas detectors.

(a) *Availability.* A mine operator shall provide an MSHA-approved, handheld, multi-gas detector that can measure methane, oxygen, and carbon monoxide to each group of underground miners and to each person who works alone, such as pumpers, examiners, and outby miners.

(b) *Qualified person.* At least one person in each group of underground miners shall be a qualified person under § 75.150 of this part and each person who works alone shall be trained to use the multi-gas detector.

(c) *Maintenance and calibration.* Multi-gas detectors shall be maintained and calibrated as specified in § 75.320 of this part.

§ 75.1714–8 Reporting SCSR inventory and malfunctions; retention of SCSRs.

(a) *SCSR inventory.* A mine operator shall submit to MSHA a complete inventory of all SCSRs at each mine. New mines shall submit the inventory within 3 months of beginning operation.

(1) The inventory shall include—

(i) Mine name, MSHA mine ID number, and mine location; and

(ii) For each SCSR unit, the manufacturer, the model type, the date of manufacture, and the serial number.

(2) In the event that a change in the inventory occurs, a mine operator shall report the change to MSHA within the quarter that the change occurs (Jan–Mar, Apr–Jun, Jul–Sep, Oct–Dec).

(b) *Reporting SCSR problems.* A mine operator shall report to MSHA any defect, performance problem, or malfunction with the use of an SCSR. The report shall include a detailed description of the problem and, for each SCSR involved, the information required by paragraph (a)(1) of this section.

(c) *Retention of problem SCSRs.* The mine operator shall preserve and retain each SCSR reported under paragraph (b) of this section for 60 days after reporting the problem to MSHA.

[FR Doc. 06–9608 Filed 12–7–06; 8:45 am]

BILLING CODE 4510–43–P

Federal Register

Friday,
December 8, 2006

Part VI

The President

Executive Order 13417—Establishing an Emergency Board To Investigate Disputes Between Metro-North Railroad and Certain of Its Employees Represented by Certain Labor Organizations

Federal Register
Vol. 71, No. 236
Friday, December 8, 2006

Presidential Documents

Title 3—

The President

Executive Order 13417 of December 6, 2006

Establishing an Emergency Board To Investigate Disputes Between Metro-North Railroad and Certain of Its Employees Represented by Certain Labor Organizations

Disputes exist between Metro-North Railroad (Metro-North) and certain of its employees represented by certain labor organizations. The labor organizations involved in these disputes are designated on the attached list, which is made a part of this order.

The disputes have not heretofore been adjusted under the provisions of the Railway Labor Act, as amended, 45 U.S.C. 151 *et. seq.* (RLA).

A party empowered by the RLA has requested that the President establish an emergency board pursuant to section 9A of the RLA (45 U.S.C. 159a).

Section 9A(c) of the RLA provides that the President, upon such request, shall appoint an emergency board to investigate and report on the disputes.

NOW, THEREFORE, by the authority vested in me as President by the Constitution and the laws of the United States, including section 9A of the RLA, it is hereby ordered as follows:

Section 1. *Establishment of Emergency Board (Board).* There is established, effective 12:01 a.m. eastern standard time on December 7, 2006, a Board of three members to be appointed by the President to investigate and report on these disputes. No member shall be pecuniarily or otherwise interested in any organization of railroad employees or any carrier. The Board shall perform its functions subject to the availability of funds.

Sec. 2. *Report.* The Board shall report to the President with respect to the disputes within 30 days of its creation.

Sec. 3. *Maintaining Conditions.* As provided by section 9A(c) of the RLA, from the date of the creation of the Board and for 120 days thereafter, no change in the conditions out of which the disputes arose shall be made by the parties to the controversy, except by agreement of the parties.

Sec. 4. *Records Maintenance.* The records and files of the Board are records of the Office of the President and upon the Board's termination shall be maintained in the physical custody of the National Mediation Board.

Sec. 5. *Expiration.* The Board shall terminate upon the submission of the report provided for in section 2 of this order.

THE WHITE HOUSE,
December 6, 2006.

Billing code 3195–01–P

Labor Organizations

International Association of Machinists & Aerospace Workers

International Brotherhood of Electrical Workers

International Brotherhood of Teamsters

Service Employees International Union-National Conference of Firemen & Oilers

Sheet Metal Workers' International Association

Transportation Communications International Union (including Transportation Communications International Union - American Railway and Airline Supervisors Association)

Transport Workers Union of America

[FR Doc. 06–9632
Filed 12–7–06; 8:50 am]
Billing code 3195–01–P

Reader Aids

Federal Register

Vol. 71, No. 236

Friday, December 8, 2006

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **http://www.gpoaccess.gov/nara/index.html**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **http://www.archives. gov/federal__register**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, 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.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, DECEMBER

69429–70274 1
70275–70456 4
70457–70642 5
70643–70850 6
70851–71036 7
71037–71462 8

CFR PARTS AFFECTED DURING DECEMBER

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.

2 CFR
901 70457

3 CFR
Proclamations:
8087 70455
8088 70851
8089 70853
Executive Orders:
12866 (See EO 13416) 71033
13415 70641
13416 71033
13417 71459

5 CFR
Proposed Rules:
3201 70325

7 CFR
33 70643
981 70646
1220 69429
1792 70275
Proposed Rules:
51 69497
272 71075
273 71075
319 70330
981 70683

8 CFR
1003 70855

10 CFR
70 69430
430 71340
431 71340
433 70275
434 70275
435 70275
600 70457
606 70457

11 CFR
Proposed Rules:
104 71084
111 ..... 71088, 71090, 71093

12 CFR
205 69430
Proposed Rules:
205 69500

14 CFR
13 70460
25 70646
39 ..... 70284, 70286, 70294, 70297, 70300, 70648, 70857, 70860, 70862, 70865, 70868
71 ..... 69438, 70302, 70465, 70650
73 70466
97 69438
Proposed Rules:
39 ..... 70908, 71096, 71099, 71101, 71103
71 ..... 70909, 70911
145 70254
399 71106

17 CFR
200 71037
Proposed Rules:
240 71109

18 CFR
50 69440
380 69440
Proposed Rules:
2 70692
33 70692
40 70695
365 70692
366 70692

19 CFR
12 69447
Proposed Rules:
210 71113

21 CFR
2 70870
80 70873
520 ..... 70302, 71038
558 70304
1301 69478
Proposed Rules:
2 70912
1312 69504

25 CFR
Proposed Rules:
292 70335
502 71115
546 71115
547 71115

26 CFR
1 ..... 70875, 70877, 71039, 71040, 71045
301 71040
602 ..... 71039, 71040, 71045
Proposed Rules:
1 ..... 71116, 71241
301 70335

27 CFR
Proposed Rules:
9 70472
40 70476
41 70476
44 70476

45.....70476

28 CFR

61.....71047

Proposed Rules:

570.....70696

29 CFR

4022.....69480
4044.....69481

Proposed Rules:

825.....69504

30 CFR

3.....71430
48.....71430
50.....71430
75.....71430

31 CFR

1.....69482

32 CFR

626.....71051
627.....71051
656.....71051

33 CFR

117 .....70305, 70467, 70468, 70877
165.....69484

Proposed Rules:

165.....69514, 69517
401.....70336

34 CFR

Proposed Rules:

674.....71117
682.....71117
685.....71117

37 CFR

253.....69486

40 CFR

52 .....69486, 70312, 70315, 70468, 70880, 70883
63.....70651
70.....70468, 70665
122.....69622
180 .....70667, 70670, 71052
239.....71241
258.....71241
300.....70318
799.....71058

Proposed Rules:

52 .....69519, 70338, 70339, 70476, 70699, 70914, 70915
70.....70476, 70702
81.....70915
180.....70703

42 CFR

405.....69624, 71062
410.....69624, 71062
411.....69624, 71062
414.....69624, 71062
415.....69624, 71062
424.....69624, 71062
460.....71244
462.....71244
466.....71244
473.....71244
476.....71244
482.....71378

44 CFR

65.....70885
67.....70894, 70904

Proposed Rules:

67.....70930

47 CFR

2.....70671
27.....70906
87.....70671

Proposed Rules:

Ch. I.....70709
2.....70710
87.....70710

48 CFR

201.....69488
208.....69489
212.....69489, 71072
215.....69492
222.....71072
230.....69492
232.....69489
252 .....69489, 69492, 71072
253.....69492
1802.....71072
1805.....71072
1819.....71072
1825.....71072
1827.....71072
1828.....71072
1852.....71072

Proposed Rules:

23.....70937
36.....70937
52.....70937
719.....70939

49 CFR

Proposed Rules:

171.....69527
172.....69527
173.....69527
174.....69527
178.....69527
213.....70590
214.....70590
215.....70590
217.....70590
218.....70590
219.....70590
220.....70590
221.....70590
222.....70590
223.....70590
224.....70590
225.....70590
228.....70590
229.....70590
230.....70590
231.....70590
232.....70590
233.....70590
234.....70590
235.....70590
236.....70590
238.....70590
239.....70590
240.....70590
241.....70590
571.....70477

50 CFR

229.....70319, 70321
622.....70680
648 .....70682, 70906, 71073
665.....69495
679.....70323

Proposed Rules:

17 .....70479, 70483, 70715, 70717
229.....70339
622.....70492
648.....70493
660.....70939, 70941
665.....69527
679.....70943

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 DECEMBER 8, 2006

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
Northeastern United States fisheries—
Atlantic herring; published 12-8-06

DEFENSE DEPARTMENT
Army Department
Environmental quality:
Installation; off-road vehicles use on army land; removed; published 12-8-06
Supplies and equipment:
Biological Defense Safety Program, Technical Safety Requirements; removed; published 12-8-06

ENERGY DEPARTMENT
Sales regulation:
Strategic Petroleum Reserve; petroleum acquisition procedures; published 11-8-06

ENVIRONMENTAL PROTECTION AGENCY
Air quality implementation plans; approval and promulgation; various States:
Ohio; published 11-8-06
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Cyproconazole; published 12-8-06

FARM CREDIT ADMINISTRATION
Farm credit system:
Regulatory burden reduction; published 11-8-06

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Animal drugs, feeds, and related products:
Lincomycin and spectinomycin powder; published 12-8-06
Oxytetracycline powder; published 12-8-06

HOMELAND SECURITY DEPARTMENT
Coast Guard
Drawbridge operations:
Florida; published 11-8-06

INTERIOR DEPARTMENT
Fish and Wildlife Service
Endangered and threatened species:
Critical habitat designations—
Willowy monardella; published 11-8-06

LABOR DEPARTMENT
Mine Safety and Health Administration
Coal mine safety and health:
Underground mines—
Emergency evacuations; emergency temporary standard; published 12-8-06

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
Federal Acquisition Regulation (FAR):
Supplemental administrative changes; published 12-8-06

SECURITIES AND EXCHANGE COMMISSION
Securities:
Tender-offer best-price rules; amendments; published 11-8-06

TREASURY DEPARTMENT
Internal Revenue Service
Income taxes:
Business electronic filing; guidance; published 12-8-06

TREASURY DEPARTMENT
Alcohol and Tobacco Tax and Trade Bureau
Alcohol; viticultural area designations:
Tracy Hills, San Joaquin and Stanislaus Counties, CA; published 11-8-06

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT
Animal and Plant Health Inspection Service
Animal welfare:
Captive elephants; space and living conditions; comments due by 12-11-06; published 8-9-06 [FR E6-12935]
Hawaiian and territorial quarantine notices:
Bell pepper, eggplant, Italian squash, and tomato moved interstate from Hawaii; vapor heat treatment approval; comments due by 12-11-06; published 10-11-06 [FR E6-16754]
Plant-related quarantine, domestic:
Asian longhorned beetle; comments due by 12-11-06; published 10-11-06 [FR E6-16755]

AGRICULTURE DEPARTMENT
Energy Policy and New Uses Office, Agriculture Department
Biobased products; designation guidance for Federal procurement; comments due by 12-11-06; published 10-11-06 [FR 06-08368]

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
Alaska; fisheries of Exclusive Economic Zone—
Bering Sea and Aleutian Islands groundfish; Greenland turbot; comments due by 12-14-06; published 12-4-06 [FR 06-09501]
Marine mammals:
Commercial fishing authorizations—
Atlantic Large Whale Take Reduction Plan; comment request; comments due by 12-15-06; published 11-15-06 [FR 06-09206]

DEFENSE DEPARTMENT
Personnel, military and civilian:
Armed Forces members serving on State or local juries; comments due by 12-11-06; published 10-10-06 [FR E6-16643]
Organizations seeking to represent or organize Armed Forces members in negotiation or collective bargaining; policies; comments due by 12-11-06; published 10-12-06 [FR E6-16926]

ENERGY DEPARTMENT
Federal Energy Regulatory Commission
Electric utilities (Federal Power Act):
Transmission service; preventing undue discrimination and preference; comments due by 12-15-06; published 11-27-06 [FR E6-19998]

ENVIRONMENTAL PROTECTION AGENCY
Air quality implementation plans; approval and promulgation; various States:
California; comments due by 12-11-06; published 11-9-06 [FR E6-18874]
Louisiana; comments due by 12-13-06; published 11-13-06 [FR E6-19020]
Hazardous waste program authorizations:
Idaho; comments due by 12-11-06; published 11-9-06 [FR E6-18486]
Louisiana; comments due by 12-13-06; published 11-13-06 [FR E6-19089]

FARM CREDIT ADMINISTRATION
Farm credit system:
Processing and marketing operations; eligibility and scope of financing; comments due by 12-15-06; published 10-16-06 [FR E6-17170]

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Medical devices:
Reprocessed single-use devices; premarket notification exemptions termination; validation data submission requirement; comments due by 12-11-06; published 9-25-06 [FR 06-08166]

HOUSING AND URBAN DEVELOPMENT DEPARTMENT
Agency information collection activities; proposals, submissions, and approvals; comments due by 12-11-06; published 10-10-06 [FR E6-16616]

INTERIOR DEPARTMENT
Surface Mining Reclamation and Enforcement Office
Permanent program and abandoned mine land reclamation plan submissions:
Indiana; comments due by 12-13-06; published 11-13-06 [FR E6-19085]
Texas; comments due by 12-13-06; published 11-13-06 [FR E6-19084]
Surface coal mining and reclamation operations:
Ownership, control, transfer, assignment or sale of permit rights; comments due by 12-11-06; published 10-10-06 [FR E6-16575]

LABOR DEPARTMENT
Employee Benefits Security Administration
Employee Retirement Income Security Act:

Independence of employee benefit plan accountants; comments due by 12-11-06; published 9-11-06 [FR E6-14913]

INTERIOR DEPARTMENT

National Indian Gaming Commission

Classification standards:

Class II Gaming; bingo, lotto, et al.

Analytical reports availability; comments due by 12-15-06; published 11-13-06 [FR E6-19065]

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Air traffic operating and flight rules, etc.:

Chicago O'Hare International Airport, IL; congestion and delay reduction; comments due by 12-12-06; published 10-13-06 [FR 06-08651]

Airworthiness directives:

Airbus; comments due by 12-15-06; published 11-15-06 [FR E6-19228]

Boeing; comments due by 12-11-06; published 10-11-06 [FR E6-16670]

Dowty Propellers; comments due by 12-11-06; published 11-9-06 [FR E6-18840]

Raytheon; comments due by 12-11-06; published 10-10-06 [FR E6-16552]

Airworthiness standards:

Special conditions—

Boeing Model 737-700 IGW airplane; comments due by 12-15-06; published 10-31-06 [FR E6-18281]

General Electric Co. GEnx turbofan engine models; Open for comments until further notice; published 11-17-06 [FR 06-09230]

Class D airspace; comments due by 12-11-06; published 10-25-06 [FR 06-08848]

Class D and Class E airspace; comments due by 12-15-06; published 10-31-06 [FR E6-18264]

TRANSPORTATION DEPARTMENT

Federal Railroad Administration

Practice and procedure:

Direct final rulemaking procedures; expedited processing of noncontroversial changes; comments due by 12-11-06; published 10-11-06 [FR E6-16825]

Railroad operating rules and practices:

Operational tests and inspections program; equipment, switches, and derails handling; comments due by 12-11-06; published 10-12-06 [FR 06-08568]

TRANSPORTATION DEPARTMENT

Federal Transit Administration

Clean Fuels Grant Program; comments due by 12-15-06; published 10-16-06 [FR E6-17071]

TREASURY DEPARTMENT

Privacy Act; implementation; comments due by 12-11-06; published 11-9-06 [FR E6-18853]

VETERANS AFFAIRS DEPARTMENT

Loan guaranty:

Housing loans in default; servicing, liquidating, and claims procedures; comments due by 12-11-06; published 11-27-06 [FR 06-09403]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

H.R. 409/P.L. 109–375

Sierra National Forest Land Exchange Act of 2006 (Dec. 1, 2006; 120 Stat. 2656)

H.R. 860/P.L. 109–376

To provide for the conveyance of the reversionary interest of the United States in certain lands to the Clint Independent School District, El Paso County, Texas. (Dec. 1, 2006; 120 Stat. 2659)

H.R. 1129/P.L. 109–377

Pitkin County Land Exchange Act of 2006 (Dec. 1, 2006; 120 Stat. 2660)

H.R. 3085/P.L. 109–378

To amend the National Trails System Act to update the feasibility and suitability study originally prepared for the Trail of Tears National Historic Trail and provide for the inclusion of new trail segments, land components, and campgrounds associated with that trail, and for other purposes. (Dec. 1, 2006; 120 Stat. 2664)

H.R. 5842/P.L. 109–379

Pueblo of Isleta Settlement and Natural Resources Restoration Act of 2006 (Dec. 1, 2006; 120 Stat. 2666)

S. 101/P.L. 109–380

To convey to the town of Frannie, Wyoming, certain land withdrawn by the Commissioner of Reclamation. (Dec. 1, 2006; 120 Stat. 2671)

S. 1140/P.L. 109–381

To designate the State Route 1 Bridge in the State of Delaware as the ''Senator William V. Roth, Jr. Bridge''. (Dec. 1, 2006; 120 Stat. 2672)

S. 4001/P.L. 109–382

New England Wilderness Act of 2006 (Dec. 1, 2006; 120 Stat. 2673)

Last List November 29, 2006

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.