AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 77 Thursday,
No. 86 May 3, 2012

Pages 26149–26412

OFFICE OF THE 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.ofr.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 at *www.fdsys.gov*, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** 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 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Printing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpo@custhelp.com.*

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: U.S. Government Printing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; 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: 77 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, May 15, 2012
9 a.m.–12:30 p.m.

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. 77, No. 86

Thursday, May 3, 2012

Agency for Healthcare Research and Quality
NOTICES
Patient Safety Organizations:
Voluntary Relinquishment from CareRise LLC, 26280–26281
Requests for Nominations:
National Advisory Council for Healthcare Research and Quality, 26281

Agriculture Department
See Rural Utilities Service

Army Department
See Engineers Corps

Bonneville Power Administration
NOTICES
Environmental Impact Statements; Availability, etc.:
Montana-to-Washington Transmission System Upgrade Project, 26275–26276

Bureau of Consumer Financial Protection
RULES
Interstate Land Sales Registration Program:
Special Rules of Practice; Correction, 26154

Centers for Medicare & Medicaid Services
PROPOSED RULES
Medicaid Program:
State Plan Home and Community-Based Services, 5-Year Period for Waivers, etc., 26362–26406
State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Setting Requirements for Community First Choice; Correction, 26232

Commerce Department
See Economic Analysis Bureau
See Foreign-Trade Zones Board
See International Trade Administration
See National Oceanic and Atmospheric Administration

Consumer Product Safety Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Requirements for Coal and Woodburning Appliances, 26253–26254
Meetings; Sunshine Act, 26254

Corporation for National and Community Service
NOTICES
Meetings; Sunshine Act, 26254

Defense Department
See Engineers Corps
PROPOSED RULES
Federal Acquisition Regulations:
Nondisplacement of Qualified Workers Under Service Contracts, 26232–26238
NOTICES
Meetings:
National Defense University Board of Visitors; Cancellation, 26254
Privacy Act; Systems of Records, 26261–26262
Renewal of Department of Defense Federal Advisory Committees, 26264–26265

Economic Analysis Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Quarterly Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons, 26251–26252

Education Department
NOTICES
Applications for New Awards:
Reentry of Students with Disabilities from Juvenile Justice Facilities into Education, Employment, and Community Programs, 26265–26273

Energy Department
See Bonneville Power Administration
See Energy Efficiency and Renewable Energy Office
NOTICES
Meetings:
Environmental Management Advisory Board, 26275
Environmental Management Site-Specific Advisory Board, Northern New Mexico, 26273
Nuclear Energy Advisory Committee, 26274–26275
President's Council of Advisors on Science and Technology, 26273–26274

Energy Efficiency and Renewable Energy Office
NOTICES
Meetings:
Biomass Research and Development Technical Advisory Committee, 26276–26277

Engineers Corps
PROPOSED RULES
Restricted Areas:
Meloy Channel, U.S. Coast Guard Base Miami Beach, FL, 26229–26231

Environmental Protection Agency
PROPOSED RULES
Underground Injection Control Program Primacy:
Tennessee; Public Hearing, 26231–26232

Executive Office of the President
See Presidential Documents

Export-Import Bank
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 26277
Economic Impact Policy, 26277–26278

Federal Accounting Standards Advisory Board
NOTICES
Issuance of Statement of Federal Financial Accounting Standard 42, 26278

Federal Aviation Administration
RULES
Airworthiness Directives:
Airbus Airplanes, 26154–26156
Cessna Aircraft Company Airplanes, 26156–26158
Saab AB, Saab Aerosystems Airplanes, 26158–26160
Modification of VOR Federal Airway V–14:
Missouri, 26160–26161
PROPOSED RULES
Airworthiness Directives:
Rolls-Royce plc Turbofan Engines, 26216–26218

Federal Communications Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 26278–26279
Meetings, 26279

Federal Election Commission
NOTICES
Meetings; Sunshine Act, 26279

Federal Financial Institutions Examination Council
NOTICES
Meetings:
Appraisal Subcommittee, 26279–26280

Federal Highway Administration
NOTICES
Final Federal Agency Actions on Avenida Rio Salado/Broadway Road, 26355
Surface Transportation Project Delivery Pilot Program:
Caltrans Audit Report, 26355–26356

Federal Railroad Administration
NOTICES
Petitions for Waivers of Compliance, 26356–26359

Federal Reserve System
NOTICES
Changes in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 26280
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 26280

Fish and Wildlife Service
RULES
Endangered and Threatened Wildlife and Plants:
Reclassifying the Wood Bison Under the Endangered Species Act as Threatened Throughout Its Range, 26191–26212

Food and Drug Administration
RULES
Amendments to Sterility Test Requirements for Biological Products, 26162–26175
New Animal Drugs:
Ceftiofur Crystalline Free Acid; Gamithromycin; Tylosin, 26161–26162
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents, 26284–26287
Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim, 26283–26284
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments, etc., 26281–26283
Cooperative Agreement to Support the Joint Institute for Food Safety and Applied Nutrition, 26287–26288
Determination of Regulatory Review Period for Purposes of Patent Extension:
HALAVEN, 26288–26289
KRYSTEXXA, 26290–26291
LASTACAFT, 26291–26292
PRADAXA, 26289–26290
Risk Evaluation and Mitigation Strategy Assessments:
Social Science Methodologies to Assess Goals Related to Knowledge; Public Workshop; Issue Paper, 26292–26294

Foreign Claims Settlement Commission
NOTICES
Meetings; Sunshine Act, 26316

Foreign-Trade Zones Board
NOTICES
Expansion of Manufacturing Authority:
Epson Portland, Inc., Foreign Trade Zone 45, Portland, OR, 26252

General Services Administration
PROPOSED RULES
Federal Acquisition Regulations:
Nondisplacement of Qualified Workers Under Service Contracts, 26232–26238

Health and Human Services Department
See Agency for Healthcare Research and Quality
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health

Healthcare Research and Quality Agency
See Agency for Healthcare Research and Quality

Housing and Urban Development Department
PROPOSED RULES
Federal Housing Administration:
Section 232 Healthcare Facility Insurance Program-Strengthening Accountability and Regulatory Revisions, 26218–26229
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Federal Housing Administration Healthcare Facility Documents, 26304–26314

Interior Department
See Fish and Wildlife Service
NOTICES
National Environmental Policy Act; Implementing Procedures:
Addition to Categorical Exclusions for Bureau of Indian Affairs, 26314–26315

U.S. Extractive Industries Transparency Initiative:
Stakeholder Assessment and Multi-Stakeholder Group Options, 26315–26316

Internal Revenue Service
RULES
Section 42 Qualified Contract Provisions, 26175–26181

International Trade Administration
NOTICES
North American Free Trade Agreement Panel Reviews, 26252–26253

Justice Department
See Foreign Claims Settlement Commission
RULES
Authorization to Redelegate Settlement Authority for Claims Submitted Under the Federal Tort Claims Act, 26181–26183

National Aeronautics and Space Administration
PROPOSED RULES
Federal Acquisition Regulations:
Nondisplacement of Qualified Workers Under Service Contracts, 26232–26238

National Institutes of Health
NOTICES
Government-Owned Inventions; Availability for Licensing, 26294–26300
Meetings:
Center for Scientific Review, 26300–26303
National Cancer Institute, 26301–26304
National Institute of Arthritis and Musculoskeletal and Skin Diseases, 26301
National Institute of Environmental Health Sciences, 26300
Prospective Grant of Exclusive License:
Development of Ocular Therapeutics Utilizing the Peptide C16Y and Related Peptides, 26304

National Oceanic and Atmospheric Administration
RULES
Fisheries of the Exclusive Economic Zone Off Alaska:
Atka Mackerel in the Bering Sea and Aleutian Islands Management Area, 26212
PROPOSED RULES
Fisheries of the United States:
National Standard 1 Guidelines, 26238–26240

Nuclear Regulatory Commission
RULES
Access Authorization Fees, 26149–26154
PROPOSED RULES
Access Authorization Fees, 26213–26216
NOTICES
Environmental Impact Statements; Availability, etc.:
Progress Energy Florida; Combined Licenses for Levy Nuclear Plant Units 1 and 2, 26316–26317
Exemption of Material; Proposed Disposal Procedures:
Humboldt Bay Power Plant, Unit 3, Eureka, CA, 26317–26318
Exemption:
Duke Energy Carolinas, LLC; Oconee Nuclear Station, Units 1, 2, and 3, 26318–26321
Facility Operating License Renewals:
Reed College, Reed Research Nuclear Reactor, 26321
License Issuances:
Virginia Electric and Power Co., Nos. NPF–4 and NPF–7, 26321–26323

Postal Service
RULES
POSTNET Barcode Discontinuation, 26185–26191
NOTICES
Meetings; Sunshine Act, 26323

Presidential Documents
EXECUTIVE ORDERS
Iran and Syria, Foreign Sanctions Evaders; Prohibiting Transactions and Suspending Entry Into the U.S. (EO 13608), 26407–26411

Rural Utilities Service
NOTICES
Announcement of Grant Application Deadlines and Funding Levels, 26241–26245
Household Water Well System Grant Program; Application Deadlines and Funding, 26245–26251

Securities and Exchange Commission
NOTICES
Findings, Opinions, and Orders of the Commission:
Application of BOX Options Exchange LLC for Registration as a National Securities Exchange, 26323–26340
Self-Regulatory Organizations; Proposed Rule Changes:
EDGA Exchange, Inc., 26348–26353
EDGX Exchange, Inc., 26343–26348
Financial Industry Regulatory Authority, Inc., 26340–26343

State Department
NOTICES
Culturally Significant Objects Imported for Exhibition Determinations:
Lygia Clark, 26353
Environmental Impact Statements; Availability, etc.:
Vantage Pipeline Project, 26353–26354

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See Federal Railroad Administration

Treasury Department
See Internal Revenue Service

Veterans Affairs Department
RULES
State Nursing Homes Receiving Per Diem Payments from VA:
Technical Revisions to Update Reference to the Required Assessment Tool, 26183–26184

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 26362–26406

Part III
Presidential Documents, 26407–26411

Reader Aids

Consult the Reader Aids section at the end of this page 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:
13608.....26409

10 CFR
11.....26149
25.....26149
Proposed Rules:
11.....26213
25.....26213

12 CFR
1012.....26154

14 CFR
39 (3 documents) 26154, 26156, 26158
71.....26160
Proposed Rules:
39.....26216

21 CFR
522.....26161
558.....26161
600.....26162
610.....26162
680.....26162

24 CFR
Proposed Rules:
5.....26218
200.....26218
207.....26218
232.....26218

26 CFR
1.....26175
602.....26175

28 CFR
0.....26181

33 CFR
Proposed Rules:
334.....26229

38 CFR
51.....26183

39 CFR
111.....26185

40 CFR
Proposed Rules:
147.....26231

42 CFR
Proposed Rules:
430 (2 documents) 26232, 26362
431 (2 documents) 26232, 26362
435 (2 documents) 26232, 26362
436 (2 documents) 26232, 26362
440 (2 documents) 26232, 26362
441 (2 documents) 26232, 26362
447 (2 documents) 26232, 26362

48 CFR
Proposed Rules:
2.....26232
22.....26232
52.....26232

50 CFR
17.....26191
679.....26212
Proposed Rules:
600.....26238

Rules and Regulations

Federal Register
Vol. 77, No. 86
Thursday, May 3, 2012

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 11 and 25

[NRC–2011–0161]

RIN 3150–AJ00

Access Authorization Fees

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending the NRC's access authorization fees charged to licensees for work performed under the Material Access Authorization Program (MAAP) and the Information Access Authority Program (IAAP). The amended cost is due to an increase in the review time for each application for access authorization. The NRC's formula for calculating fees remains the same and is based on current Office of Personnel Management (OPM) investigation billing rates for background investigations. The formula is designed to recover the full cost of processing a request for access authorization from an NRC licensee.

DATES: The final rule is effective June 22, 2012, unless significant adverse comments are received by June 4, 2012. A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. If the rule is withdrawn, timely notice will be published in the **Federal Register**.

ADDRESSES: Please refer to Docket ID NRC–2011–0161 when contacting the NRC about the availability of information for this final rule. You may access information and comment submittals related to this final rulemaking, which the NRC possesses and is publicly available, by the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2011–0161.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Emily Robbins, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–492–3524, email: *Emily.Robbins@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Procedural Background

The NRC is using the direct final rule procedure because it considers this action noncontroversial and routine. The amendments make a routine adjustment to the access authorization fees and are of a minor and administrative nature. Adequate protection of public health and safety continues to be ensured. The direct final rule will become effective on June 22, 2012. However, if the NRC receives significant adverse comments on the direct final rule by June 4, 2012, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in response to the proposed revisions in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC staff to make a change (other than editorial) to the rule.

Background

Certain individuals employed by NRC licensees or their contractors are assigned duties which require access to special nuclear material (plutonium, uranium-233, and uranium enriched in the isotopes uranium-233 or uranium-235) or to restricted data or national security information. Individuals who require access to this material or information must obtain an access authorization from the NRC. When a licensee requests access authorization for an employee or a contractor, the NRC initiates a background investigation of the individual seeking access authorization. Based on the results of that investigation, the NRC determines whether permitting that individual to have access to special nuclear material, restricted data, or national security information would create a security risk.

The OPM conducts the required access authorization background investigations for the NRC and sets the rates charged for these investigations. The combined cost of the OPM background investigation and any related NRC processing activities (NRC processing fee) are recovered from the

licensee through an access authorization fee assessed by the NRC. It is the NRC's practice to publish the fee schedule for special nuclear material access authorization in Title 10 of the *Code of Federal Regulations* (10 CFR) 11.15(e) and the corresponding fee schedule for restricted data and national security information access authorization in Appendix A to 10 CFR Part 25. Both schedules are based on rates charged by OPM for conducting the required background investigations (OPM investigation billing rates).

Discussion

This direct final rule amends § 11.15(e), § 25.17(f), and Appendix A to 10 CFR Part 25 by modifying the NRC processing fee charged to licensees for work performed under the MAAP and the IAAP from 31.7 percent of the OPM investigation billing rates to 55.8 percent. This direct final rule will continue to allow licensees to calculate the NRC access authorization fee for any given application by referencing to the current OPM investigation billing rates schedule for background investigation services. Reimbursable billing rates for personnel background investigations are published by OPM's Federal Investigative Services in a Federal Investigations Notice (FIN). The current OPM investigation billing rates were published in FIN 11–05 on August 29, 2011, and became effective on October 1, 2011. The FIN 11–05 is available on the OPM's Federal Investigative Services Web site at *http://www.opm.gov/investigate/fins/2011.aspx*. The NRC's licensees can also obtain the current OPM investigation billing rates schedule by contacting the NRC's Personnel Security Branch (PSB), Division of Facilities and Security (DFS), Office of Administration (ADM) by email to *Licensee_Access_Authorization_Fee@nrc.gov.*

The fee-calculation formula is designed to recover the NRC's actual in-house processing fee for each application received from the licensee. The NRC's access authorization fee for any given request is determined using the following formula: the OPM investigation billing rates on the day of NRC receipt of the application + the NRC processing fee = the NRC material access authorization fee. The NRC processing fee is determined by multiplying the OPM investigation billing rate on the day of NRC receipt of the application by 55.8 percent (i.e., OPM rate × 55.8 percent). The percentage used to determine the NRC processing fee is increasing from 31.7 percent to 55.8 percent based on a 2010 NRC audit of actual in-house costs incurred in processing licensee applications for access authorization. Specifically, the amended cost is due to an increase in the review time for each application for access authorization. It is also important to note that collection of fees to recover the NRC's costs is required by statute (42 U.S.C. 2214(b)). Specifically, the amendments are necessary to implement the Omnibus Budget Reconciliation Act of 1990, as amended, which requires the NRC to recover through fees the full cost incurred in providing a service or thing of value.

As noted previously, the OPM investigation billing rates are pulled directly from the current OPM fee schedule for investigations. The tables in new § 11.15(e)(3) and Appendix A to 10 CFR Part 25 cross-references each type of NRC access authorization request to the appropriate investigation service listed in the OPM's investigation billing rates schedule. For example, a licensee seeking a special nuclear material ''NRC–U'' access authorization requiring a single scope background investigation is directed by the table in new § 11.15(e)(3) to calculate the NRC processing fee based on the OPM investigation billing rates for a ''Code C'' Single Scope Background Investigation (SSBI). According to the current OPM investigation billing rates schedule (FIN 11–05), the OPM charges $4,005 for a ''Code C'' SSBI. The table instructs the licensee to calculate the NRC's application processing fee by multiplying $4,005 by 55.8 percent, which equals $2,234.79. The licensee then rounds the NRC's processing fee to the nearest dollar, or $2,235, and adds that amount to the OPM investigation billing rate of $4,005 to determine the total NRC access authorization fee: $6,240.

The following table illustrates the calculation process:

Current OPM investigation billing rate for SSBI–C	Plus NRC application processing fee	Equals total NRC access authorization fee for NRC–U application
	OPM Rate × NRC fee 55.8% = (rounded to nearest $)	
$4,005	$4,005 × 55.8% = $2,234.79 (rounded to $2,235)	= $6,240

Licensees applying for restricted data or national security information access authorization follow a similar procedure. The table in Appendix A to 10 CFR Part 25 cross-references each type of ''Q'' or ''L'' access authorization to the corresponding OPM investigation type. The OPM investigation billing rate for the type of investigation referenced is determined by consulting the current OPM investigation billing rates schedule. This rate is then plugged into the formula used to calculate the correct NRC access authorization fee for the type of application submitted. Copies of the current NRC access authorization fee can be obtained by contacting the NRC's Personnel Security Branch, Division of Facilities Security, Office of Administration by email to: *Licensee_Access_Authorization_Fee@nrc.gov.* Any change in the NRC's access authorization fees will be applicable to each access authorization request received on or after the effective date of the OPM's most recently published investigation billing rates schedule.

Paragraph-by-Paragraph Analysis

Section 11.15 Application for Special Nuclear Material Access Authorization

To more clearly explain the access authorization process, the NRC is amending the rule language as follows: § 11.15(e)(1), and (2) are revised; § 11.15(e)(3) is redesignated as § 11.15(e)(4); and a new § 11.15(e) introductory text and (e)(3) are added. Additional changes were made for grammatical or clarification purposes. The authority citation was changed to reflect the current statutory framework for agency fee recovery.

Section 11.15(e) introductory text is added to further explain how the OPM bills the NRC for the cost of each background investigation conducted in support of an application for special nuclear material access authorization.

Section 11.15(e)(1) is revised to clearly define the formula used in calculating the NRC material access authorization fee (the OPM investigation billing rates on the day of NRC receipt of the application + the NRC processing fee = the NRC access authorization fee). The NRC processing fee is determined

by multiplying the OPM investigation billing rate on the day of NRC receipt of the application by 55.8 percent (i.e., OPM rate × 55.8 percent). Significantly, as noted above, the percentage of the OPM investigation billing rates in the processing fee is being changed from 31.7 percent of the OPM investigation billing rate to 55.8 percent of that rate to reflect NRC's increased costs in processing licensee applications for access authorization.

Section 11.15(e)(2) is revised to further explain how to access the OPM billing rates schedule. Also, the telephone contact is changed to an email contact.

The current § 11.15(e)(3) is redesignated as § 11.15(e)(4). A new § 11.15(e)(3) is added to clearly explain that the NRC's MAAP is considered reimbursable work representing services provided to an organization for which the NRC is entitled to payment. The NRC is authorized to receive and retain fees from licensees for services performed. The NRC's Office of the Chief Financial Officer (OCFO) periodically reviews the fees charged for MAAP and makes recommendations on revising those charges to reflect costs incurred by the NRC in providing those services. The reviews are performed using cost analysis techniques to determine the direct and indirect costs. The new § 11.15(e)(3) also provides information on where to obtain current copies of the NRC access authorization fee via an email contact and includes a table of the NRC's MAAP fee schedules. The NRC fee schedule for NRC–R (expedited processing) is removed given that this type of access authorization is no longer being performed by OPM. Other minor changes to the table are made to reflect the types of access authorization currently being performed by OPM.

Section 25.17 Approval for Processing Applicants for Access Authorization

To more clearly explain the access authorization process, the NRC is amending the rule language as follows: § 25.17(f)(1), and (2) are revised; § 25.17(f)(3) is redesignated as § 25.17(f)(4); and a new § 25.17(f) introductory text and (f)(3) are added. Additional changes were made for grammatical or clarification purposes. The authority citation was changed to reflect the current statutory framework for agency fee recovery.

Section 25.17(f) introductory text is added to further explain how OPM bills the NRC for the cost of each background investigation conducted in support of an application for access authorization.

Section 25.17(f)(1) is revised to clearly define the formula used in calculating the NRC access authorization fee (the OPM investigation billing rates on the day of NRC receipt of the application + the NRC processing fee = the NRC access authorization fee). The NRC processing fee is determined by multiplying the OPM investigation billing rate on the day of NRC receipt of the application by 55.8 percent (i.e., OPM rate × 55.8 percent). Significantly, as noted above, the percentage of the OPM investigation billing rates in the processing fee is being changed from 31.7 percent of the OPM investigation billing rate to 55.8 percent of that rate to reflect the NRC's increased costs in processing licensee applications for access authorization.

Section 25.17(f)(2) is revised to further explain how to access the OPM billing rates schedule. Also, the telephone contact is changed to an email contact.

The current § 25.17(f)(3) is redesignated as § 25.17(f)(4). A new § 25.17(f)(3) is added to clearly explain that the NRC's IAAP is considered reimbursable work representing services provided to an organization for which the NRC is entitled to payment. The NRC is authorized to receive and retain fees from licensees for services performed. The NRC's OCFO periodically reviews the fees charged for IAAP and makes recommendations on revising those charges to reflect costs incurred by the NRC in providing those services. The reviews are performed using cost analysis techniques to determine the direct and indirect costs. The new § 25.17(f)(3) also provides information on where to obtain current copies of the NRC access authorization fee via an email contact.

Appendix A to 10 CFR Part 25—Fees for NRC Access Authorization

The revised table in Appendix A to 10 CFR Part 25 cross-references each type of NRC ''Q'' or ''L'' access authorization request to a type of investigation in the current OPM investigation billing rates schedule, and directs licensees to calculate the application fee according to the stated formula: the OPM investigation billing rates on the day of NRC receipt of the application + the NRC processing fee = the NRC access authorization fee. The NRC processing fee is determined by multiplying the OPM investigation billing rate on the day of NRC receipt of the application by 55.8 percent (i.e., OPM rate × 55.8 percent). The NRC fee schedule for Initial ''L'' access authorization (expedited processing) is removed given that this type of access authorization is no longer being performed by OPM. Other minor changes to the table are made to reflect the types of access authorization currently being performed by OPM and for grammatical or clarification purposes.

Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires Federal agencies to use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or is otherwise impractical. This direct final rule amends the formula for calculating the NRC's access authorization fee charged to licensees for work performed under MAAP and IAAP from 31.7 percent of the OPM investigation billing rate for an investigation of a given type to 55.8 percent.

This action is administrative in nature and does not involve the establishment or application of a technical standard containing generally applicable requirements.

Environmental Impact: Categorical Exclusion

The NRC has determined that this direct final rule is the type of action described in categorical exclusions § 51.22(c)(1) and (2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this direct final rule.

Paperwork Reduction Act Statement

This direct final rule does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget (OMB), Approval Numbers 3150–0046 and 3150–0062.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Regulatory Analysis

A regulatory analysis has not been prepared for this direct final rule. This direct final rule ensures that the NRC recovers the full cost of application processing from licensees submitting access authorization requests, as is required by statute (42 U.S.C. 2214(b)). The formula method for calculating these fees continues to provide an

efficient and effective mechanism for updating the NRC access authorization fees in response to changes in the underlying OPM investigation billing rates schedule for required personnel background investigations. These amendments are administrative in nature and will neither impose new safety requirements nor relax existing ones and therefore do not call for the sort of safety/cost analysis described in the NRC's regulatory analysis guidelines in NUREG/BR–0058, Revision 4, ''Regulatory Analysis Guidelines of the USNRC,'' September 2004 (ADAMS Accession No. ML042820192).

Regulatory Flexibility Act Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this direct final rule amending 10 CFR Parts 11 and 25 does not have a significant economic impact on a substantial number of small entities. This direct final rule applies to those licensees who use, process, store, transport, or deliver to a carrier for transport, formula quantities of special nuclear material (as defined in 10 CFR Part 73) or generate, receive, safeguard, and store National Security Information or Restricted Data (as defined in 10 CFR Part 95). Two licensees, both fuel cycle facilities, are currently required to comply with 10 CFR Part 11. Seventy-eight licensees and other organizations, mostly power reactors and fuel cycle facilities, are currently required to comply with 10 CFR Part 25. None of these licensees are ''small entities'' as defined in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810). This direct final rule also applies to contractors of those licensees required to comply with this direct final rule who use, process, store, transport, or deliver to a carrier for transport, formula quantities of special nuclear material (as defined in 10 CFR Part 73) or generate, receive, safeguard, and store National Security Information or Restricted Data (as defined in 10 CFR Part 95). Some of these contractors may be ''small entities'' as defined in the Regulatory Flexibility Act or the NRC's size standards. However, some of these contractors are reimbursed through the contract for the cost of securing access authorization. There are not a substantial number of unreimbursed ''small entity'' contractors who apply for access authorization, nor is the NRC aware of any significant impact on these unreimbursed ''small entity'' contractors.

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this direct final rule and that a backfit analysis is not required. Collection of fees to recover the NRC's costs is required by statute (42 U.S.C. 2214(b)). Therefore, changes to rules designating the amount to be collected are not subject to the backfitting provisions or issue finality provisions in 10 CFR Chapter I.

Congressional Review Act

In accordance with the Congressional Review Act, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 11

Hazardous materials—transportation, Investigations, Nuclear materials, Reporting and recordkeeping requirements, Security measures, Special nuclear material.

10 CFR Part 25

Classified information, Criminal penalties, Investigations, Reporting and recordkeeping requirements, Security measures.

For the reasons set forth in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Parts 11 and 25.

PART 11—CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO OR CONTROL OVER SPECIAL NUCLEAR MATERIAL

■ 1. The authority citation for part 11 is revised to read as follows:

Authority: Atomic Energy Act sec. 161 (42 U.S.C. 2201); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note).

Section 11.15(e) also issued under Independent Offices Appropriations Act sec. 501, (31 U.S.C. 9701); Omnibus Reconciliation Act of 1990 sec. 6101 (42 U.S.C. 2214).

Federal Register Citation: October 10, 2003; 68 FR 58792, 58800.

■ 2. In § 11.15:
■ i. Add paragraph (e) introductory text;
■ ii. Revise paragraphs (e)(1) and (e)(2);
■ iii. Redesignate paragraph (e)(3) as paragraph (e)(4); and
■ iv. Add a new paragraph (e)(3).

The revisions and addition read as follows:

§ 11.15 Application for special nuclear material access authorization.

* * * * *

(e) The Office of Personnel Management (OPM) bills the NRC for the cost of each background investigation conducted in support of an application for special nuclear material access authorization (application). The combined cost of the OPM investigation and the NRC's application processing overhead (NRC processing fee) are recovered through a material access authorization fee imposed on applicants for special nuclear material access authorization.

(1) Each application for a special nuclear material access authorization, renewal, or change in level must be accompanied by a remittance, payable to the U.S. Nuclear Regulatory Commission, which is equal to the NRC material access authorization fee. This fee must be determined using the following formula: the OPM investigation billing rates on the day of NRC receipt of the application + the NRC processing fee = the NRC material access authorization fee. The NRC processing fee is determined by multiplying the OPM investigation billing rate on the day of NRC receipt of the application by 55.8 percent (i.e., OPM rate × 55.8 percent).

(2) Updated OPM investigation billing rates are published periodically in a Federal Investigations Notice (FIN) issued by the OPM's Federal Investigative Services. Copies of the current OPM investigation billing rates schedule can be obtained by contacting the NRC's Personnel Security Branch, Division of Facilities Security, Office of Administration by email to: *Licensee_Access_Authorization_Fee@nrc.gov.*

(3) The NRC's Material Access Authorization Program (MAAP) is considered reimbursable work representing services provided to an organization for which the NRC is entitled payment. The NRC is authorized to receive and retain fees from licensees for services performed. The NRC's Office of the Chief Financial Officer periodically reviews the fees charged for MAAP and makes recommendations on revising those charges to reflect costs incurred by the NRC in providing those services. The reviews are performed using cost analysis techniques to determine the direct and indirect costs. Based on this review the MAAP fees are adjusted to reflect the current cost for the program. Copies of the current NRC material access authorization fee may be obtained by contacting the NRC's Personnel Security Branch, Division of Facilities Security, Office of Administration by email to: *Licensee_Access_Authorization_Fee@nrc.gov.* Any change in the NRC's access

authorization fees will be applicable to each access authorization request received on or after the effective date of the OPM's most recently published investigation billing rates schedule. Applicants shall calculate the access authorization fee according to the stated formula (i.e., OPM rate × 55.8 percent) and with reference to the following table:

The NRC application fee for an access authorization of type . . .	Is the sum of the current OPM investigation billing rate charged for an investigation of type . . .	Plus the NRC's processing fee (rounded to the nearest dollar), which is equal to the OPM investigation billing rate for the type of investigation referenced multiplied by . . .
I. NRC—R [1]	NACLC—National Agency Check with Law and Credit (Standard Service, Code C).	55.8%
ii. NRC—R Based on Certification of Comparable Investigation [2].	No fee assessed for most applications	
iii. NRC—R renewal [1]	NACLC—National Agency Check with Law and Credit (Standard Service, Code C).	55.8%
iv. NRC—U requiring single scope investigation	SSBI—Single Scope Background Investigation (Standard Service, Code C).	55.8%
v. NRC—U requiring single scope investigation (expedited processing).	SSBI—Single Scope Background Investigation (Priority Handling, Code A).	55.8%
vi. NRC—U based on certification of comparable investigation [2].	No fee assessed for most applications	
vii. NRC—U renewal [2]	SSBI–PR—Periodic Reinvestigation for SSBI (Standard Service, Code C).	55.8%

[1] If the NRC, having reviewed the available data, deems it necessary to perform a single scope investigation, the appropriate NRC–U fee will be assessed before the conduct of the investigation.

[2] If the NRC determines, based on its review of available data, that a single scope investigation is necessary, the appropriate NRC–U fee will be assessed before the conduct of the investigation.

* * * * *

PART 25—ACCESS AUTHORIZATION

■ 3. The authority citation for part 25 is revised to read as follows:

Authority: Atomic Energy Act secs. 145, 161, 223, 234 (42 U.S.C. 2165, 2201, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); E.O. 10865, as amended, 3 CFR 1959–1963 Comp., p. 398 (50 U.S.C. 401, note); E.O. 12829, 3 CFR, 1993 Comp., p. 570; E.O. 13526, 3 CFR 2010 Comp., pp. 298–327; E.O. 12968, 3 CFR, 1995 Comp, p. 396;

Section 25.17(f) and Appendix A also issued under 31 U.S.C. 9701; Omnibus Reconciliation Act of 1990 sec. 6101 (42 U.S.C. 2214).

Federal Register Citation: November 30, 2010; 75 FR 73935, 73941.

■ 4. In § 25.17:

■ i. Add paragraph (f) introductory text;

■ ii. Revise paragraphs (f)(1) and (f)(2);

■ iii. Redesignate paragraph (f)(3) as paragraph (f)(4); and

■ iv. Add a new paragraph (f)(3).

The revisions read as follows:

§ 25.17 Approval for processing applicants for access authorization.

* * * * *

(f) The Office of Personnel Management (OPM) bills the NRC for the cost of each background investigation conducted in support of an application for access authorization (application). The combined cost of the OPM investigation and the NRC's application processing overhead (NRC processing fee) are recovered through an access authorization fee imposed on applicants for access authorization.

(1) Each application for access authorization, renewal, or change in level must be accompanied by a remittance, payable to the U.S. Nuclear Regulatory Commission, which is equal to the NRC access authorization fee. This fee must be determined using the following formula: the OPM investigation billing rates on the day of NRC receipt of the application + the NRC processing fee = the NRC access authorization fee. The NRC processing fee is determined by multiplying the OPM investigation billing rate on the day of NRC receipt of the application by 55.8 percent (i.e., OPM rate × 55.8 percent).

(2) Updated OPM investigation billing rates are published periodically in a Federal Investigations Notice (FIN) issued by the OPM's Federal Investigative Services. Copies of the current OPM investigation billing rates schedule can be obtained by contacting the NRC's Personnel Security Branch, Division of Facilities Security, Office of Administration by email to *Licensee_Access_Authorization_Fee@nrc.gov.*

(3) The NRC's Information Access Authority Program (IAAP) is considered reimbursable work representing services provided to an organization for which the NRC is entitled payment. The NRC is authorized to receive and retain fees from licensees for services performed. The NRC's Office of the Chief Financial Officer periodically reviews the fees charged for IAAP and makes recommendations on revising those charges to reflect costs incurred by the NRC in providing those services. The reviews are performed using cost analysis techniques to determine the direct and indirect costs. Based on this review the IAAP fees are adjusted to reflect the current cost for the program. Copies of the current NRC access authorization fee may be obtained by contacting the NRC's Personnel Security Branch, Division of Facilities Security, Office of Administration by email to: *Licensee_Access_Authorization_Fee@nrc.gov.* Any change in the NRC's access authorization fee will be applicable to each access authorization request received on or after the effective date of the OPM's most recently published investigation billing rates schedule.

* * * * *

■ 5. Appendix A to part 25 is revised to read as follows:

Appendix A to Part 25—Fees for NRC Access Authorization

The NRC application fee for an access authorization of type . . .	Is the sum of the current OPM investigation billing rate charged for an investigation of type . . .	Plus the NRC's processing fee (rounded to the nearest dollar), which is equal to the OPM investigation billing rate for the type of investigation referenced multiplied by . . .
Initial "L" access authorization [1]	ANACI—Access National Agency Check with Inquiries (Standard Service, Code C).	55.8%
Reinstatement of "L" access authorization [2]	No fee assessed for most applications	
Renewal of "L" access authorization [1]	NACLC—Access National Agency Check with Law and Credit (Standard Service, Code C).	55.8%
Initial "Q" access authorization	SSBI—Single Scope Background Investigation (Standard Service, Code C).	55.8%
Initial "Q" access authorization (expedited processing)	SSBI—Single Scope Background Investigation (Priority Handling, Code A).	55.8%
Reinstatement of "Q" access authorization [2]	No fee assessed for most applications	
Renewal of "Q" access authorization [1]	SSBI–PR—Periodic Reinvestigation for SSBI (Standard Service, Code C).	55.8%

[1] If the NRC determines, based on its review of available data, that a single scope investigation is necessary, the appropriate fee for an Initial "Q" access authorization will be assessed before the conduct of investigation.
[2] Full fee will only be charged if an investigation is required.

Dated at Rockville, Maryland, this 19th day of April 2012.

For the Nuclear Regulatory Commission.

R.W. Borchardt,

Executive Director for Operations.

[FR Doc. 2012–10711 Filed 5–2–12; 8:45 am]

BILLING CODE 7590–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1012

[Docket No. CFPB–2011–0025]

RIN 3170–AA06

Interstate Land Sales Registration Program, Special Rules of Practice; Correction

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Correcting amendments.

SUMMARY: The Bureau of Consumer Financial Protection published an interim final rule on December 21, 2011 (76 FR 79486), republishing implementing regulations under the Interstate Land Sales Full Disclosure Act (ILSA). The interim final rule contained a typographical error, which this document corrects.

DATES: This correcting amendment is effective on May 3, 2012.

FOR FURTHER INFORMATION CONTACT: Whitney Patross, Office of Regulations, at (202) 435–7700.

SUPPLEMENTARY INFORMATION: The Bureau of Consumer Financial Protection (Bureau) published an interim final rule republishing and making technical and conforming amendments to regulations of the Department of Housing and Urban Development (HUD) in connection with the transfer of rulemaking authority for ILSA from HUD to the Bureau. The interim final rule contained a typographical error, which this document corrects. The heading of Part 1012—Special Rules of Practice is incorrectly labeled as ''Regulation J'' and should be labeled ''Regulation L.''

List of Subjects in 12 CFR Part 1012

Advertising disclaimers, Adjudicatory proceedings, Certification of substantially equivalent state law, Filing assistance, Purchasers' revocation rights, Land registration, Reporting requirements, Unlawful sales practices.

Accordingly, 12 CFR Part 1012 is amended by making the following correcting amendments:

PART 1012—SPECIAL RULES OF PRACTICE (REGULATION L)

■ 1. The authority citation for part 1012 continues to read as follows:

Authority: 12 U.S.C. 5512, 5581; 15 U.S.C. 1718.

■ 2. The heading of part 1012 is revised to read as set forth above.

Dated: April 25, 2012.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2012–10602 Filed 5–2–12; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0041; Directorate Identifier 2011–NM–167–AD; Amendment 39–17037; AD 2012–09–02]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus Model A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes. This AD was prompted by analysis that in a specific failure case of the upper primary attachment of the trimmable horizontal stabilizer actuator (THSA), the THSA upper secondary attachment engaged because it could only withstand the loads for a limited period of time. This AD requires installing three secondary retention plates for the gimbal bearings on the THSA upper primary attachment. We are issuing this AD to prevent failure of the secondary load path, which could result in loss of control of the airplane.

DATES: This AD becomes effective June 7, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 7, 2012.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation,

Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on February 6, 2012 (77 FR 5726). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> A specific failure case of the THSA [trimmable horizontal stabilizer actuator] upper primary attachment, which may result in a loading of the upper secondary attachment, has been identified by analysis.
>
> Primary load path failure can be caused by bearing migration from the upper attachment gimbal by failure or loss of a retention bolt.
>
> In case of failure of the THSA upper primary attachment, the THSA upper secondary attachment would engage. Because the upper attachment secondary load path can only withstand the loads for a limited period of time, the condition where it would be engaged could lead, if not detected and corrected, to the failure of the secondary load path, which would likely result in loss of control of the aeroplane.
>
> For the reasons explained above, this [EASA] AD requires installation of three secondary retention plates for the gimbal bearings on the THSA upper primary attachment.

You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (77 FR 5726, February 6, 2012) or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (77 FR 5726, February 6, 2012) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (77 FR 5726, February 6, 2012).

Costs of Compliance

We estimate that this AD will affect about 15 products of U.S. registry. We also estimate that it will take about 2 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $6,541 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $100,665, or $6,711 per product.

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM 77 FR 5726, February 6, 2012), the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–09–02 Airbus: Amendment 39–17037. Docket No. FAA–2012–0041; Directorate Identifier 2011–NM–167–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective June 7, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus Model A300 B2–1C, B2K–3C, B2–203, B4–2C, B4–103, and B4–203 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 27: Flight controls.

(e) Reason

This AD was prompted by analysis that in a specific failure case of the upper primary attachment of the trimmable horizontal stabilizer actuator (THSA), the THSA upper secondary attachment engaged because it could only withstand the loads for a limited period of time. We are issuing this AD to prevent failure of the secondary load path, which could result in loss of control of the airplane.

(f) Compliance

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

(g) Actions

Within 30 months after the effective date of this AD, install 3 retention plates for the gimbal bearings on the THSA upper primary attachment, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–27–0204, dated March 11, 2011.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to Attn: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–2125; fax (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(i) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2011–0112, dated June 15, 2011; and Airbus Mandatory Service Bulletin A300–27–0204, dated March 11, 2011; for related information.

(j) Material Incorporated by Reference

(1) You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) of the following service information under 5 U.S.C. 552(a) and 1 CFR part 51:

(i) Airbus Mandatory Service Bulletin A300–27–0204, dated March 11, 2011.

(2) For service information identified in this AD, contact Airbus SAS—EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.*

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on April 23, 2012.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–10471 Filed 5–2–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1413; Directorate Identifier 2011–NM–062–AD; Amendment 39–17036; AD 2012–09–01]

RIN 2120–AA64

Airworthiness Directives; Cessna Aircraft Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Cessna Aircraft Company Model 560XL airplanes. This AD was prompted by reports of wheel inserts becoming loose and damaging brake assemblies on Model 560XL airplanes. This AD requires an inspection of the torque lug and surrounding components (wheel base, side rim, lock ring) for damage (such as corrosion, cracks, dents, bent areas, damaged or missing paint or primer, or wear on the metal), and of the bearing cup for corrosion, turned cup, or clearance that exceeds limits, and repair as applicable; measuring the torque lugs for width and replacing screws and inserts with new, improved screws and inserts; and re-identifying the wheel assemblies. We are issuing this AD to prevent brake failure, which could result in an airplane not being able to stop on the runway.

DATES: This AD is effective June 7, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of June 7, 2012.

ADDRESSES: For Cessna service information identified in this AD, contact Cessna Aircraft Co., P.O. Box 7706, Wichita, Kansas 67277–7706; telephone 316–517–6215; fax 316–517–5802; email *citationpubs@cessna.textron.com;* Internet *https://www.cessnasupport.com/newlogin.html.* For Goodrich service information identified in this AD, contact Goodrich Corporation, Aircraft Wheels & Brakes, P.O. Box 340, Troy, Ohio 45373–3872; telephone 937–440–2130; fax 937–440–2055; email *WBPubs-Admin@goodrich.com;* Internet *http://www.goodrich.com/TechPubs.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: David Fairback, Aerospace Engineer, Mechanical Systems and Propulsion Branch, ACE–116W, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, KS 67209; phone: 316–946–4154; fax: 316–946–4107; email: *david.fairback@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM published in the **Federal Register** on January 19, 2012 (77 FR 2659). That NPRM proposed to require an inspection of the torque lug and surrounding components (wheel base, side rim, lock ring) for damage (such as corrosion, cracks, dents, bent areas, damaged or missing paint or primer, or wear on the metal), and of the bearing

cup for corrosion, turned cup, or clearance that exceeds limits, and repair as applicable; measuring the torque lugs for width and replacing screws and inserts with new, improved screws and inserts; and re-identifying the wheel assemblies.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (77 FR 2659, January 19, 2012) or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting the AD as proposed, except for minor editorial changes. In addition, we have re-identified Note 2 of the NPRM (77 FR 2659, January 19, 2012) as paragraph (h) of this final rule. We also revised the language in paragraph (j) of this AD; this change does not affect the intent of this AD. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (77 FR 2659, January 19, 2012) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (77 FR 2659, January 19, 2012).

Costs of Compliance

We estimate that this AD affects 473 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection, and measurement of the torque lugs, replacement of screws and inserts, and re-marking.	Up to 11 work-hours × $85 per hour = $935.	Up to $6,462	Up to $7,397	Up to $3,498,781.

We estimate the following costs to do any necessary repairs or replacements as applicable that would be required based on the results of the inspection. We have no way of determining the number of aircraft that might need these repairs or replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair or replacement as applicable.	Between 1 and 9 work-hour[s] × $85 per hour = Between $85 and $765 per wheel assembly.	Between $0 and $24,000 per wheel assembly.	Between $85 and $24,765 per wheel assembly.

According to the manufacturer, all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

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

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

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

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

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

(3) Will not affect intrastate aviation in Alaska, and

(4) 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.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2012–09–01 Cessna Aircraft Company: Amendment 39–17036; Docket No. FAA–2011–1413; Directorate Identifier 2011–NM–062–AD.

(a) Effective Date

This AD is effective June 7, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Cessna Aircraft Company Model 560XL airplanes; certificated in any category; having serial numbers 5002 through 5372 inclusive, 5501 through 5830 inclusive, 6001 through 6055

inclusive, 6057 through 6066 inclusive, 6069 through 6071 inclusive, and 6073 through 6077 inclusive.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 32, Landing Gear.

(e) Unsafe Condition

This AD was prompted by reports of wheel inserts becoming loose and damaging brake assemblies on Model 560XL airplanes. We are issuing this AD to prevent brake failure, which could result in an airplane not being able to stop on the runway.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection, Corrective Action, and Replacement

Within 1 year after the effective date of this AD, or during the next tire change accomplished after the effective date of this AD, whichever occurs first: Do the actions specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD on both main wheels, in accordance with the Accomplishment Instructions of Cessna Service Bulletin SB560XL–32–41, Revision 1, dated May 5, 2011, including Supplemental Data, dated February 25, 2011. Do all applicable repairs and replacements before further flight.

(1) Do a general visual inspection of the torque lug and surrounding components (wheel base, side rim, lock ring) for damage (such as corrosion, cracks, dents, bent areas, damaged or missing paint or primer, or wear on the metal), and of the bearing cup for corrosion, turned cup, or clearance that exceeds limits, and all applicable repairs.

(2) Measure the torque lugs for width and replace screws and inserts with new, improved screws and inserts.

(3) Re-identify the wheel assembly.

Note 1 to paragraph (g) of this AD: Cessna Service Bulletin SB560XL–32–41, Revision 1, dated May 5, 2011, including Supplemental Data, dated February 25, 2011, refers to Goodrich Service Bulletin 3–1571–32–7, dated February 25, 2011, as an additional source of guidance on inspecting and repairing the torque lugs, surrounding components, and bearing cup, and re-identifying the wheel assemblies.

(h) Definition

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.''

(i) Parts Installation

As of the effective date of this AD, no person may install, on any airplane, a wheel assembly having P/N 3–1571–3 or 3–1571–4, unless it has been inspected, measured, and re-identified, in accordance with paragraph (g) of this AD, and all applicable repairs or replacements have been done.

(j) Credit for Previous Actions

This paragraph provides credit for actions, as required by paragraph (g) of this AD, if those actions were done before the effective date of this AD in accordance with Cessna Service Bulletin SB560XL–32–41, dated February 25, 2011.

(k) No Reporting Required

Although Cessna Service Bulletin SB560XL–32–41, Revision 1, dated May 5, 2011, specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

(m) Related Information

For more information about this AD, contact contact David Fairback, Aerospace Engineer, Mechanical Systems and Propulsion Branch, ACE–116W, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, KS 67209; phone: 316–946–4154; fax: 316–946–4107; email: *david.fairback@faa.gov*.

(n) Material Incorporated by Reference

(1) You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise.

(2) The Director of the Federal Register approved the incorporation by reference (IBR) under 5 U.S.C. 552(a) and 1 CFR part 51 of the following service information:

(i) Cessna Service Bulletin SB560XL–32–41, Revision 1, dated May 5, 2011, including Supplemental Data, dated February 25, 2011.

(3) For Cessna service information identified in this AD, contact Cessna Aircraft Co., P.O. Box 7706, Wichita, Kansas 67277; telephone 316–517–6215; fax 316–517–5802; email *citationpubs@cessna.textron.com;* Internet *https://www.cessnasupport.com/newlogin.html.*

(4) For Goodrich service information identified in this AD, contact Goodrich Corporation, Aircraft Wheels & Brakes, P.O. Box 340, Troy, Ohio 45373–3872; telephone 937–440–2130; fax 937–440–2055; email *WBPubs-Admin@goodrich.com;* Internet *http://www.goodrich.com/TechPubs.*

(5) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(6) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on April 24, 2012.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–10473 Filed 5–2–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1410; Directorate Identifier 2011–NM–033–AD; Amendment 39–17038; AD 2012–09–03]

RIN 2120–AA64

Airworthiness Directives; Saab AB, Saab Aerosystems Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Saab AB, Saab Aerosystems Model SAAB 2000 airplanes. This AD was prompted by reports of hydraulic accumulator failure. This AD requires replacing certain hydraulic accumulators with stainless steel hydraulic accumulators, and structural modifications in the nose landing gear bay. We are issuing this AD to prevent failure of hydraulic accumulators, which may result in damage to the airplane and injury to occupants.

DATES: This AD becomes effective June 7, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 7, 2012.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the U.S. Department of Transportation, Docket Operations, M–30, West

Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1112; fax (425) 227–1149

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on December 29, 2011 (76 FR 81889). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> Three cases of failure have been reported, affecting the same type of hydraulic accumulator as installed on SAAB 2000 aeroplanes, although all occurred on other aeroplane types. The reported cause of these failures has been traced to corrosion. Any of the end parts on the accumulator may depart from the pressure vessel if they are affected by corrosion.
>
> This condition, if not detected and corrected, may lead to fatigue failure of a hydraulic accumulator, possibly resulting in damage to the aeroplane and injury to occupants. In addition, a quality issue during the replacement of the base material in the end parts of the accumulator may have affected the service life of the accumulator.
>
> To address this unsafe condition, SAAB has introduced a new type of hydraulic accumulator, which is made of stainless steel.
>
> For the reasons described above, this [EASA] AD requires the replacement of all Part Number (P/N) 08 8423 030 1 hydraulic accumulators with stainless steel P/N 40800–2050 hydraulic accumulators and associated structural modifications in the nose landing gear bay.

You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We have considered the comment received.

Request To Include a Statement From the Service Information

Saab AB (the commenter) requested that we revise the NPRM (76 FR 81889, December 29, 2011) to include a statement as follows: ''In addition, a quality issue during the replacement of the base material in the end parts of the accumulator may have affected the service life of the accumulator.''

We infer that the commenter requested that we add the statement to the Discussion section of the NPRM (76 FR 81889, December 29, 2011). We agree that Saab Service Bulletin 2000–29–024, Revision 01, dated November 5, 2010, states, ''In addition, a qualification issue during the change of the base material, for the end parts of the accumulator back in 1993, can have affected the life limit of the accumulator.'' However, we have not included the statement in the final rule because we do not restate the Discussion section in the final rule. We have not changed the AD in this regard.

Explanation of Additional Change Made to This AD

We have revised the heading and wording in paragraph (i) of this AD; this change has not changed the intent of that paragraph.

Conclusion

We reviewed the available data, including the comment received, and determined that air safety and the public interest require adopting the AD with the changes described previously—except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (76 FR 81889, December 29, 2011) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (76 FR 81889, December 29, 2011).

Costs of Compliance

We estimate that this AD will affect 8 products of U.S. registry. We also estimate that it will take about 12 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $9,995 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $88,120, or $11,015 per product.

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM (76 FR 81889, December 29, 2011), the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–09–03 Saab AB, Saab Aerosystems: Amendment 39–17038. Docket No. FAA–2011–1410; Directorate Identifier 2011–NM–033–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective June 7, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Saab AB, Saab Aerosystems Model SAAB 2000 airplanes, certificated in any category; all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 29: Hydraulic Power.

(e) Reason

This AD was prompted by reports of hydraulic accumulator failure. We are issuing this AD to prevent failure of hydraulic accumulators, which may result in damage to the airplane and injury to occupants.

(f) Compliance

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

(g) Actions

Within 12 months after the effective date of this AD, replace all hydraulic accumulators having part number (P/N) 08 8423 030 1, with stainless steel hydraulic accumulators having P/N 40800–2050, and do the structural modifications in the nose landing gear bay, in accordance with the Accomplishment Instructions of Saab Service Bulletin 2000–29–024, Revision 01, dated November 5, 2010.

(h) Parts Installation

After replacing hydraulic accumulators having P/N 08 8423 030 1 with hydraulic accumulators having P/N 40800–2050, and doing the structural modifications in the nose landing gear bay, as required by paragraph (g) of this AD, no person may install any hydraulic accumulator having P/N 08 8423 030 1 on any airplane.

(i) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Saab Service Bulletin 2000–29–024, dated November 18, 2009.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, ANM–116, International Branch, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Shahram Daneshmandi, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1112; fax (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(k) Related Information

Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2011–0004, dated January 17, 2011; and Saab Service Bulletin 2000–29–024, Revision 01, dated November 5, 2010; for related information.

(l) Material Incorporated by Reference

(1) You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) of the following service information under 5 U.S.C. 552(a) and 1 CFR part 51:

(i) Saab Service Bulletin 2000–29–024, Revision 01, dated November 5, 2010. (2) For service information identified in this AD, contact Saab AB, Saab Aerosystems, SE–581 88, Linköping, Sweden; telephone +46 13 18 5591; fax +46 13 18 4874; email *saab2000.techsupport@saabgroup.com;* Internet *http://www.saabgroup.com.*

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on April 23, 2012.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–10469 Filed 5–2–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2012–0227; Airspace Docket No. 12–ACE–1]

Modification of VOR Federal Airway V–14; Missouri

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, technical amendment.

SUMMARY: This action amends VOR Federal airway V–14 in the vicinity of St. Louis, MO. The FAA is taking this action to correct the V–14 description contained in Part 71 to ensure it matches the information contained in the FAA's aeronautical database, matches the depiction on the associated charts, and to ensure the safety and efficiency of the National Airspace System (NAS).

DATES: Effective date 0901 UTC May 3, 2012. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace, Regulations and ATC Procedures Group, Office of Mission Support Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

After a recent review of aeronautical data, the Aeronautical Navigation Products Group identified the VOR Federal airway V–14 description published in FAA Order 7400.9, Airspace Designations and Reporting Points, did not match the airway information contained in the FAA's aeronautical database or the charted depiction of the airway. When V–14 was amended in the **Federal Register** of May 7, 1990 (55 FR 18862), the St. Louis, MO, VOR/DME was deleted from the description in error. The FAA aeronautical database retained the

navigation aid in the route description correctly and the associated aeronautical charts were published accordingly. To overcome any confusion or flight safety issues associated with conflicting route description information being published, the FAA is amending the V–14 legal description to reflect the airway aligned over the St. Louis, MO, VOR/DME. Accordingly, since this is an administrative correction to update the V–14 description to be in concert with the FAA's aeronautical database and charting, notice and public procedures under Title 5 U.S.C. 553(b) are unnecessary.

The Rule

The FAA amends Title 14 Code of Federal Regulations (14 CFR) part 71 by amending the legal description of VOR Federal airway V–14 in the vicinity of St. Louis, MO. Specifically, the FAA amends V–14 to reflect the airway aligned over the St. Louis, MO, VOR/DME; thus, matching the information currently contained in the FAA's aeronautical database and the charted depiction of the airway.

VOR Federal airways are listed in paragraph 6010 of FAA Order 7400.9V dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airway listed in this document will be revised subsequently in the Order.

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

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends an existing VOR Federal airway within the NAS.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with 311a, FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures.'' This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9V, Airspace Designations and Reporting Points, signed August 9, 2011, and effective September 15, 2011, is amended as follows:

Paragraph 6010 VOR Federal airways.

(a) Domestic VOR Federal airways.

* * * * *

V–14

From Chisum, NM; Lubbock, TX; Childress, TX; Hobart, OK; Will Rogers, OK; INT Will Rogers 052° and Tulsa, OK 246° radials; Tulsa; Neosho, MO; Springfield, MO; Vichy, MO; INT Vichy 067° and St. Louis, MO, 225° radials; St. Louis; Vandalia, IL; Terre Haute, IN; Brickyard, IN; Muncie, IN; Flag City, OH; INT Flag City 079° and Dryer, OH, 240° radials; Dryer; Jefferson, OH; Erie, PA; Dunkirk, NY; Buffalo, NY; Geneseo, NY; Georgetown, NY; INT Georgetown 093° and Albany, NY, 270° radials; Albany; INT Albany 084° and Gardner, MA, 284° radials; Gardner; to Norwich, CT.

* * * * *

Issued in Washington, DC, April 24, 2012.

Paul Gallant,

Acting Manager, Airspace, Regulations and ATC Procedures Group.

[FR Doc. 2012–10362 Filed 5–2–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 558

[Docket No. FDA–2012–N–0002]

New Animal Drugs; Ceftiofur Crystalline Free Acid; Gamithromycin; Tylosin

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 actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during February 2012. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective May 3, 2012.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9019, email:*george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA's Center for Veterinary Medicine is adopting the use of a monthly **Federal Register** document to codify approval actions for NADAs and ANADAs. CVM will no longer publish a separate rule for each action. This approach will allow a more efficient use of available resources.

In this document, FDA is amending the animal drug regulations to reflect the original and supplemental approval actions during February 2012, as listed in table 1 of this document. FDA is also informing the public of the availability of summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA) and of environmental review documents required under the National Environmental Policy Act (NEPA), where applicable.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING FEBRUARY 2012

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Section	FOIA Summary	NEPA Review
141–328 ...	Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.	ZACTRAN (gamithromycin) Injectable Solution.	Supplement adding treatment of bovine respiratory disease (BRD) associated with *M. bovis.*	522.1014	yes	CE[1]
141–209 ...	Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017.	EXCEDE (ceftiofur crystalline free acid) Sterile Suspension.	Supplement adding treatment of acute bovine metritis in lactating dairy cows; and modified injection techniques.	522.313a	yes	CE
200–484 ...	Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria.	TYLOVET 100 (tylosin phosphate) Type A medicated Article.	Original approval as generic copy of NADA 012–491.	558.625	yes	CE

[1] The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment (EA) or an environmental impact statement (EIS) because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

The basis of approval of actions requiring review of safety or effectiveness data is discussed in an FOI Summary that 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.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

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 parts 522 and 558 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. In 522.313a, revise paragraphs (e)(2)(i), (e)(2)(ii), and (e)(2)(iii) to read as follows:

§ 522.313a Ceftiofur crystalline free acid.

* * * * *

(e) * * *

(2) * * *

(i) *Amount.* For subcutaneous (SC) injection in the posterior aspect of the ear where it attaches to the head (base of the ear) in lactating dairy cattle. For SC injection in the middle third of the posterior aspect of the ear or in the base of the ear in beef and non-lactating dairy cattle.

(A) Single-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight as a single injection.

(B) Two-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight given as two injections in the base of the ear approximately 72 hours apart.

(ii) *Indications for use*—(A) Single-dose regimen: For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in beef, non-lactating dairy, and lactating dairy cattle. For the control of respiratory disease in beef and non-lactating dairy cattle which are at high risk of developing BRD associated with *M. haemolytica, P. multocida,* and *H. somni.* For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii* in beef, non-lactating dairy, and lactating dairy cattle.

(B) Two-dose regimen: For the treatment of acute metritis (0-to 10-days postpartum) associated with bacterial organisms susceptible to ceftiofur in lactating dairy cattle.

(iii) *Limitations.* Following label use as either a single-dose or 2-dose regimen, a 13-day pre-slaughter withdrawal period is required after the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

* * * * *

■ 3. In 522.1014, revise paragraph (d)(1)(ii) to read as follows:

§ 522.1014 Gamithromycin.

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni,* and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida.*

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 4. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 5. In § 558.625, add paragraph (b)(90) to read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(90) No. 016592: 100 grams per pound for use as in paragraph (f) of this section.

* * * * *

Dated: April 26, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012–10632 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 610, and 680

[Docket No. FDA–2011–N–0080]

Amendments to Sterility Test Requirements for Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the sterility test requirements for biological products. This rule provides manufacturers of biological products greater flexibility, as appropriate, and encourages use of the most appropriate and state-of-the-art test methods for assuring the safety of biological

products. FDA is taking this action as part of its ongoing efforts to comprehensively review and, as necessary, revise its regulations related to biological products.

DATES: This rule is effective June 4, 2012.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background
II. Summary of the Final Rule
III. Comments on the Proposed Rule and FDA's Responses
A. General Comments and FDA's Responses
B. Comments and FDA's Responses on Specific Topics From the Proposed Rule
IV. Revisions to Other Regulations
V. Legal Authority
VI. Analysis of Impacts
VII. Environmental Impact
VIII. Federalism
IX. The Paperwork Reduction Act of 1995

I. Background

This rule revises the sterility requirements for most biological products under title 21 of the Code of Federal Regulations (CFR), subchapter F, parts 600 through 680 (21 CFR parts 600 through 680) [1] and is intended to promote improvement and innovation in the development of sterility test methods by allowing manufacturers the flexibility needed for sterility testing of some novel products that may be introduced to the market, enhancing sterility testing of currently approved products, and encouraging manufacturers to utilize scientific and technological advances in sterility test methods as they become available.

In the **Federal Register** of June 21, 2011 (76 FR 36019), FDA published a proposed rule that proposed revisions to update requirements for sterility testing of biological products. As described in the preamble of the proposed rule (76 FR 36019 at 36019 to 36020), any product that purports to be sterile should be free of viable contaminating microorganisms to assure product safety (§ 600.3(q) (21 CFR 600.3(q)). Absolute sterility of a lot cannot be practically demonstrated without complete destruction of every finished article in that lot (USP, Chapter 1211). Therefore, sterility assurance is accomplished primarily by validation of the sterilization process or of aseptic processing under current good manufacturing practice (CGMP), and is supported by sterility testing using validated and verified test methods (see e.g., USP Chapter 71, European Pharmacopeia 2.6.1.).

In the **Federal Register** of November 20, 1973 (38 FR 32048), we reorganized and republished the biologics regulations, which included regulations governing sterility testing, as parts 600 through 680.

Over the years, FDA has amended the biologics regulations, as necessary, to clarify and update the sterility test requirements. On March 11, 1976 (41 FR 10427) and March 2, 1979 (44 FR 11754), we updated § 610.12 (21 CFR 610.12) to clarify the procedures for repeat testing. On December 15, 1986 (51 FR 44903), we clarified and updated certain requirements for sterility testing to ensure the reliability of the growth-promoting qualities of the sterility test culture media and to provide greater consistency with the test methods of USP XXI. Finally, on September 15, 1997 (62 FR 48174), we incorporated by reference into § 610.12(f) the 1995 edition of the USP concerning the procedures for the membrane filtration test method.

Prior to this final rule, § 610.12 required that the sterility of most licensed biological products [2] be demonstrated through the performance of tests prescribed in § 610.12(a) and (b). Specifically, § 610.12 provided that the sterility of each lot of each product, with the exception of certain products,[3] be demonstrated by the performance of prescribed sterility tests for both bulk and final container material, unless different sterility tests were prescribed in the license (see § 610.12(g)(1)) or the manufacturer submitted adequate data [4] establishing that the mode of administration, the method of preparation, or the special nature of the product precluded or did not require a sterility test, or that the sterility of the lot was not necessary to assure the safety, purity, and potency of the product (§ 610.12(g)(4)(ii)).

The regulation also specified the test method and culture media to be used. For example, the prescribed sterility test methods relied upon culture media (either Fluid Thioglycollate Medium or Soybean-Casein Digest Medium) to detect growth of microorganisms (§ 610.12(a)(1) and (a)(2)). Moreover, § 610.12 specified criteria, such as incubation conditions (time and temperature) to be used during testing, suitable test organisms for the evaluation of the growth-promoting qualities of the culture media, storage and maintenance of test organism cultures, and storage and condition of media.

Since we last clarified and updated our regulations governing sterility testing, advances in technology in recent years have allowed the development of new sterility test methods that yield accurate and reliable test results in less time and with less operator intervention than the currently prescribed methods. Some examples of novel methods include the Adenosine Triphosphate bioluminescence, chemiluminescence, and carbon dioxide head space measurement. Manufacturers may benefit from using such sterility test methods with rapid and advanced detection capabilities.

Accordingly, we have amended § 610.12 to promote improvement and innovation in the development of sterility test methods, to address the challenges of novel products that may be introduced to the market in the future, and to potentially enhance sterility testing of currently approved products. This final rule provides manufacturers the flexibility to take advantage of methods as they become available, provided that these methods meet certain criteria.

II. Summary of the Final Rule

FDA is adopting as final, without material change, the proposed requirements for sterility testing. Specifically, this final rule:

- Eliminates specified sterility test methods, culture media formulae (or formulation), and culture media test requirements;
- Eliminates specified membrane filtration procedure requirements for certain products;
- Eliminates specified sterility test requirements for most bulk material;

[1] The sterility test provisions of this regulation do not apply to Whole Blood, Cryoprecipitated Antihemophilic Factor (AHF), Platelets, Red Blood Cells, Plasma, Source Plasma, Smallpox Vaccine, Reagent Red Blood Cells, Anti-Human Globulin, or Blood Grouping Reagents. The provisions also do not apply in cases where the Director of the Center for Biologics Evaluation and Research (CBER) or the Director of the Center for Drug Evaluation and Research (CDER), as appropriate, exempts a product from the requirements because the Director finds the manufacturer's data adequate to establish that the mode of administration, the method of preparation, or the special nature of the product precludes or does not require a sterility test or that the sterility of the lot is not necessary to assure the safety, purity, and potency of the product. (See 21 CFR 610.12(g)(4).)

[2] See list of exemptions in § 610.12(g)(4).

[3] Whole Blood, Cryoprecipitated AHF, Platelets, Red Blood Cells, Plasma, Source Plasma, Smallpox Vaccine, Reagent Red Blood Cells, Anti-Human Globulin, or Blood Grouping Reagents (§ 610.12(g)(4)(i)).

[4] In such an instance, the Director of CBER or CDER, as appropriate, would determine the adequacy of the data (§ 610.12(g)(4)(ii)).

• Modifies the repeat sterility test requirements, so that repeat tests will occur only once for each lot. These repeat tests are limited to situations when the quality control unit conclusively determines, after conducting an investigation upon detection of viable microbial contamination during the initial test of the lot, that the contamination is the result of laboratory error or faulty materials used in conducting the sterility test;

• Replaces the storage and maintenance requirements for cultures of test organisms used to determine the ''growth-promoting qualities'' of culture media with: (1) Validation requirements specifying that any sterility test used is able to consistently detect the presence of viable contaminating microorganisms and (2) verification of ''growth-promoting properties'' or microorganism-detection capabilities of test and test components;

• Replaces the sample size or amount requirement with a requirement that the sample be appropriate to the material being tested;

• Replaces the *Interpretation of test results* section under § 610.12(c) with a requirement that manufacturers establish, implement, and follow written procedures for sterility testing that describe, at a minimum, the test method used, the method of sampling, and the written specifications for acceptance or rejection of each lot;

• Simplifies and clarifies the *Exceptions* section under § 610.12(h); and

• Identifies the Director of CDER as one of the two Center directors authorized to grant an exemption under the exception provision at § 610.12(h)(2). In the proposed rule, the Center for Devices and Radiological Health was erroneously identified in this exception, instead of the Center for Drug Evaluation and Research.

• Revises the definition of the term ''sterility'' under § 600.3(q); and

• Eliminates certain exceptions for allergenic products related to sterility testing under § 680.3(c).

III. Comments on the Proposed Rule and FDA's Responses

We received 17 letters of comments on the proposed rule. These comments were received from biologics manufacturers, industry associations, and other interested persons. A summary of the comments received and our responses follow. We first respond to general comments and then respond to comments on the specific topics set forth in the preamble of the proposed rule.

To make it easier to identify the comments and our responses, the word ''Comment,'' in parentheses, will appear before the comment's description, and the word ''Response,'' in parentheses, will appear before our response. We have also numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was received. Certain comments were grouped together because the subject matter of the comments was similar.

A. General Comments and FDA's Response

(Comment 1) Thirteen of the letters of comments supported the proposed rule. Many of the comments agreed that the proposed amendments would provide manufacturers of biological products greater flexibility and would promote improvement and innovation in the development of sterility test methods. Several comments agreed that the proposed amendments would allow manufacturers to use the most appropriate and state-of-the-art test methods for assuring the safety of biological products. Several comments applauded FDA's effort to amend sterility test requirements to permit the use of new methods and systems in assessing microbiological contamination in sterile products. Another comment was pleased to see FDA's commitment to advancing the principles of innovation in product development for public health.

(Response) FDA acknowledges and appreciates the supportive comments. As stated previously, the rule provides needed flexibility and encourages manufacturers to benefit from scientific and technological advances in sterility test methods as they become available.

(Comment 2) One comment noted an error in the reference to the European Pharmacopeia 2.6.2. provided in the first paragraph in section I of the preamble to the proposed rule. The comment pointed out that European Pharmacopeia 2.6.2. is the chapter for *Mycobacteria* testing.

(Response) We agree with this comment. The reference should have been to European Pharmacopeia 2.6.1. Sterility testing.

(Comment 3) One comment concurred with the preamble statement that ''* * * sterility assurance is accomplished primarily by validation of the sterilization process or by the aseptic processing procedures under CGMP, and is supported by sterility testing using validated and verified test methods,'' (76 FR 36019 at 36019). However, the commenter went on to state that ''* * * the regulations would be better suited by ensuring that the aseptic manufacturing processes follow strict GMP, further leveraging the requirements for aseptic environments, media fill programs, and strict oversight of the aseptic process as opposed to the perceived assurance that sterility testing of samples provides. This is best illustrated through existing verbiage in § 211.113(b) (21 CFR 211.113(b)) but should be further expanded upon to provide improved guidance to industry and investigators.''

(Response) We acknowledge that product sterility testing does not provide absolute assurance of product sterility. However, we believe validation of aseptic processes,[5] using process simulations or media fills, together with operational controls and product sterility testing, provide a sufficient level of assurance that products purported to be sterile are in fact sterile. Therefore, we do not agree that additional requirements are necessary because the existing CGMP requirements under parts 210 and 211 (21 CFR parts 210 and 211) and the other applicable regulations in parts 600 through 680 already address the concerns raised by the commenter. We believe this final rule, together with the other applicable regulations and Agency guidance, provide manufacturers appropriate latitude to determine how to achieve the level of control necessary for compliance.

(Comment 4) One comment expressed a concern that an environmental requirement is not part of the proposed rule. The commenter stated, ''Environmental conditions are important to avoid cross-contamination'' and proposed the addition of the following wording described in European Pharmacopeia 2.6.1. ''The test for sterility is carried out under aseptic conditions. In order to achieve such conditions, the test environment has to be adapted to the way in which the sterility test is performed. The precautions taken to avoid contamination are such that they do not affect any microorganisms which are to be revealed in the test. The working conditions in which the tests are performed are monitored regularly by appropriate sampling of the working area and by carrying out appropriate controls.''

[5] See the applicable requirements in parts 210, 211, and 600 through 680, and FDA's guidance document entitled ''Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice,'' dated September 2004.

(Response) In discussing ''environmental conditions,'' we understand the comment to mean environmental controls. We have considered the issue, including the points raised in this comment and have decided not to adopt the suggested language or revise the rule in light of the suggested language because the concerns expressed by the commenter are currently addressed in the CGMP requirements in parts 210 and 211 and the applicable regulations in parts 600 through 680. In addition, manufacturers may turn to relevant Agency guidance documents for additional guidance. Furthermore, as the commenter states, the proposed wording regarding environmental controls under which the sterility test is to be performed is already described in European Pharmacopeia 2.6.1., and USP Chapter 71, both of which are additional, valuable resources for manufacturers.

(Comment 5) One comment noted that while § 610.12 addresses aspects of sterility, the current theme of the section is specific to sterility testing. The commenter therefore suggested either renaming the title of § 610.12 as ''Sterility Test,'' or broadening § 610.12 so that the regulation addresses all critical elements in the content area of sterility.

(Response) We decline to adopt either recommended change because we believe that the current title of § 610.12 remains appropriate and that the suggested title change is unnecessary. In response to the comment expressing a desire to broaden § 610.12 to address all critical elements in the content area of sterility, FDA notes that this comment is outside the scope of this final rule.

B. Comments and FDA's Response on Specific Topics From the Proposed Rule

The following are comments and FDA's responses, as identified by the specific topic in the proposed rule to which the comment and FDA's response applies.

1. When is sterility testing required?

For the reasons discussed in the preamble to the proposed rule (76 FR 36019 at 36020 to 36021), we proposed amending § 610.12 to eliminate the sterility test requirement for most bulk materials. We have determined that, in most cases, for purposes of sterility testing, the most appropriate test material is the final container material. We recognize that due to the nature of some biological products, testing the final container material may not always be feasible or appropriate. Thus, as finalized, § 610.12 requires that prior to release, manufacturers of biological products must perform sterility testing of each lot of each biological product's final container material or other material (e.g., bulk material or active pharmaceutical ingredient (API), in-process material, stock concentrate material), as appropriate, and as approved in the biologics license application (BLA) or BLA supplement. For example, as discussed in the preamble to the proposed rule (76 FR 36019 at 36021), certain allergenic and cell and gene therapy products may need to be tested for sterility at an in-process stage or some other stage of the manufacturing process (e.g., intermediate, API, bulk drug substance) instead of the final container material because the final container material may interfere with the sterility test. Likewise, as discussed in the preamble to the proposed rule, some cell therapy products and cell-based gene therapy products may need to be tested for sterility at an in-process stage or some other stage of manufacturing process because low production volumes may result in an insufficient final container material sample for sterility testing or a short product shelf-life may necessitate administration of the final product to a patient before sterility test results on the final container material are available.

(Comment 6) Three comments were particularly supportive of FDA's proposal to eliminate the sterility test requirements for bulk material. One comment noted this change will be particularly helpful for cellular therapy products.

(Response) We appreciate the supportive comments. We agree that the elimination of specified sterility test requirements for most bulk materials will provide manufacturers with greater flexibility and in most cases, for purposes of sterility testing, the most appropriate test material is the final container (76 FR 36019 at 36021). We also acknowledge that due to the nature of some biological products, this change could result in the need for some manufacturers to modify their testing procedures to eliminate testing for bulk materials. However, we note that these modifications to eliminate testing for bulk materials would be made following existing change control procedures and a submission to FDA to report the change would not be required.

If it is determined that sterility testing needs to be performed on material other than the final product, due to the nature of the final product, we would expect the manufacturer, as required under §§ 601.2 and 601.12, to include in its BLA or BLA supplement: (1) A description of the details of the sterility test method used, including the procedure for testing the alternate material instead of the final container material; and (2) the scientific rationale for selecting the specific test material instead of the final container material.

As discussed in the preamble to the proposed rule (76 FR 36019 at 36021), a manufacturer who desires to utilize an alternate sterility test method other than the one approved in its BLA must submit a BLA supplement in accordance with § 601.12(b).

(Comment 7) One comment asserted that upon finalization of the rule, a manufacturer who desires to utilize an alternative sterility test other than the one approved in its BLA should be permitted to submit the change to FDA in its annual report in accordance with § 601.12(d), as opposed to a prior approval supplement to an approved application under § 601.12(b).

(Response) We consider changes that may affect the sterility assurance level of a product to have substantial potential to affect the safety, purity, or potency of a product and have consistently identified this change as one that requires prior approval. Therefore, a manufacturer who desires to utilize an alternate sterility test method other than the one approved in its BLA must submit a prior approval supplement to an approved application in accordance with § 601.12(b). We note that approval of the supplement will be based on the determination that the data submitted with the request establishes a regulatory basis for approval.

2. What are the sterility test requirements?

a. *Test methods*—We proposed amending § 610.12 to eliminate references to specific test methods and culture media for sterility testing and to instead require that the sterility test be appropriate to the material being tested such that the material does not interfere with or otherwise hinder the test. As discussed in the preamble to the proposed rule (76 FR 36019 at 36021), we believe this revision recognizes current practices and provides manufacturers the flexibility to take advantage of suitable modern sterility test methods and keep pace with advances in science and technology.

As also discussed in the preamble to the proposed rule (76 FR 36019 at 36021), because we are expanding potentially acceptable sterility test methods to include non-culture-based methods in addition to culture-based methods, we also have removed the definition of ''a lot of culture medium.'' Previously, § 610.12(e)(2)(i) defined this term as ''* * * that quantity of uniform material identified as having been

thoroughly mixed in a single vessel, dispensed into a group of vessels of the same composition and design, sterilized in a single autoclave run, and identified in a manner to distinguish one lot from another.'' Although we have deleted this term from § 610.12, we believe (as stated in the preamble to the proposed rule) that this concept is captured by the definition of ''lot'' in § 600.3(x). We note that this change is also consistent with our understanding that prepared culture media may be purchased, in which case a lot may be predetermined by the vendor.

(Comment 8) Two comments opposed the elimination of the specified sterility test methods and culture media because eliminating the specific requirements may lead to different interpretations by industry, as well as FDA investigators. One comment stated that the current text on acceptable culture media, reference organisms, and incubation temperatures for sterility testing represents essential guidance for industry. The comments suggested that either the current regulations be retained in addition to the proposed amendments or retained as guidance.

(Response) We reiterate that the purpose of this rule is to provide manufacturers of biological products greater flexibility and to encourage use of the most appropriate and state-of-the-art test methods for assuring the safety of biological products. Accordingly, at this time, we decline to retain the current specified sterility test methods, culture media, reference organisms, and incubation temperatures in regulation or guidance. Furthermore, we disagree that this rule may lead to inconsistent interpretations by industry and FDA staff because sterility test methods for biological products are approved in the manufacturer's BLA or BLA supplement, and hence, the data submitted with the request are reviewed in a consistent manner in accordance with review management procedures. Therefore, we believe the commenters' concerns about inconsistencies in interpretation are unfounded.

(Comment 9) One commenter expressed concern about the applicability of the proposed changes in the global regulatory market in that the use of approved alternative sterility methods would not be globally applicable in the absence of compendial harmonization. The commenter inquired whether FDA has plans to harmonize the use of alternative sterility methods with the three main global compendia.

(Response) We do not agree that the final rule and the use of a suitable modern sterility test method will interfere with the global regulatory market. The purpose of the rule is to provide for greater flexibility and to encourage use of the most appropriate and state-of-the-art test methods for assuring the safety of biological products. We believe this final rule will foster the adoption of novel methods and that alignment with global pharmacopeial methods will occur over time. With respect to FDA's future plans to harmonize the use of alternative sterility methods with the three main global compendia, we note that any such discussion is outside the scope of this rule.

(Comment 10) One comment proposed adding a reference in the regulations to a compendial method and allowing for the implementation of alternative methods. The commenter expressed concern that, in the global marketplace, implementation of a novel method different from USP Chapter 71 would not be harmonized with other compendia and might pose risks to approval of marketing authorizations if new tests are not recognized or accepted by foreign health authorities.

(Response) We do not agree with the comment and note that incorporating such a reference would be inconsistent with the intent of this rule. We reiterate that we do not agree that this final rule will interfere with the global marketplace. Rather, we believe that facilitating flexibility and encouraging the use of the most appropriate and state-of-the-art test methods will foster the adoption of novel method technologies and that alignment with pharmacopeia methods will occur over time. Furthermore, as we have explained in the preamble to the proposed rule, FDA considers established USP compendial sterility test methods to already have been validated using an established validation protocol; therefore their accuracy, specificity, and reproducibility need not be reestablished to fulfill the validation requirements under the final rule. Only a manufacturer who desires to utilize an alternative method other than the one approved in its BLA must submit a BLA supplement in accordance with § 601.12(b). This rule does not require manufacturers to utilize an alternative method other than the one approved in their BLA.

(Comment 11) One comment stated that the absence of references to standards such as USP Chapter 71 within § 610.12 may lead to confusion and suggested that a general disclaimer that FDA is not endorsing any particular standard or the provision of specific examples within the regulation may provide an important point of reference for compliance. Two comments stated that USP Chapter 71 and European Pharmacopeia 2.6.1. should be listed within § 610.12 as a baseline or standard for sterility testing. Two other comments recommended referring to the USP Chapter 71 as the ''referee'' method instead of referring to it as an example.

(Response) The concerns expressed in the comments are unfounded. We reiterate that we consider the current sterility test methods in a manufacturer's BLA or BLA supplement to already have been validated. In contrast, newer methods (for example, non-culture-based methods that have not been validated according to an established protocol) or those that deviate from the official compendial sterility test methods will require validation.

Moreover, the final rule requires that a novel method be validated in accordance with an established protocol to demonstrate that the test is capable of consistently detecting the presence of viable microorganisms. We believe methods validation is a well recognized activity and can be performed without comparison to a ''referee'' test method.

Furthermore, we note that there is no single ''referee'' test method that would work for all products and that some novel methods cannot be easily compared to culture-based methods such as USP Chapter 71 because these testing methods do not measure microbial growth. Therefore, we believe that it is neither necessary nor appropriate to add a reference to a standard or ''baseline'' in this final rule.

(Comment 12) We received two comments regarding growth-promotion testing. One comment asserted that the proposal to eliminate the requirements to test culture media with specific test organisms, to eliminate the number of organisms that must be used to demonstrate growth-promoting qualities of culture media, and to eliminate specific incubation conditions and visual examination requirements may lead to different interpretations on which organisms can and should be used. The comment proposed that a reference to a ''referee'' method be added to the regulation including requirements for growth promotion and the strains and number of organisms to be used. The other comment supported the elimination of the list of specified organisms, while also stating that providing a list of organisms for manufacturers to consider would be a benefit to facilities that do not have the necessary expertise or staffing.

(Response) Because we are providing manufacturers the flexibility to use

sterility test methods that are either culture-based or non-culture-based, which may necessitate different verification activities, we decline to retain the existing requirements for specified sterility test reference organisms. For similar reasons, we do not believe a reference to a ''referee'' method is necessary or appropriate and we decline to adopt the recommended change.

Instead of specifying the number and type of test organisms, under § 610.12(b) of the final rule, we require that: (1) The sterility test must be appropriate to the material being tested such that the material does not interfere with or otherwise hinder the test; (2) the sterility test must be validated to demonstrate that the test is capable of reliably and consistently detecting the presence of viable contaminating microorganisms; and (3) the sterility test and test components must be verified to demonstrate that the test method can consistently detect the presence of viable contaminating microorganisms.

Due to the variety of currently available and potential future sterility test methods, we have eliminated specified incubation conditions (time and temperature) and visual examination requirements previously prescribed in § 610.12. Since we are allowing any validated sterility test method that is appropriate to the material being tested, rather than specifying the test and the media used, we have also eliminated the Fluid Thioglycollate Medium incubation temperatures previously prescribed in § 610.12(a)(1)(ii) for the final container material containing a mercurial preservative.

(Comment 13) One comment recommended that, with respect to validation, a definition for the terms ''reliably'' and ''consistently'' be added to the regulation for greater utility in understanding expectations when validating a method. The commenter offered, for example, ''* * * that a validated method, though performing consistently and reliably, may still not be centered on the true value of the specific parameter being tested. Consequently, when this method would be used during testing the results may be in a statistical state of control, but not necessarily statistically capable of measuring the true value.'' The commenter asked FDA to consider ''* * * that the use of the terms 'reliably and consistently' may infer that the validation of a test for non-sterility does not require proof of performance at least equivalent to the USP referee method.'' The comment therefore asked that § 610.12(b)(2) be revised to require that the sterility test be validated to demonstrate an equivalent or superior detection of viable contaminating microorganisms compared to the USP compendial or like method.

(Response) FDA has considered the issues raised by these comments and has determined that making the suggested changes would be inconsistent with the intent of this rule. With respect to the comment that the rule should be revised to require that the sterility test be validated to demonstrate an equivalent or superior detection of viable contaminating microorganisms compared to the USP compendial or like method, we reiterate that some novel methods cannot be easily compared to culture-based methods such as USP Chapter 71 because they do not measure microbial growth. Moreover, we note that the final rule requires that a novel method be validated in accordance with an established protocol to demonstrate that the test is capable of consistently detecting the presence of viable microorganisms. With respect to the comment that the terms ''reliably'' and ''consistently'' should be defined, we note that these terms are already well understood in the industry.

b. *Validation*—As discussed in the preamble to the proposed rule (76 FR 36019 at 36021 to 36022), the International Conference on Harmonisation (ICH) publication entitled ''Validation of Analytical Procedures: Text and Methodology Q2(R1)'' dated November 2005, states that ''The objective of validation of an analytical procedure is to demonstrate that it is suitable for its intended purpose.'' [6] Similarly, USP General Chapter 1223, ''Validation of Alternative Microbiological Methods,'' states ''Validation of a microbiological method is the process by which it is experimentally established that the performance characteristics of the method meet the requirements for the intended application.'' For sterility testing, this means that the test can consistently detect the presence of viable contaminating microorganisms.

We have eliminated the prescribed sterility test methods found in § 610.12 and instead will allow the use of sterility test methods that are validated in accordance with established protocols to be capable of consistently detecting the presence of viable contaminating microorganisms. If an established USP compendial sterility test method is used, a manufacturer must verify that this established method is suitable for application to the specific product (see §§ 211.165(e) and 211.194(a)); however, FDA considers established USP compendial sterility test methods to already have been validated using an established validation protocol, so their accuracy, specificity, and reproducibility need not be reestablished to fulfill the validation requirement under the final rule. In contrast, novel methods and any methods that deviate from the USP compendial sterility test methods require the detailed validation discussed in this document and elsewhere in this preamble.

We again note that § 610.12 requires the use of a material sample that does not interfere with or otherwise hinder the sterility test from detecting viable contaminating microorganisms. This requirement is crucial because the material itself or substances added to the material during formulation may make some sterility tests inappropriate for use. A validated sterility test method is a critical element in assuring the safety, purity, and potency of the product. USP General Chapter 1223, as well as the ICH guideline referenced earlier entitled ''Text on Validation of Analytical Procedures,'' dated March 1995 (ICH–Q2A), provide general descriptions of typical validation parameters, how they are determined, and which subset of each parameter is required to demonstrate validity, based on the method's intended use. Validation of each test method should be performed on a case-by-case basis to ensure that the parameters are appropriate for the method's intended use. In the context of reviewing sterility test methods as part of BLAs and BLA supplements, FDA may decide, as appropriate, to encourage the use of the compendial method as a benchmark or starting point for validation of novel methods and certain other methods.

(Comment 14) One comment requested clarification regarding validation of novel methods and any methods that deviate from the USP. This commenter stated that to validate novel test methods, ''the sponsor not only has to test the matrix effects'', but also has to validate the new method against the USP compendial method. The

[6] This guideline for industry was previously named ''Text on Validation of Analytical Procedures'' (ICH–Q2A), dated March 1995 (approved by the Steering Committee in October 1994). An accompanying guideline entitled ''Validation of Analytical Procedures: Methodology (Q2B),'' dated November 6, 1996, was subsequently developed and approved by the Steering Committee in November 1996. The parent guideline is now renamed ''Validation of Analytical Procedures: Text and Methodology Q2(R1)'' and was revised in November 2005. At that time, the guideline on methodology (Q2B) was incorporated into the parent guideline.

commenter also stated that this would impede the use of innovative technologies and increase the risk and cost to the sponsor. In addition, the commenter recommended that duplicative testing requirements be avoided and that the manufacturer of the technology or a third party be allowed to perform the validation of new methods.

(Response) The commenter misinterpreted the validation requirements under the proposed (and final) rule. The revisions we are adopting in the final rule do not require duplicative validation of novel methods against the USP compendial method or testing under a separate validation procedure. Instead, novel methods and any methods that deviate from the USP compendial sterility test methods will require a single, detailed validation study to be conducted, which may include the use of the compendial method as a benchmark or starting point. We disagree that such validation will impede the use of innovative technologies and will increase the risk and cost to the sponsor. Instead, we believe that, as discussed elsewhere in this document and in the preamble to the proposed rule, that this final rule will encourage the use of innovative technology.

(Comment 15) One comment referenced the preamble statement that ''* * * FDA may decide, as appropriate, to encourage the use of the compendial method as a benchmark or starting point for validation of novel methods and certain other methods.'' (76 FR 36019 at 36022) and suggested that the use of the compendial method as a benchmark or starting point should be more strongly encouraged.

(Response) While FDA may decide, as appropriate, to encourage the use of the compendial method as a benchmark or starting point for validation of some novel or other methods, we also may decide not to encourage such use for some (for example, non-culture-based) methods that cannot easily be compared to culture-based methods such as the USP compendial method. Therefore, we disagree that the use of the compendial method as a benchmark or starting point should be more strongly encouraged or required.

(Comment 16) We received two comments in response to our request in the proposed rule for comments on whether the proposed requirements are sufficient to ensure adequate validation of novel sterility test methods or whether additional criteria or guidance is needed. One comment recommended that any guidance to accompany the final rule be developed to include such things as a list of organisms for manufacturers to consider in the development of their validation and verification plans, including examples of when verification is required. One comment suggested that such additional guidance include information related to a determination of the panel of relevant organisms in the sample matrix used in challenging the sterility test during validation.

(Response) We appreciate the interest in additional guidance for validation of novel sterility test methods and will consider the need to develop future guidance in accordance with the good guidance practices set out in 21 CFR 10.115.

As discussed in the preamble to the proposed rule, it is important to consider validation principles, such as limit of detection, specificity, ruggedness, and robustness, while developing the validation protocol and performing validation studies. These terms are defined as follows:

- The ''limit of detection'' reflects the lowest number of microorganisms that can be detected by the method in a sample matrix. This is necessary to define what is considered contaminated.
- ''Specificity'' is the ability of the test method to detect a range of organisms necessary for the method to be suitable for its intended use. This is demonstrated by challenging the sterility test with a panel of relevant organisms in the sample matrix.
- ''Ruggedness'' is the degree of reproducibility of results obtained by analysis of the same sample under a variety of normal test conditions, such as different analysts, different instruments, and different reagent lots.
- ''Robustness'' is the capacity of the test method to remain unaffected by small, but deliberate, variations in method parameters, such as changes in reagent concentration or incubation temperatures.

(Comment 17) One comment stated that for the detailed validation of a novel method, the validation principles should be restricted to the limit of detection, specificity, and robustness (i.e., to not include ruggedness).

(Response) We agree that the validation principles of limit of detection, specificity, and robustness are important to consider when developing protocols and performing validation studies. However, we understand the comment to suggest excluding ruggedness. We view ruggedness as an important validation principle to be considered, and we do not agree with excluding it from the scope of this rule. We note that the final rule does not include prescriptive details on how to conduct validation studies; it simply codifies our longstanding policy that the sterility test must be validated to demonstrate that the test is capable of reliably and consistently detecting the presence of viable contaminating microorganisms.

(Comment 18) One comment objected to the requirement in existing § 211.160(b) as to the establishment of sampling plans because ''* * * it is not practical or feasible to develop a scientifically sound sampling plan to ensure a product conforms to standards of sterility.'' The comment recommended as a solution to either remove the requirement for scientific sampling plans with respect to sterility testing or to provide a clarification of ''scientifically sound'' versus ''appropriate.''

(Response) The suggested revisions go beyond the scope of the proposed changes to the sterility test requirements. Furthermore, § 211.160(b) is an existing current good manufacturing practice requirement for finished pharmaceuticals, which states that laboratory controls must include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. We consider such laboratory controls to be needed for both culture-based and non-culture-based sterility test methods. As stated in the preamble to the proposed rule (76 FR 36019 at 36022), the manufacturer must establish and document the test method's accuracy, sensitivity, specificity, and reproducibility (§ 211.165(e)), as specified in the BLA or BLA supplement (§§ 601.2, 601.12). For sterility tests, FDA believes that a validation protocol that would meet these standards would, at a minimum, include samples of the material to be marketed and incorporate appropriate viable contaminating microorganisms to demonstrate the sterility test's growth-promoting properties or the method's detection system capabilities, depending on the type of test method used. In addition, validation protocols for culture-based methods should include both aerobic and anaerobic microorganisms when selecting test organisms and include microorganisms that grow at differing rates so that manufacturers can establish that the test media are capable of supporting the growth of a wide range of microorganisms.

When utilizing culture-based methods, where appropriate, validation protocols should require that challenge organisms be added directly to the product prior to membrane filtration or direct inoculation. If this is not possible due to inhibition by the product, then validation protocols should require that the challenge organism be added to the final portion of sterile diluent used to rinse the filter, if a membrane filtration test method is used, or directly to the media containing the product if a direct inoculation test method is used.

For non-culture-based methods, the feasibility of identifying microorganisms from a contaminated sample should be evaluated during validation. If a method does not have the capability to identify microorganisms to the species level, the validation protocol should require that an additional method for species identification be utilized for investigation of detected contaminants. The test organisms selected should reflect organisms that could be found in the product, process, or manufacturing environment.

(Comment 19) Two comments sought clarification of the following statement in the preamble to the proposed rule: ''When utilizing culture-based methods, validation protocols should require that challenge organisms be added directly to the product prior to membrane filtration or direct inoculation. If this is not possible due to inhibition by the product, then validation protocols should require that the challenge organism be added to the final portion of sterile diluent used to rinse the filter if a membrane filtration test method is used, or directly to the media containing the product if a direct inoculation test method is used.'' (76 FR 36019 at 36022)

One commenter stated that this language is inconsistent with the harmonized compendial method suitability test which states, ''After transferring the content of a container or containers to be tested to the membrane, add an inoculum of small number of viable microorganisms (not more that 100 colony-forming units) to the final portion of sterile diluents used to rinse the filter.'' Another comment sought clarification of the suggested limits for the density of the inoculum of challenge organisms added directly to the product.

(Response) The intent of these statements was to clarify that for certain biological products utilizing culture-based methods, method suitability testing necessitates adding the challenge organism directly to the product prior to membrane filtration or direct inoculation. Therefore, we are now clarifying that when utilizing culture-based methods, where appropriate, validation protocols should require that challenge organisms be added directly to the product before membrane filtration or direct inoculation. If this is not possible due to inhibition by the product, then validation protocols should require that the challenge organism be added to the final portion of sterile diluent used to rinse the filter if a membrane filtration test method is used or directly to the media containing the product if a direct inoculation test method is used.

(Comment 20) One comment addressed the selection of organisms to be used. The comment suggested that with respect to validation protocols, for consistency, the wording regarding the selection of organisms should specifically include wild-type isolates that have been recovered from the controlled manufacturing environment and past contaminants of the product or any of its sterile components. The comment also suggested that this requirement should extend beyond culture-based methods. Further, the comment suggested that the statement in the preamble that '' '*The test organisms selected should reflect organisms that could be found in the product, process, or manufacturing environment* (emphasis added) [76 FR 36019 at 36022],' should be tightened to require use of strains actually isolated from the product, process, or manufacturing environment, as the word 'reflect' probably implies use of relevant species that might be sourced from culture collections rather than explicitly requiring use of wild-type strains (plant isolates).''

(Response) Our intention with respect to this statement was to include those organisms recovered both from the controlled manufacturing environment and from the product. Furthermore, the preamble statement was intended to refer to validation protocols in general, where appropriate, to both culture-based and non-culture-based test methods.

The validation study design should contain the appropriate controls to evaluate the product sample's potential to generate false-positive and false-negative results. Validation of the sterility test should be performed on all new products, and repeated whenever there are changes in the test method or production method that could potentially inhibit or enhance detection of viable contaminating microorganisms.

(Comment 21) One comment recommended the addition of ''or production method'' to the statement in the preamble so that it would now read, ''Validation of the sterility test should be performed on all new products, and repeated whenever there are changes in the test method *or production method* that could potentially inhibit or enhance detection of viable contaminating microorganisms.'' (See original statement 76 FR 36019 at 36022.) The commenter stated that the additional language is appropriate because the production process may influence the matrix of the test article, which may in turn influence the sterility test verification.

(Response) We agree that changes in the production method or manufacturing process could affect the results of testing conducted on the product. Therefore, we agree that validation of the sterility test should be performed on all new products and repeated whenever there are changes in the test method or *production method* that could potentially inhibit or enhance detection of viable contaminating microorganisms.

c. *Verification*—As stated in the proposed rule (76 FR 36019 at 36022), verification is the confirmation that specified requirements have been fulfilled as determined by examination and provision of objective evidence. While validation of a sterility test method is the initial process of demonstrating that the procedure is suitable to detect viable contaminating microorganisms, verification occurs over the lifetime of the sterility test method and is the process of confirming that the sterility test and test components continue to be capable of consistently detecting viable contaminating microorganisms in the samples analyzed. This verification activity may be necessary on a periodic basis or each time a sample is tested, depending upon the test method used. Under § 610.12(e) of the final rule, we require that the sterility test and test components be verified, as appropriate, to demonstrate that they can continue to consistently detect viable contaminating microorganisms.

(Comment 22) One comment maintained that the section of the preamble to the proposed rule regarding verification was not totally clear and should be reworded to explain the intended purpose. Specifically, the comment suggested, in order to clarify the goal of verification, adding the following sentence, ''The intended purpose of the verification is to confirm that all the reagents utilized in the sterility test are qualified.'' The commenter also noted that validation is to be done using the product to be tested and proposed adding the phrase ''in the product to be tested'' to the following statement in the preamble ''While

validation of a sterility test method is the initial process of demonstrating that the procedure is suitable to detect viable contaminating microorganisms, verification occurs over the lifetime of the sterility test method and is the process of confirming that the sterility test and test components continue to be capable of consistently detecting viable contaminating microorganisms in the samples analyzed.'' (76 FR 36019 at 36022 to 36023)

(Response) To the extent that the commenter is arguing that our explanation is unclear, we disagree. As stated in the preamble to the proposed rule at section III.E (76 FR 36019 at 36022 to 36023), we believe that in order to verify the sterility test, verification activities are necessary to demonstrate that sterility test methods can continue to reliably and consistently detect viable contaminating microorganisms and that verification is the process of confirming that the sterility test and test components continue to be capable of consistently detecting viable contaminating microorganisms in the samples analyzed. In addition, we acknowledge that method suitability testing using the product is an important part of a validation protocol for a sterility test method.

3. What information is needed in written procedures for sterility testing?

We have finalized, as proposed, the replacement of the requirements found in current § 610.12(c) entitled *Interpretation of test results,* with the requirements that manufacturers must establish, implement, and follow written procedures for sterility testing. Written procedures are essential to ensure consistency in sampling, testing, and interpretation of results and to provide prospective acceptance criteria for the sterility test. Written procedures should include all steps to be followed in the sterility test method for initial and repeat tests and be detailed, clear, and unambiguous. Under the current good manufacturing practice regulations, manufacturers are required to document that a drug product satisfactorily conforms to final specifications for the drug product (§ 211.165(a)). As such, scientifically sound and appropriate specifications, standards, sampling plans, and test procedures must be designed and written to ensure that materials conform to appropriate standards of sterility; and written procedures must include a description of the sampling method and the number of units per batch to be tested (see § 211.165(c)).

Under the final rule, manufacturers may use either culture-based or non-culture-based sterility test methods to evaluate material for sterility. There are marked differences between culture-based and non-culture-based sterility tests. Section 610.12(c) provides the minimum critical considerations that must be included in the written procedures for culture-based and non-culture-based sterility tests.

For culture-based sterility test methods, the written procedures must include, at a minimum, a description of the composition of the culture media, growth-promotion test requirements, and incubation conditions (time and temperature). For non-culture-based sterility test methods, the written procedures must include the composition of test components, test parameters, including the acceptance criteria, and the controls used to verify the test method's ability to consistently detect the presence of viable contaminating microorganisms.

4. What is an appropriate sample for sterility testing?

Selection of an appropriate sample of a lot is critical for purposes of sterility testing. Under § 610.12(d) as finalized, due to the variety of products covered under § 610.12, the regulation requires that the sample be appropriate to the material being tested.

(Comment 23) Five comments requested clarification of the proposed requirement that the sample be ''appropriate to the material being tested,'' with respect to the size or volume of the final product lot. The comments asserted that the example provided in the preamble of the proposed rule, ''For example, a final product lot size of 100,000 units would necessitate a greater number of samples to be evaluated than a final product lot size of 5,000 units,'' (76 FR 36019 at 36023), conflicts with USP Chapter 71 regarding the minimum number of articles to be tested in relation to the number of articles in the batch.

(Response) We acknowledge that the example provided in the preamble of the proposed rule erroneously compared a final product lot size of 100,000 units to one of 5,000 units. We had intended to compare a final product lot size of 100,000 to one of 500 units. We recognize that this error may have caused confusion among some readers, and that the example was inconsistent with the USP Chapter 71 methods for the minimum number of articles to be tested in relation to the number of articles in the batch. It was not our intent to suggest that established USP compendial sterility test methods, including the minimal number of articles to be tested in relation to the number of articles in the batch, were unacceptable under the new requirements in § 610.12(d).

In order to clarify the new requirement that the sample be ''appropriate to the material being tested,'' we reiterate that in selecting an appropriate sample size, § 610.12(d) requires that the following minimal criteria be considered:

- The size or volume of the final product lot. For example, a final product lot size of 100,000 units would necessitate a greater number of samples to be evaluated than a final product lot size of 500 units;
- The duration of manufacturing of the drug product.[7] For example, it is important that samples be taken at different points of manufacture, which, at a minimum, should include the beginning, middle, and end of manufacturing, in an effort to provide evidence of sterility of the drug product throughout the duration of the manufacturing process;[8]
- The final container configuration and size. We believe this will ensure appropriate representation of the lot;
- The quantities or concentrations of inhibitors, neutralizers, and preservatives, if present, in the test material;
- For a culture-based test method, the volume of test material that results in a dilution of the product that was determined not to be bacteriostatic or fungistatic; and
- For a non-culture-based test method, the volume of test material that results in a dilution of the product that does not inhibit or otherwise hinder the detection of viable contaminating microorganisms.

(Comment 24) Two comments stated that the proposed changes related to sample size are vague and leave too much room for interpretation by industry as well as investigators or auditors when determining an appropriate sample size.

(Response) We disagree that requiring the sample to be appropriate to the material being tested is vague and leaves too much open to interpretation. Our intent in requiring that the sample be ''appropriate to the material being tested,'' with consideration of a list of minimal criteria, is to provide manufacturers flexibility to retain their existing procedures for sterility testing using culture-based methods, or to take

[7] See § 210.3(b)(4) for the definition of the term ''drug product.''

[8] See § 211.160(b) for general requirements for laboratory controls.

advantage of modern methods as they become available, provided that these modern methods meet certain criteria, as described in our response to Comment 23. In addition, as noted previously, sterility test methods are approved by FDA in either a manufacturer's BLA or BLA supplement, thereby alleviating concern that the final rule leaves too much room for interpretation.

(Comment 25) One comment asked FDA to clarify whether the quantities or concentrations of inhibitors, neutralizers, and preservatives, if present in the test material, have an impact on sample size and selection. The comment also asked about the relationship between the impact of preservatives and any increase in the sample size.

(Response) In selecting an appropriate sample size, § 610.12(d) requires consideration of certain minimal criteria, including the quantities or concentrations of inhibitors, neutralizers, and preservatives, if present in the test material. The consideration of the quantities or concentrations of inhibitors, neutralizers, and preservatives, if present in the test material, will depend upon the product and the test method utilized. This provides both manufacturers of future innovative products, as well as manufacturers of currently approved products, the flexibility to take advantage of modern methods or to retain the sterility testing method as approved in the BLA or BLA supplement.

5. What is required to verify the sterility test?

As discussed in the preamble to the proposed rule (76 FR 36019 at 36023), verification activities are necessary to demonstrate that sterility test methods can continue to reliably and consistently detect viable contaminating microorganisms. The degree of verification that is necessary depends upon the sterility test method employed. Depending upon the sterility test method, verification of each individual test might be appropriate. On the other hand, some sterility test methods may only need verification activities performed on the selected culture media or test organisms. Under § 610.12(e), a manufacturer must perform verification activities appropriate for the sterility test method chosen, as set forth in the final rule.

(Comment 26) In the proposed rule (76 FR 36019 at 36020, footnote 6), we proposed to refer to ''growth-promoting properties'' rather than ''growth-promoting qualities'' and requested comments on which term is most appropriate. We received two comments in response to our request. Both comments support the use of ''growth-promoting properties'' and agree that ''growth-promoting properties'' reflects more accurate and current terminology.

(Response) We appreciate and agree with these comments and have retained the term ''growth-promoting properties'' in the final rule.

(Comment 27) Two comments requested clarification of the requirements for verification of culture-based test methods. One comment asked if, for culture-based test methods, all media must undergo growth-promotion testing over their shelf-life, and if validation were performed for three lots, whether it is acceptable to perform growth-promotion testing on the media only when it is initially received. One comment acknowledged that each media lot would have to be tested for growth-promotion at least at the beginning and the end of its use; however, the comment sought clarification whether companies would be expected to keep performing the test at regular intervals.

(Response) For culture-based methods, it is important that each lot of all culture media undergo growth-promotion testing at regular intervals over the shelf-life of the media, not just when the media is initially received. The final rule requires that the sterility test and test components be verified, as appropriate, to demonstrate that they can continue to consistently detect viable contaminating microorganisms. The degree of verification depends upon the sterility test method employed.

For culture-based test methods, studies must be conducted to demonstrate that the performance of the test organisms and culture media are suitable to consistently detect the presence of viable contaminating microorganisms, including tests for each lot of culture media to verify its growth-promoting properties over the shelf-life of the media and not only at the beginning and end of use. Growth-promotion testing is important to demonstrate that the culture media are capable of supporting the growth of microorganisms.

(Comment 28) One comment recommended that with the proposal to remove the definition of a lot of culture medium currently defined in § 610.12(e)(2)(i), revisions to the rule should clearly state that each delivery of each vendor lot of media be ''QC tested'' by the end user to verify its ability to detect viable microorganisms. The comment states, ''It must be made clear that the vendor cannot be totally in control of the product once it has been shipped from the distribution centre.'' Further, the comment states it is the user's responsibility to test each delivery of each vendor lot to ensure that undetected mistreatment of the testing product during its shipment and delivery to the end-user has not caused deterioration in its efficacy.

(Response) We agree that the user of the culture media must verify that each lot can continue to consistently detect viable contaminating microorganisms. For the reasons noted previously, we do not believe the suggested changes are needed because the rule, as proposed and now finalized, already reflects this requirement.

(Comment 29) One comment stated that usually validation data provided by the media suppliers are used to cover the shelf-life of the media and proposed adding the following text ''or media supplier validation data must be available'' after the text ''over the shelf-life of the media'' in proposed § 610.12(e)(1) to capture the fact that the supplier of the media may also supply this parameter.

(Response) We do not agree that reliance on media supplier validation data alone, in lieu of testing by the manufacturer, would be acceptable. Under § 610.12(e)(1) of the final rule, for culture-based test methods, manufacturers must conduct tests to demonstrate that the performance of the test organisms and culture media are suitable to consistently detect the presence of viable contaminating microorganisms, including tests for each lot of culture media to verify its growth-promoting properties over the shelf-life of the media. Therefore, reliance on media supplier validation data alone, in lieu of testing by the manufacturer, would not be acceptable.

6. Can a sterility test be repeated?

For the reasons discussed in the preamble to the proposed rule (76 FR 36019 at 36023 to 36024), we have amended the regulations in § 610.12(b) for repeat testing. Therefore, we have eliminated the reference to repeat testing of bulk material because, under the final rule, sterility testing is no longer required on bulk material in most instances. We also have finalized the proposal to eliminate the use of a second repeat test for final container material to harmonize our regulatory expectations with current scientific understanding of quality manufacturing controls.[9] Under the final rule,

[9] See also Barr D., A. Celeste, R. Fish, et al., *Application of Pharmaceutical CGMPs;* FDLI (1997)

Continued

consistent with USP Chapter 71, if the initial test indicates the presence of microorganisms, then the product being examined does not comply with the sterility test requirements, unless a thorough investigation by the quality control unit can conclusively ascribe the initial evidence of microbial presence to a laboratory error or faulty materials used in conducting the test.

If the test of the initial sample is conclusively found to be invalid, due to laboratory error or faulty test materials, the sterility test may be repeated one time. If no evidence of microorganisms is found in the repeat test, the product examined complies with the test requirements for sterility. If, however, evidence of microorganisms is found in the repeat test, the product examined does not comply with the test requirements for sterility.

Further, as discussed in the preamble to the proposed rule, both a comparable product that is reflective of the initial sample in terms of sample location and the stage in the manufacturing process from which it was taken, and the same sterility test method must be used for both the initial and repeat tests. This is intended to ensure that the same volume of material is used for the initial test and each repeat test, and that the interpretation of the results is conducted in the same manner.

(Comment 30) One comment supported FDA's proposal to modify the provision for repeat testing to harmonize regulatory expectations with current scientific understanding of quality manufacturing controls by eliminating the use of a second repeat test of final container material and agreed with FDA that the proposed modification of the provision for repeat testing is in accordance with the USP and the European Pharmacopeia. However, the commenter noted that FDA's proposed requirement to take repeat test samples that are reflective of the initial samples may be difficult to fulfill. For instance, the commenter states, ''* * * at the time when the sterility test might show a positive result (after a few days), it could be that it is no longer possible to distinguish which vials were filled at which point in time.'' The comment suggested deleting the requirement in proposed § 610.12(f)(3) that the repeat test must be conducted with ''comparable product that is reflective of the initial sample in terms of sample location and the stage in the manufacturing process from which it was obtained.''

(Response) We appreciate the supportive comments. However, we do not agree with the recommended change to § 610.12(f)(3). We believe the final rule is consistent with current scientific understanding of quality manufacturing controls. If a repeat test is conducted, the same test method must be used for both the initial and repeat tests, and the repeat test must be conducted with comparable product that is reflective of the initial sample in terms of sample location and the stage in the manufacturing process from which it was obtained.

As discussed in the preamble to the proposed rule, we appreciate that this final rule could result in the need for some manufacturers to modify their repeat test procedures. We continue to consider these modifications to be minor changes in accordance with § 601.12(d) and to have a minimal potential for an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product. Therefore, such changes must be reported in the annual report within 60 days of the anniversary date of approval of the BLA.

7. What records must be kept relating to sterility testing?

Previously, § 610.12(h) incorporated by reference the record keeping and maintenance requirements contained in §§ 211.167 and 211.194. We continue to maintain these requirements. As discussed in the preamble to the proposed rule (76 FR 36019 at 36024), this is intended to assure that data derived from sterility tests comply with established specifications. This includes describing the samples received for testing, stating the method used to test the samples, identifying the location of relevant validation or verification data, recording all calculations performed, and stating how the results of tests performed compare to set specifications.

8. Are there any exceptions to sterility test requirements?

In the proposed rule we invited comments on whether any of the current exceptions should be removed (76 FR 36019 at 36024). We specifically requested comments on whether to remove the exemption for platelets. Bacterial contamination of platelets is a recognized public health risk, and the blood collection industry has already called for and implemented methods to detect and limit or inactivate bacteria in platelet components. Requiring testing for platelets would be consistent with these industry practices.

(Comment 31) In response to our request for comment, a joint comment from industry groups recommended that FDA continue to except Whole Blood, Cryoprecipitated Antihemophilic Factor (AHF), Platelets, Red Blood Cells, and Plasma from the sterility test requirements in § 610.12. The comment acknowledged that the blood industry has called for and implemented methods to detect and limit or inactivate bacteria in platelet components and that some culture-based methods are in wide use as a quality control tool. However, there are currently no available tests that will ensure the sterility of platelet products. In addition, the joint comment noted that if the current exception for platelets would be removed, manufacturers of blood and blood components would not be able to satisfy the new requirement. Further, the comment recommended that FDA vigorously support applications for pathogen inactivation processes for platelet components. Moreover, the joint comment noted that any sterility test requirement tied to a BLA is too narrow an approach to ensure optimal bacterial testing of platelet products, as any platelet collected or manufactured by a facility that does not have a BLA would not be subject to the sterility test regulation. Accordingly, the joint comment recommended that FDA use a different mechanism to require testing of all platelet products for bacterial contamination when testing becomes technologically feasible.

(Response) We appreciate these comments and we generally agree. We recognize that blood establishments have begun to take steps to test for bacterial contamination in platelet components. We welcome the acknowledgement of the importance of bacterial testing and pathogen inactivation processes for platelet components and believe that appropriate microbial testing of platelet components may be necessary to assure product quality. However, while these technologies are developing, we have retained the exception from this rule for these products. Instead, we will continue to review these issues and available technologies and will take appropriate steps at another time to address microbial testing of blood components.

(Comment 32) One comment recommended adding an exception stating that a manufacturer with parametric release programs is not required to comply with the sterility test requirements. The comment noted that parametric release for articles sterilized

at p. 146 (''In the case of a clearly identified laboratory error, the retest results substitute for the original test results. * * * If, on the other hand, no laboratory error could be identified in the first test, then there is no scientific basis for discarding the initial out-of-specification results in favor of passing retest results.'').

with moist heat has been recognized by FDA since 1987, and that many companies have adopted this approach.

(Response) We disagree with the proposed change and decline to add an exception for drug products terminally sterilized by moist heat processes and subject to parametric release because the exception under § 610.12(h) (previously under § 610.12(g)) already provides for an exception for such parametric release programs. As noted in FDA's guidance document entitled ''Guidance for Industry: Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes,'' dated February 2010, FDA approval of parametric release must be requested either in an original application submission under 21 CFR 314.50 or 601.2, or in a prior approval supplement under 21 CFR 314.70 or 601.12.

(Comment 33) Two comments recommended adding other exceptions to the sterility test requirements. One comment recommended adding granulocytes to the exception, and one comment recommended adding in vitro diagnostic devices regulated as biological products, which do not purport to be sterile.

(Response) We decline to adopt the suggested changes because neither granulocytes nor in vitro diagnostic devices, which do not purport to be sterile, are subject to the sterility test requirements in § 610.12. Therefore, we believe the recommendations are beyond the scope of this rule.

(Comment 34) One comment recommended that the exceptions provision be revised to ''specifically include or exclude various biological product types such as Bioequivalent/Biosimilars and combination products.''

(Response) We do not believe the suggested change is needed. Biological products must comply with the applicable requirements in parts 600 through 680, in addition to other applicable regulations.

For the reasons discussed in the preamble to the proposed rule (76 FR 36019 at 36024), we have finalized the proposed minor modifications to the current exception in § 610.12(g)(4)(ii), under which the Director of CBER or CDER, as appropriate, determines that data submitted adequately establish that the mode of administration, the method of preparation, or the special nature of the product precludes or does not require a sterility test or that the sterility of the lot is not necessary to assure the safety, purity, and potency of the product. Specifically, the minor modification that we refer to is the ''route of administration'' rather than the ''mode of administration'' and to ''any other aspect of the product'' rather than ''the special nature of the product'' in finalized § 610.12(h)(2) so as to account for novel products that may be introduced to the market in the future. This exception allows the Director of CBER or CDER, as appropriate, to exempt biological material from the sterility test requirements of this section if, based upon the scientific evidence presented in the BLA or BLA supplement, the data adequately establish that the route of administration, method of preparation, or any other aspect of the product precludes or does not necessitate a sterility test to assure the safety, purity, and potency of the product. We note that in the proposed rule, the Center for Devices and Radiological Health was erroneously identified in this exception, instead of CDER. In the final rule, we have correctly identified CDER in the exception provision at § 610.12(h)(2).

In addition to comments regarding exceptions as stated in this document, we have also eliminated, as proposed, the current exceptions under § 610.12(g)(1) and (2) because they are no longer necessary given the flexibility now built into the final rule. In addition, we have eliminated, as proposed, the current exceptions in § 610.12(g)(5) through (g)(9) because they are no longer necessary and because the revised rule now requires manufacturers to determine the appropriate sample volume and size for the material being tested and requires that the sterility test be ''appropriate to the material being tested.'' (See 76 FR 36019 at 36024 to 36025 for more information.)

IV. Revisions to Other Regulations

In addition to the revisions to the sterility regulation in § 610.12, we have also revised, as proposed, two other FDA regulations in this final rule. These revisions are as follows:

- Section 600.3(q): Previously, § 600.3(q) defined ''sterility'' to mean ''freedom from viable contaminating microorganisms, as determined by the tests prescribed in § 610.12 of this chapter.'' As proposed, we have reworded this definition to eliminate the term ''prescribed'' since § 610.12 no longer prescribes specific test methods. Thus, we have amended § 600.3(q) to define ''sterility'' as ''freedom from viable contaminating microorganisms, as determined by tests conducted under § 610.12 of this chapter.''
- Section 680.3(c) (21 CFR 680.3(c)): As proposed, we have amended § 680.3(c) to eliminate the term ''prescribed.'' Section 680.3(c) now states that ''A sterility test shall be performed on each lot of each Allergenic Product, as required by § 610.12 of this chapter.'' Additionally, we have eliminated § 680.3(c)(1) through (c)(4) because these exceptions are no longer necessary under the revisions to § 610.12. (See 76 FR 36019 at 36025 for more information.)

V. Legal Authority

FDA is issuing this regulation under the biological products provisions of the Public Health Service Act (the PHS Act) (42 U.S.C. 262 and 264) and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (sections 201, 301, 501, 502, 503, 505, 510, 701, and 704) (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 371, and 374). Under these provisions of the PHS Act and the FD&C Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, effective, pure, and potent, and to prevent the introduction, transmission, and spread of communicable disease.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1996 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. While the rule restricts retesting when sterility tests are failed, the change codifies an approach for retesting that is similar to the approach prescribed by the USP. The rule does not otherwise add any new regulatory responsibilities and generally increases flexibility for sterility testing. Therefore, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an

assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

These amendments would generally provide manufacturers of biological products with more flexibility as to how they evaluate the sterility of their products and reduce the number of evaluations required. The net effect would be to reduce costs.

One part of these amendments might impose some additional costs on manufacturers, however. Under the current regulations, if a biological product fails a sterility test, the test may be repeated. If the product passes a subsequent test, it is inferred that the first test was flawed and only the latter results are used. Under the new regulations, the test may be repeated only if it is possible to ''ascribe definitively'' the initial failure to ''a laboratory error or faulty materials used in conducting the sterility testing.''

This change could increase costs for manufacturers because additional products could be discarded. The size of the increase, if any, would be determined by the number of additional lots discarded, the lot sizes, and the production costs per unit. Some or all of the costs of this change, could, in turn, be mitigated by the reduction in losses associated with the provision of contaminated products.

This change is expected to affect few manufacturers. The method for sterility testing described in USP Chapter 71 already limits the repetition of tests to circumstances similar to those described in these amendments. It is anticipated that, in the absence of these amendments, the majority of manufacturers would limit the repetition of sterility tests in order to comply with USP Chapter 71.

The benefit of limiting retests would be fewer illnesses caused by contaminated biological products. We are unable to quantify the value of the reduction in illnesses because we do not have an estimate of the risk of illness from contaminated biological products or the decline in that risk associated with limiting retests.

VII. Environmental Impact

The Agency has determined under 21 CFR 25.31(h) 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.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. The Paperwork Reduction Act of 1995

This final rule contains collections of information that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 211.165 and 610.12 have been approved and assigned OMB control number 0910–0139.

List of Subjects

21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 680

Biologics, Blood, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 600, 610, and 680 are amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 1. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

§ 600.3 [Amended]

■ 2. Section 600.3 is amended in paragraph (q) by removing ''prescribed in'' and by adding in its place the phrase ''conducted under''.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 3. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

■ 4. Section 610.12 is revised to read as follows:

§ 610.12 Sterility.

(a) *The test.* Except as provided in paragraph (h) of this section, manufacturers of biological products must perform sterility testing of each lot of each biological product's final container material or other material, as appropriate and as approved in the biologics license application or supplement for that product.

(b) *Test requirements.* (1) The sterility test must be appropriate to the material being tested such that the material does not interfere with or otherwise hinder the test.

(2) The sterility test must be validated to demonstrate that the test is capable of reliably and consistently detecting the presence of viable contaminating microorganisms.

(3) The sterility test and test components must be verified to demonstrate that the test method can consistently detect the presence of viable contaminating microorganisms.

(c) *Written procedures.* Manufacturers must establish, implement, and follow written procedures for sterility testing that describe, at a minimum, the following:

(1) The sterility test method to be used;

(i) If culture-based test methods are used, include, at a minimum:

(A) Composition of the culture media;

(B) Growth-promotion test requirements; and

(C) Incubation conditions (time and temperature).

(ii) If non-culture-based test methods are used, include, at a minimum:

(A) Composition of test components;

(B) Test parameters, including acceptance criteria; and

(C) Controls used to verify the method's ability to detect the presence of viable contaminating microorganisms.

(2) The method of sampling, including the number, volume, and size of articles to be tested;

(3) Written specifications for the acceptance or rejection of each lot; and

(4) A statement of any other function critical to the particular sterility test method to ensure consistent and accurate results.

(d) *The sample.* The sample must be appropriate to the material being tested, considering, at a minimum:

(1) The size and volume of the final product lot;

(2) The duration of manufacturing of the drug product;

(3) The final container configuration and size;

(4) The quantity or concentration of inhibitors, neutralizers, and preservatives, if present, in the tested material;

(5) For a culture-based test method, the volume of test material that results in a dilution of the product that is not bacteriostatic or fungistatic; and

(6) For a non-culture-based test method, the volume of test material that results in a dilution of the product that does not inhibit or otherwise hinder the detection of viable contaminating microorganisms.

(e) *Verification.* (1) For culture-based test methods, studies must be conducted to demonstrate that the performance of the test organisms and culture media are suitable to consistently detect the presence of viable contaminating microorganisms, including tests for each lot of culture media to verify its growth-promoting properties over the shelf-life of the media.

(2) For non-culture-based test methods, within the test itself, appropriate controls must be used to demonstrate the ability of the test method to continue to consistently detect the presence of viable contaminating microorganisms.

(f) *Repeat test procedures.*—(1) If the initial test indicates the presence of microorganisms, the product does not comply with the sterility test requirements unless a thorough investigation by the quality control unit can ascribe definitively the microbial presence to a laboratory error or faulty materials used in conducting the sterility testing.

(2) If the investigation described in paragraph (f)(1) of this section finds that the initial test indicated the presence of microorganisms due to laboratory error or the use of faulty materials, a sterility test may be repeated one time. If no evidence of microorganisms is found in the repeat test, the product examined complies with the sterility test requirements. If evidence of microorganisms is found in the repeat test, the product examined does not comply with the sterility test requirements.

(3) If a repeat test is conducted, the same test method must be used for both the initial and repeat tests, and the repeat test must be conducted with comparable product that is reflective of the initial sample in terms of sample location and the stage in the manufacturing process from which it was obtained.

(g) *Records.* The records related to the test requirements of this section must be prepared and maintained as required by §§ 211.167 and 211.194 of this chapter.

(h) *Exceptions.* Sterility testing must be performed on final container material or other appropriate material as defined in the approved biologics license application or supplement and as described in this section, except as follows:

(1) This section does not require sterility testing for Whole Blood, Cryoprecipitated Antihemophilic Factor, Platelets, Red Blood Cells, Plasma, Source Plasma, Smallpox Vaccine, Reagent Red Blood Cells, Anti-Human Globulin, and Blood Grouping Reagents.

(2) A manufacturer is not required to comply with the sterility test requirements if the Director of the Center for Biologics Evaluation and Research or the Director of the Center for Drug Evaluation and Research, as appropriate, determines that data submitted in the biologics license application or supplement adequately establish that the route of administration, the method of preparation, or any other aspect of the product precludes or does not necessitate a sterility test to assure the safety, purity, and potency of the product.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

■ 5. The authority citation for 21 CFR part 680 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

■ 6. Section 680.3 is amended by revising paragraph (c) to read as follows:

§ 680.3 Tests.

* * * * *

(c) *Sterility.* A sterility test shall be performed on each lot of each Allergenic Product as required by § 601.12 of this chapter.

Dated: April 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10649 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9587]

RIN 1545–BD20

Section 42 Qualified Contract Provisions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final Regulations.

SUMMARY: This document contains final regulations that provide guidance concerning taxpayers' (that is, owners') requests to housing credit agencies to obtain a qualified contract (as defined in section 42(h)(6)(F) of the Internal Revenue Code) for the acquisition of a low-income housing credit building. Section 42(h)(6)(F) requires the Secretary to prescribe such regulations as may be necessary or appropriate to carry out the provisions of section 42(h)(6)(F), including regulations to prevent the manipulation of the qualified contract amount. The regulations will affect owners requesting a qualified contract, potential buyers, and low-income housing credit agencies responsible for the administration of the low-income housing credit program.

DATES: *Effective Date:* These regulations are effective May 3, 2012.

Applicability Date: For the applicability date, see § 1.42–18(e).

FOR FURTHER INFORMATION CONTACT: David Selig at (202) 622–3040 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final 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 1545–2088. The collection of information is required for an owner to provide a written request to a housing credit agency to obtain a qualified contract (as defined in section 42(h)(6)(F) of the Internal Revenue Code) for the acquisition of a low-income housing credit building. The collecting of information is voluntary to obtain a benefit.

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

Books or records relating to a collection of information must be retained as long as their contents might 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 final regulations that amend the Income Tax Regulations (26 CFR part 1) relating to the low-income housing credit under section 42 of the Internal Revenue Code (Code). On June 19, 2007, a notice of proposed rulemaking (REG–114084–04) and notice of public hearing relating to the qualified contract provisions under section 42(h)(6)(F) was published in the **Federal Register** (72 FR 33706). Written and electronic comments responding to the proposed regulations were received and a public hearing was held on the proposed regulations on October 15, 2007. After consideration of all the comments, the proposed regulations are adopted as amended by this Treasury decision.

General Overview

Section 42 provides a tax credit for investment in low-income housing buildings placed in service after December 31, 1986. The section 42 credit is a general business credit subject to the provisions of section 38.

Section 42(h)(6)(A) provides that no credit will be allowed with respect to any building for the taxable year unless an extended low-income housing commitment (commitment) (as defined in section 42(h)(6)(B)) is in effect as of the end of the taxable year.

Section 42(h)(6)(B) provides in part that the term commitment means any agreement between the owner and the housing credit agency (Agency) that requires that the applicable fraction (as defined in section 42(c)(1)(B)) for the building for each taxable year in the extended use period will not be less than the applicable fraction specified in the commitment. Section 42(h)(6)(E)(ii) prohibits the eviction or termination of tenancy (other than for good cause) of an existing tenant of any low-income unit or any increase in the gross rent with respect to such unit not otherwise permitted under section 42 until three years after the termination of such an agreement.

Section 42(h)(6)(D) defines the term extended use period as the period beginning on the first day in the compliance period (as defined in section 42(i)(1)) on which the building is part of a qualified low-income housing project and ending on the later of: (1) The date specified by the Agency in the commitment, or (2) the date which is 15 years after the close of the compliance period.

Section 42(h)(6)(E)(i)(II) provides for the termination of the extended use period if the Agency is unable to present within a specified period of time a qualified contract for the acquisition of the low-income portion of the building by any person who will continue to operate such portion as a qualified low-income building.

Section 42(h)(6)(F) defines the term qualified contract as a bona fide contract to acquire (within a reasonable period of time after the contract is entered into) the non low-income portion of the building for fair market value and the low-income portion of the building for an amount not less than the applicable fraction (specified in the commitment) of the sum of: (I) The outstanding indebtedness secured by, or with respect to the building, (II) the adjusted investor equity in the building, plus (III) other capital contributions not reflected in these amounts; reduced by cash distributions from (or available for distribution from) the project.

Section 42(h)(6)(F) also provides that the Secretary shall prescribe regulations as may be necessary or appropriate to carry out that paragraph, including regulations to prevent the manipulation of the amount determined under section 42(h)(6)(F).

Section 42(h)(6)(I) provides that the Agency must present the qualified contract within the 1-year period beginning on the date (after the 14th year of the compliance period) the owner submits a written request to the Agency to find a person to acquire the owner's interest in the low-income portion of the building.

The proposed regulations addressed the application of the qualified contract provisions of section 42. Section 1.42–18(c)(1) of the proposed regulations defined the qualified contract formula used to compute the purchase price amount of the low-income housing building generally as: (1) The non low-income portion of the building for fair market value; plus (2) the low-income portion of the building for the low-income portion amount.

Section 1.42–18(c)(2) of the proposed regulations defined the low-income portion amount as an amount not less than the applicable fraction (as specified in the commitment) of the total of: (a) Outstanding indebtedness secured by, or with respect to the building; plus (b) the adjusted investor equity in the building; plus (c) other capital contributions, not including amounts described in (a) and (b); minus (d) cash distributions from (or available for distribution from) the building.

Summary of Comments

Fair-Market-Value Cap

Prior to the issuance of the proposed regulations, comments were received recommending the inclusion of a fair-market-value cap for the low-income portion of the qualified contract amount as defined in section 42(h)(6)(F). These comments noted that the qualified contract price may, in some cases, exceed the fair market value of a project. One reason given to explain why the qualified contract price might exceed the fair market value of a project is the formula component for adjusted investor equity, which includes the Consumer-Price-Index-based cost of living adjustments. As explained in the preamble to the proposed regulations, this recommendation was not adopted as a proposed rule because section 42(h)(6)(F) defines a qualified contract, in part, as a contract to acquire the low-income portion of the building for an amount ''not less than'' the applicable fraction of the statutorily provided formula. Similar comments were received after publication of the proposed regulations. The IRS and the Treasury Department continue to believe that they do not have the authority under section 42(h)(6)(F) to adopt a fair-market-value cap. Accordingly, the final regulations do not provide a rule providing a fair-market-value cap under section 42(h)(6)(F).

The IRS and the Treasury Department in the preamble to the proposed regulations requested comments on the extent of Agency and State authority to provide more stringent requirements than those contained in section 42(h)(6)(F). The preamble referenced the flush language of section 42(h)(6)(E)(i), which provides that the qualified contract exception to the termination of an extended use period shall not apply to the extent more stringent requirements are provided in the agreement or in State law. Specifically, the IRS and the Treasury Department requested comments on the authority of Agency or State regulators to require in agreements a fair-market-value cap that would restrict any qualified contract price to fair market value. In response, two comments were received, both opining that an Agency did not possess authority under section 42(h)(6)(E) to set a fair market value limitation. The commentators reasoned that the language ''more stringent requirements'' relates to the date the extended use period will terminate, rather than to the qualified contract formula. The IRS and

Treasury Department received no comment asserting the view that section 42(h)(6)(E)(i) authorizes an Agency or State regulators to require in agreements a fair-market-value cap that would restrict a qualified contract price to fair market value. The IRS and Treasury Department do not believe that section 42(h)(6)(E)(i) was intended to authorize a fair-market-value cap on the low-income portion of the building, and, accordingly, the final regulations do not provide for such a cap.

Adjustments to Fair Market Value of the Non-Low-Income Portion of the Building

Some commentators questioned the provision in the proposed regulations that would allow Agencies to adjust the fair market value of a building, if, after a reasonable period of time within the one-year offer-of-sale period, no buyer has made an offer or market values have adjusted downward. One commentator noted that, as a result of this provision, in order to secure a more favorable price for the building, prospective buyers might wait out the qualified contract process until an Agency reduces the qualified contract price. Another commentator noted the unfairness of granting Agencies the unilateral right to reduce the fair market value of the non low-income portion of the building, particularly when the proposed regulations provide no limitation on how much the Agency may reduce the fair market value.

The IRS and the Treasury Department believe these concerns are valid. Accordingly, the final regulations revise this provision to provide that the Agency may adjust the fair market value of the non low-income portion of the building after the Agency's offer of sale of the building to the general public and before the close of the one-year offer of sale period only with the consent of the owner. If no agreement between the Agency and owner is reached, the fair market value of the non low-income portion of the building determined at the time of the Agency's offer of sale of the building to the general public remains unchanged.

Land

The proposed regulations provide that the fair market value of the non low-income portion of a building is determined at the time of an Agency's offer of sale of the building to the general public. This valuation must take into account the existing and continuing requirements contained in the commitment for the building. The non low-income portion also includes the fair market value of the land underlying the entire building, including the land underlying the low-income portion of the building.

Commentators questioned the statutory authority of the IRS under section 42(h)(6)(F) to include land value in the qualified contract amount. Specifically, commentators noted that the language under section 42(h)(6)(F) refers to the fair market value of the non low-income portion of the building without addressing the issue of land valuation. Other commentators asserted that adopting a fair market value approach for land underlying the entire building may decrease the likelihood of finding a qualified buyer willing to pay the qualified contract price while continuing to operate the building as a low income building.

The IRS and the Treasury Department believe that land is inherently part of the cost underlying the acquisition or construction of a building and should not be ignored in determining the qualified contract amount. Applying fair market value to land is consistent with industry practice regarding land valuation and provides an equitable means for arriving at a contract price between buyers and owners. By valuing land underlying the entire building at fair market value, taking into account the existing and continuing requirements contained in the commitment for the building, the proposed regulations provided an approach that maintains industry practice for valuing land and provided an objective and equitable solution that favors neither the buyer nor the owner. Accordingly, the final regulations provide that the land underlying the entire building (both low-income and non low-income units) is valued at fair market value subject to the existing and continuing restrictions contained in the commitment for the building.

Responsibility To Adjust the Qualified Contract Price To Reflect the Changing Amount of Outstanding Indebtedness

One commentator expressed concern that the proposed regulations would impose too much burden on Agencies by requiring them to adjust the qualified contract amount between the date on which the sales price under a qualified contract is first determined and the sale's actual closing date. (For example, an adjustment is needed to reflect mortgage payments that reduce outstanding indebtedness.) The IRS and the Treasury Department concur with this comment, and the final regulations provide that the buyer and owner, and not the Agency, must adjust the amount of the low-income portion of the qualified contract formula to reflect changes in the components of the qualified contract formula, such as mortgage payments that reduce outstanding indebtedness between the time the Agency first offers the property for sale and the actual sale closing date.

Cash Distributions

One commentator recommended that the final regulations clarify that the rule in the proposed regulations providing that cash available for distribution includes reserve funds should apply only to the extent that the reserve funds are not legally required to remain with the project after the sale. Other commentators noted the potential for double-counting if cash available for distribution includes the proceeds from refinancing indebtedness or additional mortgages, while simultaneously any refinancing indebtedness or additional mortgages in excess of qualifying building costs are not outstanding indebtedness for purposes of section 42(h)(6)(F).

The IRS and the Treasury Department agree with these comments. Accordingly, the final regulations provide that cash available for distribution includes reserve funds that are not legally required by mortgage restrictions, regulatory agreements, or third party contractual agreements to remain with the building following the sale of the building. The final regulations further provide that proceeds from refinancing indebtedness or additional mortgages that are in excess of qualifying building costs are not considered cash available for distribution. The text of the final regulations also adopts the rule discussed in the preamble to the proposed regulations, but not stated in the text of the proposed regulations, that any refinancing indebtedness or additional mortgages in excess of qualifying building costs do not qualify as outstanding indebtedness for purposes of section 42(h)(6)(F).

Discounting Indebtedness Removed

Some commentators questioned the rationale for the requirement in the proposed regulations that would discount outstanding indebtedness having an interest rate below the applicable Federal rate (AFR) under section 1274 of the Code. In response, the final regulations remove the provision of discounting indebtedness altogether. Instead, the final regulations define outstanding indebtedness to include only those amounts secured by, or with respect to, the building that (1) do not exceed qualifying building costs, (2) are indebtedness under general principles of Federal income tax law, and (3) upon the sale of the building, are

actually paid to the lender or are assumed by the buyer as part of the sale.

Appraiser Standards

Several commentators noted the absence of any uniform standards for appraisal methodology and qualifications for appraisers. Rather than adopt appraisal standards, the final regulations provide that Agencies shall not utilize any individual or organization as an appraiser if that individual or organization is currently on any list for active suspension or revocation for performing appraisals in any State or is listed on the Excluded Parties Lists System (EPLS) maintained by the General Services Administration for the United States Government. The final regulations also provide the Agencies with the discretion to select the appraisers involved in the qualified contract process and to require all appraisers to be State-certified general appraisers.

Actual Offer of Sale

The proposed regulations provide that in order to satisfy the qualified contract requirements under section 42(h)(6)(F), the Agency must offer the building for sale to the general public at the determined qualified contract price upon receipt of a written request by the owner to find a buyer to acquire the building. In addressing the issue of how Agencies should advertise the availability of a building to the general public, the final regulations provide a reasonable efforts standard for guiding Agencies in their efforts to find a qualified buyer during the one year offer period. If the determined qualified contract price is not a multiple of $1,000, the final regulations permit the Agency to round up the offering price of the building to the next highest multiple of $1,000.

Definition of Bona Fide Contract and Resolution of Disputes

Some commentators suggested the inclusion of a specific definition of a bona fide contract under section 42(h)(6)(F), addressing issues such as whether the terms and conditions of any offered contract are unreasonable or impractical. Further, commentators suggested the creation of a mechanism for resolving disputes among the parties concerning the meaning of a bona fide contract. The IRS and the Treasury Department believe that because of variations under State laws concerning the terms of a bona fide contract and methods for resolving disputes, the final regulations should not explicitly address these issues. Instead, the final regulations provide that an Agency has the administrative discretion to specify other conditions applicable to the qualified contract consistent with section 42 of the Code and the final regulations.

Adjusted Investor Equity

To avoid ambiguity in the determination of the qualified contract amount, the final regulations require adjusted investor equity to be calculated in a manner that is consistent with inflation adjustments made under section 1(f). Thus, as was required in the proposed regulations, the calculations must use not seasonally adjusted values of the Consumer Price Index for all urban consumers (the data series that the Bureau of Labor Statistics refers to as ''CPI–U''). The final regulations provide a computational process that is mathematically equivalent to the process described in the proposed regulations but that will be simpler to implement. Because of the uncertainty that can be introduced when one number is divided by another and because different people might choose to retain in the answer different numbers of digits, the regulations require the quotient in this process to be carried out to 10 decimal places. (If standard, off-the-shelf spreadsheet software is used to compute the adjusted investor equity, the computations will generally have at least this degree of accuracy by default.) In addition, the example in the final regulations has been updated to use more recent data. Finally, the final regulations make it possible for the Commissioner to reduce the computational burden by, for example, providing the possible adjustment factors in annual publications or creating a calculator on the IRS Web site.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. 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. The information required to be provided by a taxpayer (that is, by the owner of a low-income building) to a State agency to determine the qualified contract amount is already maintained by the taxpayer for other purposes of the low-income tax credit under section 42. Because only a minimal amount of additional time is required for a taxpayer to access and provide the information, this collection of information does not impose a significant burden on the taxpayer. Accordingly, a Regulatory Flexibility Analysis under the provisions of the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, the notice of proposed regulations preceding these final regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business, and no comments were received.

Drafting Information

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

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

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

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

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

Section 1.42–18 also issued under 26 U.S.C. 42(h)(6)(F) and 42(h)(6)(K); * * *

■ **Par. 2.** Section 1.42–18 is added to read as follows:

§ 1.42–18 Qualified contracts.

(a) *Extended low-income housing commitment*—(1) *In general.* No credit under section 42(a) is allowed by reason of section 42 with respect to any building for the taxable year unless an extended low-income housing commitment (commitment) (as defined in section 42(h)(6)(B)) is in effect as of the end of such taxable year. A commitment must be in effect for the extended use period (as defined in paragraph (a)(1)(i) of this section).

(i) *Extended use period.* The term *extended use period* means the period beginning on the first day in the compliance period (as defined in section 42(i)(1)) on which the building is part of a qualified low-income housing project (as defined in section 42(g)(1)) and ending on the later of—

(A) The date specified by the low-income housing credit agency (Agency) in the commitment; or

(B) The date that is 15 years after the close of the compliance period.

(ii) *Termination of extended use period.* The extended use period for any building will terminate—

(A) On the date the building is acquired by foreclosure (or instrument in lieu of foreclosure) unless the Commissioner determines that such acquisition is part of an arrangement with the taxpayer (''the owner'') a purpose of which is to terminate such period; or

(B) On the last day of the one-year period beginning on the date (after the 14th year of the compliance period) on which the owner submits a written request to the Agency to find a person to acquire the owner's interest in the low-income portion of the building if the Agency is unable to present during such period a qualified contract for the acquisition of the low-income portion of the building by any person who will continue to operate such portion as a qualified low-income building (as defined in section 42(c)(2)).

(iii) *Owner non-acceptance.* If the Agency provides a qualified contract within the one-year period and the owner rejects or fails to act upon the contract, the building remains subject to the existing commitment.

(iv) *Eviction, gross rent increase concerning existing low-income tenants not permitted.* Prior to the close of the three year period following the termination of a commitment, no owner shall be permitted to evict or terminate the tenancy (other than for good cause) of an existing tenant of any low-income unit, or increase the gross rent for such unit in a manner or amount not otherwise permitted by section 42.

(2) *Exception.* Paragraph (a)(1)(ii)(B) of this section shall not apply to the extent more stringent requirements are provided in the commitment or under State law.

(b) *Definitions.* For purposes of this section, the following terms are defined:

(1) As provided by section 42(h)(6)(G)(iii), *base calendar year* means the calendar year with or within which the first taxable year of the credit period ends.

(2) The *low-income portion* of a building is the portion of the building equal to the applicable fraction (as defined in section 42(c)(1)(B)) specified in the commitment for the building.

(3) The *fair market value of the non-low-income portion* of the building is determined at the time of the Agency's offer of sale of the building to the general public. The fair market value of the non-low-income portion also includes the fair market value of the land underlying the entire building (both the non-low-income portion and the low-income portion). This valuation must take into account the existing and continuing requirements contained in the commitment for the building. The fair market value of the non-low-income portion also includes the fair market value of items of personal property not included in eligible basis under section 42(d) that convey under the contract with the building.

(4) *Qualifying building costs include*—

(i) Costs that are included in eligible basis of a low-income housing building under section 42(d) and that are included in the adjusted basis of depreciable property that is subject to section 168 and that is residential rental property for purposes of section 142(d) and § 1.103–8(b);

(ii) Costs that are included in eligible basis of a low-income housing building under section 42(d) and that are included in the adjusted basis of depreciable property that is subject to section 168 and that is used in a common area or is provided as a comparable amenity to all residential rental units in the building; and

(iii) Costs of the type described in paragraph (b)(4)(i) and (ii) of this section incurred after the first year of the low-income housing building's credit period under section 42(f).

(5) The *qualified contract amount* is the sum of the fair market value of the non-low-income portion of the building (within the meaning of section 42(h)(6)(F) and paragraph (b)(3) of this section) and the price for the low-income portion of the building (within the meaning of section 42(h)(6)(F) and paragraph (b)(2) of this section) as calculated in paragraph (c)(2) of this section. If this sum is not a multiple of $1,000, then when the Agency offers the building for sale to the general public, the Agency may round up the offering price to the next highest multiple of $1,000.

(c) *Qualified contract purchase price formula*—(1) *In general.* For purposes of this section, *qualified contract* means a bona fide contract to acquire the building (within a reasonable period after the contract is entered into) for the qualified contract amount.

(i) *Initial determination.* The qualified contract amount is determined at the time of the Agency's offer of sale of the building to the general public.

(ii) *Mandatory adjustment by the buyer and owner.* The buyer and owner under a qualified contract must adjust the amount of the low-income portion of the qualified contract formula to reflect changes in the components of the qualified contract formula such as mortgage payments that reduce outstanding indebtedness between the time of the Agency's offer of sale to the general public and the building's actual sale closing date.

(iii) *Optional adjustment by the Agency and owner.* The Agency and owner may agree to adjust the fair market value of the non low-income portion of the building after the Agency's offer of sale of the building to the general public and before the close of the one-year period described in paragraph (a)(1)(ii)(B) of this section. If no agreement between the Agency and owner is reached, the fair market value of the non-low-income portion of the building determined at the time of the Agency's offer of sale of the building to the general public remains unchanged.

(2) *Low-income portion amount.* The low-income portion amount is an amount not less than the applicable fraction specified in the commitment, as defined in section 42(h)(6)(B)(i), multiplied by the total of—

(i) The outstanding indebtedness for the building (as defined in paragraph (c)(3) of this section); plus

(ii) The adjusted investor equity in the building for the calendar year (as defined in paragraph (c)(4) of this section); plus

(iii) Other capital contributions (as defined in paragraph (c)(5) of this section), not including any amounts described in paragraphs (c)(2)(i) and (ii) of this section; minus

(iv) Cash distributions from (or available for distribution from) the building (as defined in paragraph (c)(6) of this section).

(3) *Outstanding indebtedness.* For purposes of paragraph (c)(2)(i) of this section, *outstanding indebtedness* means the remaining stated principal balance (which is initially determined at the time of the Agency's offer of sale of the building to the general public) of any indebtedness secured by, or with respect to, the building that does not exceed the amount of qualifying building costs described in paragraph (b)(4) of this section. Thus, any refinancing indebtedness or additional mortgages in excess of such qualifying building costs are not outstanding indebtedness for purposes of section

42(h)(6)(F) and this section. Examples of outstanding indebtedness include certain mortgages and developer fee notes (excluding developer service costs not included in eligible basis). Outstanding indebtedness does not include debt used to finance nondepreciable land costs, syndication costs, legal and accounting costs, and operating deficit payments. Outstanding indebtedness includes only obligations that are indebtedness under general principles of Federal income tax law and that are actually paid to the lender upon the sale of the building or are assumed by the buyer as part of the sale of the building.

(4) *Adjusted investor equity*—(i) *Application of cost-of-living factor.* For purposes of paragraph (c)(2)(ii) of this section, the *adjusted investor equity* for any calendar year equals the unadjusted investor equity, as described in paragraph (c)(4)(ii) of this section, multiplied by the qualified-contract cost-of-living adjustment for that year, as defined in paragraph (c)(4)(iii) of this section.

(ii) *Unadjusted investor equity.* For purposes of this paragraph (c)(4), *unadjusted investor equity* means the aggregate amount of cash invested by owners for qualifying building costs described in paragraph (b)(4)(i) and (ii) of this section. Thus, equity paid for land, credit adjuster payments, Agency low-income housing credit application and allocation fees, operating deficit contributions, and legal, syndication, and accounting costs all are examples of cost payments that do not qualify as unadjusted investor equity. Unadjusted investor equity takes an amount into account only to the extent that, as of the beginning of the low-income building's credit period (as defined in section 42(f)(1)), there existed an obligation to invest the amount. Unadjusted investor equity does not include amounts included in the calculation of outstanding indebtedness as defined in paragraph (c)(3) of this section.

(iii) *Qualified-contract cost-of-living adjustment.* For purposes of this paragraph (c)(4), the *qualified-contract cost-of-living adjustment for a calendar year* is the number that is computed under the general rule in paragraph (c)(4)(iv) of this section or a number that may be provided by the Commissioner as described in paragraph (c)(4)(v) of this section.

(iv) *General rule.* Except as provided in paragraph (c)(4)(v) of this section, the *qualified-contract cost-of-living adjustment* is the quotient of—

(A) The sum of the 12 monthly Consumer Price Index (CPI) values whose average is the CPI for the calendar year that precedes the calendar year in which the Agency offers the building for sale to the general public (The term ''CPI for a calendar year'' has the meaning given to it by section 1(f)(4) for purposes of computing annual inflation adjustments to the rate brackets.); divided by

(B) The sum of the 12 monthly CPI values whose average is the CPI for the base calendar year (within the meaning of section 1(f)(4)), unless that sum has been increased under paragraph (c)(4)(iii)(D) of this section.

(v) *Provision by the Commissioner of the qualified-contract cost-of-living adjustment.* The Commissioner may publish in the Internal Revenue Bulletin (see § 601.601(d)(2) of this chapter) a process pursuant to which the Internal Revenue Service will compute the qualified-contract cost-of-living adjustment for a calendar year and make available the results of that computation.

(vi) *Methodology.* The calculations in paragraph (c)(4)(iv) of this section are to be made in the following manner:

(A) The CPI data to be used for purposes of this paragraph (c)(4) are the not seasonally adjusted values of the CPI for all urban consumers. (The U.S. Department of Labor's Bureau of Labor Statistics (BLS) sometimes refers to these values as ''CPI–U.'') The BLS publishes the CPI data on-line (including a History Table that contains monthly CPI–U values for all years back to 1913). See *www.BLS.gov/data.*

(B) The quotient is to be carried out to 10 decimal places.

(C) The Agency may round adjusted investor equity to the nearest dollar.

(D) If the CPI for any calendar year (within the meaning of section 1(f)(4)) during the extended use period after the base calendar year exceeds by more than 5 percent the CPI for the preceding calendar year (within the meaning of section 1(f)(4)), then the sum described in paragraph (c)(4)(i)(B) is to be increased so that the excess is never taken into account under this paragraph (c)(4).

(vii) *Example.* The following example illustrates the calculations described in this paragraph (c)(4):

Example. (i) *Facts.* Owner contributed $20,000,000 in equity to a building in 1997, which was the first year of the credit period for the building. In 2011, Owner requested Agency to find a buyer to purchase the building, and Agency offered the building for sale to the general public during 2011. The CPI for 1997 (within the meaning of section 1(f)(4)) is the average of the Consumer Price Index as of the close of the 12-month period ending on August 31, 1997. The sum of the CPI values for the twelve months from September 1996 through August 1997 is 1913.9. The CPI for 2010 (within the meaning of section 1(f)(4)) is the average of the Consumer Price Index as of the close of the 12-month period ending August 31, 2010. The sum of the CPI values for the twelve months from September 2009 through August 2010 is 2605.959. At no time during this period (after the base calendar year) did the CPI for any calendar year exceed the CPI for the preceding calendar year by more than 5 percent.

(ii) *Determination of adjusted investor equity.* The qualified-contract cost-of-living adjustment is 1.3615962171 (the quotient of 2605.959, divided by 1913.9). Owner's adjusted investor equity, therefore, is $27,231,924, which is $20,000,000, multiplied by 1.3615962171, rounded to the nearest dollar.

(5) *Other capital contributions.* For purposes of paragraph (c)(2)(iii) of this section, other capital contributions to a low-income building are qualifying building costs described in paragraph (b)(4)(ii) of this section paid or incurred by the owner of the low-income building other than amounts included in the calculation of outstanding indebtedness or adjusted investor equity as defined in this section. For example, other capital contributions may include amounts incurred to replace a furnace after the first year of a low-income housing credit building's credit period under section 42(f), provided any loan used to finance the replacement of the furnace is not secured by the furnace or the building. Other capital contributions do not include expenditures for land costs, operating deficit payments, credit adjuster payments, and payments for legal, syndication, and accounting costs.

(6) *Cash distributions*—(i) *In general.* For purposes of paragraph (c)(2)(iv) of this section, the term *cash distributions from (or available for distribution from)* the building include—

(A) All distributions from the building to the owners or to persons whose relationship to the owner is described in section 267(b) or section 707(b)(1)), including distributions under section 301 (relating to distributions by a corporation), section 731 (relating to distributions by a partnership), or section 1368 (relating to distributions by an S corporation); and

(B) All cash and cash equivalents available for distribution at, or before, the time of sale, including, for example, reserve funds whether operating or replacement reserves, unless the reserve funds are legally required by mortgage restrictions, regulatory agreements, or third party contractual agreements to remain with the building following the sale.

(ii) *Excess proceeds.* For purposes of paragraph (c)(6)(i) of this section,

proceeds from the refinancing of indebtedness or additional mortgages that are in excess of qualifying building costs are not considered cash available for distribution.

(iii) *Anti-abuse rule.* The Commissioner will interpret and apply the rules in this paragraph (c)(6) as necessary and appropriate to prevent manipulation of the qualified contract amount. For example, cash distributions include payments to owners or persons whose relation to owners is described in section 267(b) or section 707(b) for any operating expenses in excess of amounts reasonable under the circumstances.

(d) *Administrative discretion and responsibilities of the Agency*—(1) *In general.* An Agency may exercise administrative discretion in evaluating and acting upon an owner's request to find a buyer to acquire the building. An Agency may establish reasonable requirements for written requests and may determine whether failure to follow one or more applicable requirements automatically prevents a purported written request from beginning the one-year period described in section 42(h)(6)(I). If the one-year-period has already begun, the Agency may determine whether failure to follow one or more requirements suspends the running of that period. Examples of Agency administrative discretion include, but are not limited to, the following:

(i) Concluding that the owner's request lacks essential information and denying the request until such information is provided.

(ii) Refusing to consider an owner's representations without substantiating documentation verified with the Agency's records.

(iii) Determining how many, if any, subsequent requests to find a buyer may be submitted if the owner has previously submitted a request for a qualified contract and then rejected or failed to act upon a qualified contract presented by the Agency.

(iv) Assessing and charging the owner certain administrative fees for the performance of services in obtaining a qualified contract (for example, real estate appraiser costs).

(v) Requiring all appraisers involved in the qualified contract process to be State certified general appraisers that are acceptable to the Agency.

(vi) Specifying other conditions applicable to the qualified contract consistent with section 42 and this section.

(2) *Actual offer.* Upon receipt of a written request from the owner to find a person to acquire the building, the Agency must offer the building for sale to the general public, based on reasonable efforts, at the determined qualified contract amount in order for the qualified contract to satisfy the requirements of this section unless the Agency has already identified a willing buyer who submitted a qualified contract to purchase the project.

(3) *Debarment of certain appraisers.* Agencies shall not utilize any individual or organization as an appraiser if that individual or organization is currently on any list for active suspension or revocation for performing appraisals in any State or is listed on the Excluded Parties Lists System (EPLS) maintained by the General Services Administration for the United States Government found at *www.epls.gov.*

(e) *Effective date/applicability date.* These regulations are applicable to owner requests to housing credit agencies on or after May 3, 2012 to obtain a qualified contract for the acquisition of a low-income housing credit building.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

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

Authority: 26 U.S.C. 7805.

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

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.42–18	1545–2088
* * * * *	

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

Approved: April 24, 2012.

Emily S. McMahon,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2012–10638 Filed 5–2–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 0

[CIV Docket No. 152; AG Order No. 3330–2012]

Authorization To Redelegate Settlement Authority for Claims Submitted Under the Federal Tort Claims Act

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: The Department of Justice is amending its internal organizational regulations to clarify the authority of the respective agency heads of the Bureau of Prisons, the Federal Prison Industries, the United States Marshals Service, the Drug Enforcement Administration, the Federal Bureau of Investigation, and the Bureau of Alcohol, Tobacco, Firearms, and Explosives to settle claims under the Federal Tort Claims Act.

DATES: This rule is effective June 4, 2012.

FOR FURTHER INFORMATION CONTACT: Phyllis J. Pyles, Director, Torts Branch, Civil Division, Department of Justice, 1331 Pennsylvania Avenue NW., Washington, DC 20004; telephone: 202–616–4400.

SUPPLEMENTARY INFORMATION:

Background

The Federal Tort Claims Act (FTCA), 28 U.S.C. 1346(b), 2671–2680, provides a remedy for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred. Prior to filing suit, a claimant must file an administrative tort claim with the appropriate agency. 28 U.S.C. 2675. Pursuant to 28 U.S.C. 2672, the head of each Federal agency or his designee, in accordance with regulations prescribed by the Attorney General, may consider, ascertain, adjust, determine, compromise, and settle FTCA claims.

In the present organizational regulations of the Department of Justice, the Attorney General delegated his authority to settle FTCA claims for amounts of $50,000 or less to the Director of the Bureau of Prisons, the Commissioner of Federal Prison Industries, the Commissioner of the Immigration and Naturalization Service (INS), the Director of the United States

Marshals Service, and the Administrator of the Drug Enforcement Administration (28 CFR 0.172), and to the Director of the Federal Bureau of Investigation (FBI) (28 CFR 0.89a) and the Director of the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) (28 CFR 0.132). The Director of the FBI is further authorized to redelegate this authority to the FBI General Counsel or his designee within the Office of the General Counsel or to the primary legal advisers of the FBI field offices.

This rule amends §§ 0.89a, 0.132, and 0.172 in order to ensure conformity across the different components of the Department of Justice, to update agency references, and to clarify the scope of the delegated FTCA settlement authority. In addition, the FTCA settlement authority of the Director of the FBI, currently contained in § 0.89a, and of the Director of ATF, currently contained in § 0.132, are being transferred by this rule to § 0.172, where the FTCA settlement authority of the other specified Department component heads is located.

Section 0.172 is being amended to remove a reference to the Commissioner of the INS. Pursuant to the Homeland Security Act of 2002, the functions of the former INS were transferred to the Department of Homeland Security. Section 0.172 also is being amended to clarify that the approval of the Assistant Attorney General in charge of the Civil Division will be required if two or more claims arise from the same subject matter and the aggregate amount of the settlement would exceed $50,000. In addition, § 0.172 is being amended to clarify when proposed settlements, regardless of amount, should be referred to the Assistant Attorney General in charge of the Civil Division. In particular, § 0.172 is being amended to require the referral of settlements to the Assistant Attorney General in charge of the Civil Division or his delegee, if the settlement, as a practical matter, would or may control or adversely influence the disposition of other claims and the total settlement value of all claims would or may exceed $50,000; or if, in the opinion of the head of the referring component, the settlement presents a question of law or policy or other issue that should receive the personal attention of the Assistant Attorney General or his delegee. Section 0.172 also is being amended to more closely conform to the language contained in 28 U.S.C. 2672 by clarifying that the Attorney General's delegees have the authority to consider or ascertain claims involving their respective agencies, in addition to their authority to adjust, determine, compromise, and settle such claims.

Finally, § 0.132 is being amended to allow the Director of ATF to delegate this authority under § 0.172 to the agency's Chief Counsel and to allow the Chief Counsel to redelegate this authority to attorneys within the Office of Chief Counsel, but not below the Associate Chief Counsel level, provided that the settlement of any one claim does not exceed $50,000. Without this provision for delegation and redelegation, the ATF Director must personally approve all submitted FTCA claims, regardless of size or merit. This rule provides flexibility to the Director of ATF and is consistent with the redelegation authority of the FBI Director under current § 0.89a(c) (which is being redesignated by this rule as § 0.89a(b)). With this flexibility, the ATF can more efficiently process FTCA claims.

The Attorney General believes that consolidating under § 0.172 the authority of heads of certain components within the Department of Justice to settle FTCA claims and ensuring uniform language across §§ 0.89a, 0.132, and 0.172 that is consistent with 28 U.S.C. 2672 will facilitate more consistent treatment of these claims.

Administrative Procedure Act (APA)

Notice and comment rulemaking is not required for this final rule. Under the APA, ''rules of agency organization, procedure or practice,'' 5 U.S.C. 553(b)(A), that do not ''affect[] individual rights and obligations,'' *Morton* v. *Ruiz,* 415 U.S. 199, 232 (1974), are exempt from the general notice and comment requirements of section 553. *See JEM Broad. Co.* v. *FCC,* 22 F.3d 320, 326 (D.C. Cir. 1994) (holding that the procedural exception applies to ''agency actions that do not themselves alter the rights or interests of parties, although [they] may alter the manner in which the parties present themselves or their viewpoints to the agency'' (quoting *Batterton* v. *Marshall,* 648 F.2d 694, 707 (D.C. Cir. 1980) (internal quotation marks omitted)). The revision to 28 CFR 0.89a, 0.132, and 0.172 is purely a matter of agency organization, procedure, and practice. The final rule will not affect substantive rights or interests of persons presenting their FTCA claims to the relevant agencies of the Department of Justice.

Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities because it pertains to personnel and administrative matters affecting the Department. Further, a Regulatory Flexibility Analysis is not required for this final rule because the Department was not required to publish a general notice of proposed rulemaking for this matter.

Executive Orders 12866 and 13563—Regulatory Review

This rule has been drafted and reviewed in accordance with Executive Order 12866, Regulatory Planning and Review, section 1(b), Principles of Regulation, and in accordance with Executive Order 13563, Improving Regulation and Regulatory Review, section 1(b), General Principles of Regulation. This rule is limited to agency organization, management, or personnel matters as described by Executive Order 12866, section 3(d)(3), and therefore is not a ''regulation'' or ''rule'' as defined by Executive Order 12866. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Department has assessed the costs and benefits of this rule and believes that the regulatory approach selected maximizes net benefits.

Executive Order 12988

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

Executive Order 13132

This rule 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. Therefore, in accordance with Executive Order 13132, Federalism, the Department has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 804. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Congressional Review Act

This action pertains to agency management, personnel, and organization and does not substantially affect the rights or obligations of non-agency parties. Accordingly, it is not a ''rule'' for purposes of the reporting requirement of 5 U.S.C. 801.

List of Subjects in 28 CFR Part 0

Authority delegations (Government agencies), Government employees, Organization and functions (Government agencies), Privacy, Reporting and recordkeeping requirements, Whistleblowing.

Authority and Issuance

Accordingly, by virtue of the authority vested in me as Attorney General, including 5 U.S.C. 301, and 28 U.S.C. 509, 510, and for the reasons set forth in the preamble, part 0 of title 28 of the Code of Federal Regulations is amended as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

■ 1. The authority citation for 28 CFR Part 0 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510, 515–519.

§ 0.89a [Amended]

■ 2. Section 0.89a is amended by—
■ a. Removing paragraph (a);
■ b. Redesignating paragraphs (b) and (c) as paragraphs (a) and (b), respectively;
■ c. Removing the word ''further'' from newly redesignated paragraph (a);
■ d. Adding a comma after the parenthetical ''(31 U.S.C. 3274)'' in newly redesignated paragraph (a); and
■ e. Removing the words ''by paragraphs (a) and (b) of this section'' from newly redesignated paragraph (b) and adding in their place the words ''by paragraph (a) of this section and by 28 CFR 0.172''.

§ 0.132 [Amended]

■ 3. Section 0.132 is amended by—
■ a. Removing paragraph (a);
■ b. Redesignating paragraphs (b) and (c) as paragraphs (a) and (b), respectively;
■ c. Adding a comma after the word ''personnel'' in newly redesignated paragraph (a); and
■ d. Removing the words ''in paragraph (b) of this section'' from newly redesignated paragraph (b) and adding in their place the words ''by paragraph (a) of this section and by 28 CFR 0.172''.

■ 4. Section 0.172 is revised to read as follows:

§ 0.172 Authority: Federal tort claims.

(a) *Delegation of authority.* Subject to the limitations set forth in paragraph (b) of this section, the Director of the Bureau of Prisons, the Commissioner of Federal Prison Industries, the Director of the United States Marshals Service, the Administrator of the Drug Enforcement Administration, the Director of the Federal Bureau of Investigation, and the Director of the Bureau of Alcohol, Tobacco, Firearms, and Explosives shall have authority under section 2672 of title 28, United States Code, relating to the administrative settlement of Federal tort claims, to consider, ascertain, adjust, determine, compromise, and settle any claim involving their respective components, provided that any award, compromise, or settlement shall not exceed $50,000.

(b) *Limitations on authority.* Any proposed award, compromise, or settlement under section 2672 of title 28, United States Code, must be referred to the Assistant Attorney General in charge of the Civil Division, or his delegee, when—

(1) Because a significant question of law or policy is presented, or for any other reason, the head of the referring component is of the opinion that the proposed award, compromise, or settlement should receive the personal attention of the Assistant Attorney General or his delegee;

(2) Two or more claims arise from the same subject matter and the total amount of any award, compromise, or settlement of all claims will or may exceed $50,000; or

(3) The award, compromise, or settlement of a particular claim, as a practical matter, will or may control or adversely influence the disposition of other claims and the total settlement value of all claims will or may exceed $50,000.

(c) Subject to the provisions of § 0.160, the Assistant Attorney General in charge of the Civil Division shall have authority to consider, ascertain, adjust, determine, compromise, and settle any other claim involving the Department under section 2672, of title 28, U.S. Code, relating to the administrative settlement of Federal tort claims.

Dated: April 27, 2012.

Eric H. Holder, Jr.,

Attorney General.

[FR Doc. 2012–10641 Filed 5–2–12; 8:45 am]

BILLING CODE 4410–12–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 51

RIN 2900–AO02

Technical Revisions To Update Reference to the Required Assessment Tool for State Nursing Homes Receiving Per Diem Payments From VA

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This rule updates the reference to the required resident assessment tool for State homes that receive per diem from VA for providing nursing home care to veterans. It requires State nursing homes receiving per diem from VA to use the most recent version of the Centers for Medicare and Medicaid Services (CMS) Resident Assessment Instrument/Minimum Data Set (MDS), which is version 3.0. This will ensure that the standard used to assess veterans is the same as the standard applicable to Medicare and Medicaid beneficiaries.

DATES: This final rule is effective June 4, 2012.

FOR FURTHER INFORMATION CONTACT: Nancy Quest, Director, Home and Community Based Services, Geriatrics and Extended Care Services (10P4G), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–6064. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: This document adopts as a final rule without change a proposed rule amending the Department of Veterans Affairs (VA) regulations. On November 10, 2011, VA published in the **Federal Register** (76 FR 70076) a proposal to amend VA regulations to update the reference to the required resident assessment tool for State homes providing nursing home care, CMS Resident Assessment

Instrument/MDS. The MDS is a core set of screening, clinical, and functional status elements that form the foundation of the comprehensive assessment for all residents of long term care facilities certified to participate in Medicare and Medicaid. The MDS is the standardized assessment instrument in long term care that is used to identify the health care needs of residents and generate a plan of care, regardless of source of payment for the individual resident. VA therefore requires State homes receiving per diem for the provision of long term care to veterans to use the MDS, and implements this requirement in 38 CFR 51.110(b)(1)(i).

On October 1, 2010, all CMS certified long term care facilities were required to update their assessment from MDS 2.0 to MDS 3.0. VA in turn proposed in a rulemaking that State homes receiving per diem to provide long term care to veterans use the most up to date version of MDS. Interested persons were invited to submit comments to the proposed rule on or before January 9, 2012, and we received no comments. Therefore, based on the rationale set forth in the proposed rule, VA is adopting the proposed rule as a final rule without change.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

This final rule contains no collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This amendment will not directly affect any small entities, as the State homes that are subject to this rulemaking are State government entities under the control of State governments. All State homes are owned, operated, and managed by State governments except for a small number that are operated by entities under contract with State governments. These contractors are not small entities. Therefore, under 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' which requires review by the Office of Management and Budget (OMB), as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined and it has been determined not to be a significant regulatory action under Executive Order 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any given year. This rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.005, Grants to States for Construction of State Home Facilities; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.015, Veterans State Nursing Home Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation, Alcohol and Drug Dependence.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on April 24, 2012, for publication.

List of Subjects in 38 CFR Part 51

Administrative practice and procedure, Claims, Day care, Dental health Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Dated: April 27, 2012

Robert C. McFetridge,

Director of Regulation Policy and Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs is amending 38 CFR part 51 as follows:

PART 51—PER DIEM FOR NURSING HOME CARE OF VETERANS IN STATE HOMES

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 38 U.S.C. 101, 501, 1710, 1720, 1741–1743; and as stated in specific sections.

§ 51.110 [Amended]

■ 2. Amend § 51.110(b)(1)(i) by removing the phrase ''Version 2.0'' and adding, in its place, ''Version 3.0''.

[FR Doc. 2012–10590 Filed 5–2–12; 8:45 am]

BILLING CODE 8320–01–P

POSTAL SERVICE

39 CFR Part 111

POSTNET Barcode Discontinuation

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service will revise the *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) throughout various sections to discontinue price eligibility based on the use of POSTNET™ barcodes on all types of mail.

DATES: *Effective date:* January 28, 2013.

FOR FURTHER INFORMATION CONTACT: Bill Chatfield, 202–268–7278 or Jeff Freeman, 202–268–2922.

SUPPLEMENTARY INFORMATION:

Background

On March 2, 2012, the Postal Service published a proposed rule in the **Federal Register** (77 FR 12764–12769) to discontinue price eligibility for POSTNET barcodes. For automation letters and flats and for Qualified Business Reply Mail (QBRM), an Intelligent Mail barcode (IMb™) will be required.

Summary of Comments and USPS Responses

The Postal Service received 27 comments from a variety of mailers and from several mailer associations. Some of the initial comments were critical of one proposed element to require a barcode clear zone on all letters. To maintain focus on the discontinuation of price eligibility based on the POSTNET barcode, USPS® quickly responded by deleting that element from the proposal. There were 11 comments specifically critical of the main proposal to discontinue POSTNET barcodes for automation letter and flat price eligibility. There were six comments specifically in agreement with the main proposal. One association strongly recommended that two IMbs be allowed on each piece, to facilitate processing by presort companies. We added language to specifically allow more than one barcode on automation letters under certain conditions. For flats, we also changed the proposed language to allow more than one barcode on each automation flat under certain circumstances, due to anticipated flats sortation software upgrades in early 2013. Other comments, and our responses, follow.

Comment: Mailers may be forced to make considerable investments in new printers; and some felt they will not be able to and will be forced to stop mailing.

Response: Print technology has evolved over the past several years increasing in efficiency, and in many instances, lowering unit cost. Additionally, instead of replacing printers, existing models may be able to be upgraded with fonts that assist in maintaining speed while printing IMbs. The Postal Service RIBBS® Web site (ribbs.usps.gov) has a tool that enables fonts to be downloaded to assist in printing IMbs.

Comment: Allow the use of the POSTNET barcode for automation prices, but at higher prices than for the use of the Intelligent Mail barcode (IMb).

Response: Since the POSTNET barcode is not capable of including information other than the routing code, we will not be including its use for any automation pricing as of January 2013.

Comment: There were problems for some mailers when they tried to convert to IMb and not enough USPS support to surmount problems.

Response: The staff of the district Business Mail Entry offices are available for customer assistance, RIBBS material and tools are being updated, and local Postal Customer Councils will be assisting customers. There will be designated support personnel at the district level to help with the transition.

Comment: There is no perceived benefit to converting to IMb for local mailers who are satisfied with their current level of service.

Response: Converting to IMb is an important first step on the way to full-service automation, which allows for free address correction as well as better mailpiece visibility. Increased mail visibility not only helps the mailers directly, but also helps them indirectly by allowing the Postal Service to fine tune its processes.

Comment: The USPS has provided plenty of time to convert to IMb. The industry as a whole will benefit by standardizing to the use of one barcode format.

Response: We appreciate the supportive comments.

Implementation

The Postal Service will discontinue price eligibility for the use of POSTNET barcodes and allow only IMbs for automation price eligibility purposes (including QBRM prices). The Postal Service understands that some mailers currently use POSTNET barcodes and we are committed to providing information to and working with individual mailers and software providers to ensure that the use of an Intelligent Mail barcode is achievable for all mailing customers.

Change for Letters and Flats

For the past several years, both USPS and the mailing industry have used the IMb to gain information about letters and flats as they move from induction to delivery. As of January 27, 2013, the use of the IMb will be required for all automation letters, including Business Reply Mail® letters that qualify for Qualified Business Reply Mail prices, Permit Reply Mail letters, and automation flats.

Withdrawn Change for Letters Only

To maintain focus on the POSTNET barcode discontinuation, the Postal Service removed the proposal to require barcode clear zones on all automation letters and cards and all letters and cards claiming an automation carrier route letter price, and to require all machinable letters to have barcode clear zones. We will retain the current language for barcode clear zones.

Changes for Parcels

Currently, the POSTNET barcode is an available option to satisfy the parcel barcode requirement for Standard Mail® parcels. We will discontinue the eligible use of the POSTNET barcode on parcels, and disallow its use on parcels unless it is printed in the address block. EVS® parcels would not be allowed to bear POSTNET barcodes in any location.

The Postal Service adopts the following changes to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), which is incorporated by reference in the Code of Federal Regulations. See 39 CFR 111.1.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR Part 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR Part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C 301–307; 18 U.S.C. 1692–1737:39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the following sections of *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

200 Commercial Letters and Cards

201 Physical Standards

* * * * *

3.0 Physical Standards for Machinable and Automation Letters and Cards

* * * * *

3.17 Enclosed Reply Cards and Envelopes

3.17.1 Basic Standard

[Revise the text of 3.17.1 as follows:]

Mailers may enclose reply cards or envelopes, addressed for return to a domestic delivery address, within automation mailings subject to provisions in 3.0 for enclosures. See 505.1.0 for Business Reply Mail (BRM) standards, 604.4.5.2 for postage evidencing reply mail (also known as Metered Reply Mail or MRM) standards, and 3.17.2 regarding Courtesy Reply Mail (CRM).

[Revise the title and text of 3.17.2 as follows:]

3.17.2 Courtesy Reply Mail

Courtesy reply mail (CRM) is reply mail other than BRM or MRM enclosed in other mail, with or without prepayment of postage, for return to the address on the reply piece. If postage is required, the customer returning the piece affixes the applicable First-Class Mail postage. Each piece must meet the physical standards in 1.0 or 2.0.

* * * * *

202 Elements on the Face of a Mailpiece

* * * * *

3.0 Placement and Content of Mail Markings

* * * * *

3.5 Exceptions to Markings

Exceptions are as follows:

[Revise the first sentence in item 3.5a as follows:]

a. Automation letters. Automation letters do not require an ''AUTO'' marking if they bear an Intelligent Mail barcode with a delivery point routing code in the address block or on an insert visible through a window. * * *

* * * * *

5.0 Barcode Placement

5.1 Barcode Clear Zone

[Add a new first sentence and revise the second sentence of 5.1 as follows:]

Each reference to letter or letter-size piece in 5.0 includes both letters and postcards. Each letter-size piece in an automation price or an Enhanced Carrier Route mailing at automation letter prices must have a barcode clear zone unless the piece bears an Intelligent Mail barcode with a delivery point routing code (see 708.4.3) in the address block. * * *

* * * * *

5.2 General Barcode Placement for Letters

[Revise the first sentence of 5.2, and add a new second sentence, as follows:]

Each automation price letter and each letter claimed at Enhanced Carrier Route automation saturation or high density letter prices must bear an Intelligent Mail barcode with a correct delivery point routing code. A nonautomation letter may bear an Intelligent Mail barcode or a POSTNET barcode, under 708.4.0. * * *

* * * * *

[Revise the title and the first two sentences of 5.4 as follows:]

5.4 Additional Barcode Permissibility

An automation letter or a letter claimed at Enhanced Carrier Route saturation or high density automation letter prices may not bear a POSTNET barcode or a 5-digit or ZIP+4 Intelligent Mail barcode in the lower right corner (barcode clear zone). The piece may bear a POSTNET barcode or an additional Intelligent Mail barcode in the address block only if a qualifying Intelligent Mail barcode with a delivery point routing code appears in the lower right corner.

* * * * *

[Delete current 5.6, DPBC Numeric Equivalent, in its entirety, and renumber current 5.7 through 5.11 as new 5.6 through 5.10.]

5.6 Barcode in Address Block

When the barcode is included as part of the address block:

* * * * *

[Revise renumbered items 5.6c through 5.6e as follows:]

c. The minimum clearance between the Intelligent Mail barcode and any information line above or below it within the address block must be at least 0.028 inch. The separation between the barcode and top line or bottom line of the address block must not exceed 0.625 (5/8) inch. The clearance between the leftmost and rightmost bars and any adjacent printing must be at least 0.125 (1/8) inch.

d. If a window envelope is used, the clearance between the leftmost and rightmost bars and any printing or window edge must be at least 0.125 (1/8) inch. The clearance between the Intelligent Mail barcode and the top and bottom window edges must be at least 0.028 inch. These clearances must be maintained during the insert's range of movement in the envelope. Address block windows on heavy letter mail must be covered. Covers for address block windows are subject to 5.10.

e. If an address label is used, a clear space of at least 0.125 (1/8) inch must be left between the barcode and the left and right edges of the address label. The clearance between the Intelligent Mail barcode and the top and bottom edges of the address label must be at least 0.028 inch.

* * * * *

[Revise the title and introductory text of renumbered 5.7 as follows:]

5.7 Barcode on Insert in Barcode Window

If the barcode is printed on an insert to appear through a barcode window in the lower right corner of an envelope:

[Revise renumbered item 5.7a as follows:]

a. The envelope and window must meet the physical standards in 5.9 through 5.10.

* * * * *

[Revise renumbered item 5.7c as follows:]

c. When the insert showing through the window is moved to any of its limits inside the envelope, the entire barcode must remain within the barcode clear zone. In addition, a clear space must be maintained that is at least 0.125 (1/8) inch between the barcode and the left and right edges of the window, at least 0.1875 (3/16) inch between the barcode and the bottom edge of the mailpiece, and at least 0.028 inch between the barcode and the top edge of the window.

* * * * *

220 Priority Mail

223 Prices and Eligibility

* * * * *

3.0 Basic Standards for Priority Mail

* * * * *

3.2 Additional Standards for Critical Mail Letters

* * * Critical Mail letters also must:

* * * * *

[Revise item 3.2b as follows:]

b. Bear a delivery address that includes the correct ZIP Code, ZIP+4 code, or numeric equivalent to the delivery point routing code and that meets address quality standards in 233.5.5 and 708.3.0.

* * * * *

230 First-Class Mail

233 Prices and Eligibility

* * * * *

4.0 Additional Eligibility Standards for Nonautomation First-Class Mail Letters

* * * * *

4.2 Barcodes

[Revise the text of 4.2 as follows:]

Any Intelligent Mail barcode on a mailpiece in nonautomation First-Class Mail mailings must be correct for the delivery address and meet the standards in 202.5.0, 708.3.0, and 708.4.0.

* * * * *

5.0 Additional Eligibility Standards for Automation First-Class Mail Letters

5.1 Basic Standards for Automation First-Class Mail Letters

All pieces in a First-Class Mail automation mailing must:

* * * * *

[Revise item 5.1e as follows:]

e. Bear an accurate Intelligent Mail barcode encoded with the correct delivery point routing code, matching the delivery address and meeting the standards in 202.5.0 and 708.4.0.

* * * * *

5.5 Address Standards for Barcoded Pieces

* * * * *

[Revise the title and text of 5.5.3 as follows:]

5.5.3 Numeric Delivery Point Routing Code

The numeric equivalent to the delivery point routing code is formed by adding two digits directly after the ZIP+4 code.

* * * * *

[Delete 5.6, Reply Cards and Envelopes Enclosed in Automation Price First-Class Mail, in its entirety.]

* * * * *

240 Standard Mail

243 Prices and Eligibility

* * * * *

3.0 Basic Standards for Standard Mail Letters

* * * * *

3.3 Additional Basic Standards for Standard Mail

Each Standard Mail mailing is subject to these general standards:

* * * * *

[Revise item 3.3i as follows:]

i. Any Intelligent Mail barcode on a mailpiece must be correct for the delivery address and meet the standards in 202.5.0, 708.3.0, and 708.4.0.

* * * * *

6.0 Additional Eligibility Standards for Enhanced Carrier Route Standard Mail Letters

6.1 General Enhanced Carrier Route Standards

* * * * *

6.1.2 Basic Eligibility Standards

All pieces in an Enhanced Carrier Route or Nonprofit Enhanced Carrier Route Standard Mail mailing must:

* * * * *

[Revise the introductory text of item 6.1.2d as follows:]

d. Bear a delivery address that includes the correct ZIP Code, ZIP+4 code, or numeric equivalent to the delivery point routing code and that meets these address quality standards:

* * * * *

[Revise item 6.1.2g as follows:]

g. Meet the requirements for automation compatibility in 201.3.0 and bear an accurate Intelligent Mail barcode encoded with the correct delivery point routing code matching the delivery address and meeting the standards in 202.5.0 and 708.4.0, except as provided in 6.1.2h. Pieces prepared with a simplified address format are exempt from the automation-compatibility and barcode requirements. Letters entered under the full-service Intelligent Mail automation option also must meet the standards in 705.24.0.

* * * * *

6.4 High Density Enhanced Carrier Route Standards

[Revise the title and text of 6.4.1 as follows:]

6.4.1 Additional Eligibility Standards for High Density Prices

In addition to the eligibility standards in 6.1, high density letter-size mailpieces must be in a full carrier route tray or in a carrier route bundle of 10 or more pieces placed in a 5-digit (or 3-digit) carrier routes tray. Except for pieces with a simplified address, pieces that are not automation-compatible or not barcoded with an Intelligent Mail barcode under 202.5.0 are mailable only at the nonautomation high density letter prices.

* * * * *

6.5 Saturation ECR Standards

[Revise the title and text of 6.5.1 as follows:]

6.5.1 Additional Eligibility Standards for Saturation Prices

In addition to the eligibility standards in 6.1, saturation letter-size mailpieces must be in a full carrier route tray or in a carrier route bundle of 10 or more pieces placed in a 5-digit (or 3-digit) carrier routes tray. Except for pieces with a simplified address, pieces that are not automation-compatible or not barcoded with an Intelligent Mail barcode under 202.5.0 are mailable only at nonautomation saturation letter prices.

* * * * *

7.0 Eligibility Standards for Automation Standard Mail

7.1 Basic Eligibility Standards for Automation Standard Mail

All pieces in a Regular Standard Mail or Nonprofit Standard Mail automation mailing must:

* * * * *

[Revise the introductory text of item 7.1d as follows:]

d. Bear a delivery address that includes the correct ZIP Code, ZIP+4 code, or numeric equivalent to the delivery point routing code and that meets these address quality standards:

* * * * *

[Revise item 7.1e as follows:]

e. Bear an accurate Intelligent Mail barcode encoded with the correct delivery point routing code, matching the delivery address and meeting the standards in 202.5.0 and 708.4.0.

* * * * *

7.5 Address Standards for Barcoded Pieces

7.5.1 Basic Address Standards for Barcodes

[Revise the text of 7.5.1 as follows:]

To qualify for automation prices, addresses must be sufficiently complete to enable matching to the current USPS ZIP+4 Product when used with current CASS-certified address matching software. Any barcode as defined in 202.5.0 and 708.4.0 that appears on a mailpiece claimed at an automation price must be the correct barcode for the corresponding delivery address on the piece.

* * * * *

[Revise the title and text of 7.5.3 as follows:]

7.5.3 Numeric Delivery Point Routing Code

The numeric equivalent to the delivery point routing code is formed by adding two digits directly after the ZIP+4 code.

* * * * *

[Delete 7.6, Enclosed Reply Cards and Envelopes, in its entirety.]

[Renumber current 7.7 as new 7.6.]

* * * * *

300 Commercial Mail Flats

* * * * *

302 Elements on the Face of a Mailpiece

* * * * *

2.0 Address Placement

* * * * *

2.4 Type Size and Line Spacing

* * * These additional standards apply to automation pieces:

* * * * *

[Revise item 2.4c as follows:]

c. For pieces that bear an Intelligent Mail barcode with a delivery point routing code under 708.4.3, mailers may print the delivery address in a minimum of 6-point type (each character must be at least 0.065 inch high) if all capital letters are used.

* * * * *

5.0 Barcode Placement

[Revise the title and text of 5.1 as follows:]

5.1 Barcode Placement for Flats

On any flat-size piece claimed at automation prices, the piece must bear an Intelligent Mail barcode with a delivery point routing code. The barcode may be anywhere on the address side as long as it is at least ⅛ inch from any edge of the piece. The portion of the surface of the piece on which the barcode is printed must meet the barcode dimensions and spacing requirements in 708.4.2.5, and the reflectance standards in 708.4.4. Intelligent Mail barcodes are subject to standards in 708.4.3.2. A POSTNET barcode or an additional Intelligent Mail barcode may also appear in the address block of an automation flat, when the qualifying Intelligent Mail barcode is not in the address block. Other non-USPS barcodes may appear on the address side of a flat if the barcode format is not discernable to automated postal flat-sorting equipment.

* * * * *

[Delete current 5.2, Applying One Barcode, and 5.3, Applying Second Barcode, in their entirety.]

[Renumber current 5.4 through 5.7 as new 5.2 through 5.5.]

5.2 5-Digit and ZIP+4 Barcodes

[Revise the text of renumbered 5.2 as follows:]

An automation flat-size piece must not bear a 5-digit or a ZIP+4 barcode.

[Revise the title and text of renumbered 5.3 as follows:]

5.3 Delivery Point Routing Code Numeric Equivalent

In automation mailings only, the numbers corresponding to the delivery point routing code may appear in the delivery address. If read from left to right: a correct numeric equivalent consists of five digits, a hyphen, and six digits.

5.4 Barcode in Address Block

When an Intelligent Mail barcode is included as part of the address block:

* * * * *

[Revise renumbered items 5.4c through 5.4e as follows:]

c. The minimum clearance between the barcode and any information line above or below it within the address block must be at least 0.028 inch, and the separation between the barcode and top line or bottom line of the address block must not exceed 0.625 (⅝) inch. The clearance between the leftmost and rightmost bars and any adjacent printing must be at least 0.125 (⅛) inch.

d. If a window envelope is used, the clearance between the leftmost and rightmost bars and any printing or window edge must be at least 0.125 (⅛) inch, and the clearance between the barcode and the top and bottom window edges must be at least 0.028 inch. These clearances must be maintained during the insert's range of movement in the envelope. Covers for address block windows are subject to 5.5. Window envelopes also must meet the specifications in 601.6.3.

e. If an address label is used, a clear space of at least 0.125 (⅛) inch must be left between the barcode and the left and right edges of the address label, and the clearance between the barcode and the top and bottom edges of the address label must be at least 0.028 inch.

* * * * *

320 Priority Mail

323 Prices and Eligibility

* * * * *

3.0 Basic Standards for Priority Mail

* * * * *

3.2 Additional Standards for Critical Mail Flats

[Revise the introductory text of 3.2 as follows:]

Critical Mail, a category of Priority Mail, is available for barcoded, automation-compatible letters and barcoded, automation flats, using IMbs under 708.4.3. With the exception of restricted mail as described in 601.8.0, any mailable matter may be mailed via Critical Mail. USPS-produced Critical Mail flat-size envelopes must be used for all Critical Mail flats. Flats may not exceed 13 ounces in weight or ¾ inch in thickness. Critical Mail flats also must:

* * * * *

[Revise item 3.2b as follows:]

b. Bear a delivery address that includes the correct ZIP Code, ZIP+4 code, or numeric equivalent to the delivery point routing code and that meets address quality standards in 333.5.5 and 708.3.0.

* * * * *

330 First-Class Mail

333 Prices and Eligibility

* * * * *

4.0 Additional Eligibility Standards for Nonautomation First-Class Mail Flats

* * * * *

4.2 Barcodes on Nonautomation First-Class Mail

[Revise the text of 4.2 as follows:]

Any barcode on a mailpiece in a First-Class Mail nonautomation flats mailing must be correct for the delivery address and meet the standards in 708.3.0 and 708.4.0.

* * * * *

5.0 Additional Eligibility Standards for Automation First-Class Mail Flats

5.1 Basic Standards for Automation First-Class Mail

All pieces in a First-Class Mail automation flats mailing must:

* * * * *

[Revise items 5.1d through e as follows:]

d. Bear a delivery address that includes the correct ZIP Code, ZIP+4 code, or numeric equivalent to the delivery point routing code and that meets these address quality standards:

1. The address matching and coding standards in 5.5 and 708.3.0.

2. If an alternative addressing format is used, the additional standards in 602.3.0.

e. Bear an accurate Intelligent Mail barcode encoded with the correct delivery point routing code, matching the delivery address and meeting the standards in 302.5.0 and 708.4.0, either on the piece or on an insert showing through a window.

* * * * *

5.5 Address Standards for Barcoded Pieces

* * * * *

[Revise the title and text of 5.5.3 as follows:]

5.5.3 Numeric Delivery Point Routing Code

A numeric equivalent to the delivery point routing code is formed by adding two digits directly after the ZIP+4 code.

* * * * *

[Delete 5.6, Reply Cards and Envelopes Enclosed in Automation Price First-Class Mail, in its entirety.]

* * * * *

340 Standard Mail

343 Prices and Eligibility

* * * * *

3.0 Basic Standards for Standard Mail Flats

* * * * *

3.3 Additional Basic Standards for Standard Mail

Each Standard Mail mailing is subject to these general standards:

* * * * *

[Revise item 3.3i as follows:]

i. Any barcode on a mailpiece must be correct for the delivery address and meet the standards in 302.5.0, 708.3.0, and 708.4.0.

* * * * *

6.0 Additional Eligibility Standards for Enhanced Carrier Route Standard Mail Flats

6.1 General Enhanced Carrier Route Standards

* * * * *

6.1.2 Basic Eligibility Standards

All pieces in an Enhanced Carrier Route or Nonprofit Enhanced Carrier Route Standard Mail mailing must:

* * * * *

[Revise the introductory text of item 6.1.2d as follows:]

d. Bear a delivery address that includes the correct ZIP Code, ZIP+4 code, or numeric equivalent to the delivery point routing code and that meets these address quality standards:

* * * * *

7.0 Additional Eligibility Standards for Automation Standard Mail Flats

7.1 Basic Eligibility Standards for Automation Standard Mail

All pieces in a Regular Standard Mail or Nonprofit Standard Mail automation mailing must:

* * * * *

[Revise the introductory text of item 7.1d as follows:]

d. Bear a delivery address that includes the correct ZIP Code, ZIP+4 code, or numeric equivalent to the delivery point routing code and that meets these address quality standards:

* * * * *

[Revise item 7.1e as follows:]

e. Bear an accurate Intelligent Mail barcode encoded with the correct delivery point routing code, matching the delivery address and meeting the standards in 302.5.0 and 708.4.0.

* * * * *

7.4 Address Standards for Barcoded Pieces

* * * * *

[Revise the title and text of 7.4.3 as follows:]

7.4.3 Numeric Delivery Point Routing Code

A numeric equivalent to the delivery point routing code is formed by adding two digits directly after the ZIP+4 code.

* * * * *

[Delete 7.5, Enclosed Reply Cards and Envelopes, in its entirety.]

* * * * *

360 Bound Printed Matter

363 Prices and Eligibility

1.0 Prices and Fees for Bound Printed Matter

* * * * *

1.1.4 Barcoded Discount—Flats

[Revise the text of 1.1.4 as follows:]

For discount, see Notice 123–Price List. See 4.1 and 6.1 for eligibility information.

* * * * *

4.0 Price Eligibility for Bound Printed Matter Flats

4.1 Price Eligibility

* * * Price categories are as follows:

* * * * *

[Revise item 4.1d as follows:]

d. Barcoded Discount—Flats. The barcoded discount applies to BPM flats that meet the requirements for automation flats in 301.3.0 and bear an accurate Intelligent Mail barcode encoded with the correct delivery point routing code. See 6.1 for more information.

* * * * *

6.0 Additional Eligibility Standards for Barcoded Bound Printed Matter Flats

6.1 Basic Eligibility Standards for Barcoded Bound Printed Matter

[Revise the text of 6.1 as follows:]

The barcode discount applies only to BPM flat-size pieces that bear an Intelligent Mail barcode encoded with the correct delivery point routing code, matching the delivery address and meeting the standards in 302.5.0 and 708.4.0. The pieces must be part of a nonpresorted price mailing of 50 or more flat-size pieces or part of a presorted mailing of at least 300 BPM flats prepared under 365.7.0, 705.8.0, and 705.14.0. The barcode discount is not available for flats mailed at Presorted DDU prices or carrier route prices. To qualify for the barcode discount, the flat-size pieces must meet the standards in 301.3.0.

* * * * *

6.4 Address Standards for Barcode Discounts

* * * * *

[Revise the title and text of 6.4.3 as follows:]

6.4.3 Numeric Delivery Point Routing Code

A numeric equivalent to the delivery point routing code is formed by adding two digits directly after the ZIP+4 code.

* * * * *

400 Commercial Parcels

* * * * *

402 Elements on the Face of a Mailpiece

* * * * *

4.0 General Barcode Placement for Parcels

* * * * *

[Revise the title and text of current 4.3 as follows:]

4.3 Intelligent Mail Barcodes and POSTNET Barcodes

Intelligent Mail barcodes and POSTNET barcodes do not meet barcode eligibility requirements for parcels and do not qualify for any barcode-related prices for parcels, but one barcode may be included only in the address block on a parcel, except on eVS parcels. An Intelligent Mail barcode or POSTNET barcode in the address block must be placed according to 302.5.4.

[Delete current 4.3.1, General Placement of POSTNET Barcodes, 4.3.2, POSTNET Barcode in Address Block, and 4.3.3, Window Cover, in their entirety.]

* * * * *

440 Standard Mail

443 Prices and Eligibility

* * * * *

4.0 Price Eligibility for Standard Mail

* * * * *

4.4 Surcharge

Unless prepared in carrier route or 5-digit/scheme containers, Standard Mail parcels are subject to a surcharge if:

* * * * *

[Revise item 4.4c as follows:]

c. The irregular parcels do not bear a GS1–128 routing barcode or an Intelligent Mail package barcode for the delivery address.

* * * * *

6.0 Additional Eligibility Standards for Enhanced Carrier Route Standard Mail Marketing Parcels

6.1 General Enhanced Carrier Route Standards

* * * * *

6.1.2 Basic Eligibility Standards

All pieces in an Enhanced Carrier Route or Nonprofit Enhanced Carrier Route mailing of Standard Mail Marketing parcels must:

* * * * *

[Revise the introductory text of item 6.1.2d as follows:]

d. Bear a delivery address that includes the correct ZIP Code, ZIP+4 code, or numeric equivalent to the delivery point routing code and that meets these addressing standards:

* * * * *

500 Additional Mailing Services

503 Extra Services

* * * * *

14.0 Confirm Service and IMb Tracing

* * * * *

14.2 Barcodes

* * * * *

14.2.2 Intelligent Mail Barcode Requirements

[Revise the introductory text of 14.2.2 as follows:]

To obtain IMb Tracing, mailers must apply Intelligent Mail barcodes on letter-size pieces or on flat-size pieces meeting automation-compatibility standards in 201.3.0 (letters) or 301.3.0 (flats). The following standards apply:

* * * * *

505 Return Services

1.0 Business Reply Mail (BRM)

* * * * *

1.3 Qualified Business Reply Mail (QBRM) Basic Standards

1.3.1 Description

Qualified Business Reply Mail (QBRM) is First-Class Mail that:

* * * * *

[Revise item 1.3.1d as follows:]

d. Is authorized to mail at QBRM prices and fees under 1.3.2. During the authorization process, the mailer is assigned a unique ZIP+4 code for each price category of QBRM to be returned under the system (one for card-price pieces, one for letter-size pieces weighing 1 ounce or less, and one for letter-size pieces weighing over 1 ounce up to and including 2 ounces).

* * * * *

[Revise item 1.3.1f as follows:]

f. Bears the correct Intelligent Mail barcode that corresponds to the unique ZIP+4 code in the address on each piece distributed. The barcode must be correctly prepared under 1.9 and 708.4.0.

* * * * *

1.8 Format Elements

* * * * *

1.8.6 Delivery Address

The complete address (including the permit holder's name, delivery address, city, state, and BRM ZIP Code) must be printed directly on the piece, except as allowed under 1.7.5 or under item a below, subject to these conditions:

[Revise item 1.8.6a as follows:]

a. Preprinted labels with only delivery address information (including an Intelligent Mail barcode under 1.9) are permitted, but the permit holder's name and other required elements must be printed directly on the BRM piece.

* * * * *

1.9 Additional Standards for Letter-Size and Flat-Size BRM

[Revise the text of 1.9 to incorporate the current item 1.9a, including items a1 and a2, into the introductory text and revise the new introductory text as follows:]

In addition to the format standards in 1.8, QBRM letters and cards must be barcoded with an Intelligent Mail barcode. When an Intelligent Mail barcode is printed on any BRM pieces, it must contain the barcode ID, service type ID, and correct ZIP+4 routing code, as specified under 708.4.3. QBRM pieces must bear the ZIP+4 codes and equivalent Intelligent Mail barcodes assigned by the USPS. The IMb must be placed on the address side of the piece and positioned as part of the delivery address block under 202.5.7 or within the barcode clear zone in the lower right corner of the piece if printed directly on the piece.

* * * * *

2.0 Permit Reply Mail (PRM)

* * * * *

2.3 Format Elements

* * * * *

2.3.6 Delivery Address

[Revise the text of 2.3.6 as follows:]

The complete address (including the permit holder's name, delivery address, city, state, and ZIP+4 code) must be printed on the piece. PRM pieces must bear an Intelligent Mail barcode encoded with the correct delivery point routing code, matching the delivery address and meeting the standards in 202.5.0 and 708.4.0.

* * * * *

600 Basic Standards for All Mailing Services

601 Mailability

* * * * *

6.0 Mailing Containers—Special Types of Envelopes and Packaging

* * * * *

6.5 Reusable Mailpiece

* * * Except for reusable mailpieces that originate as permit imprint mailings, the piece must meet these standards:

[Revise the first sentence of 6.5a as follows:]

a. Basic Design. The piece must be designed and constructed to allow the recipient to reconfigure the piece to remove or obscure the address, barcode, postage, and any marking or endorsement applied to the piece when it was originally mailed so that these elements are not mistaken by the USPS as applying to the returned piece. * * *

* * * * *

602 Addressing

* * * * *

4.0 Detached Address Labels (DALs) and Detached Marketing Labels (DMLs)

* * * * *

4.2 Label Preparation

* * * * *

4.2.2 Addressing

* * * [Revise the last sentence of 4.2.2 as follows:] In addition, if DALs accompany saturation mailings of Periodicals or Standard Mail flats, a correct Intelligent Mail barcode with an 11-digit routing code must be printed on each DAL except when using a simplified address.

* * * * *

700 Special Standards

* * * * *

708 Technical Standards

* * * * *

[Revise the title of 4.0 as follows:]

4.0 Standards for Intelligent Mail and POSTNET Barcodes

4.1 General

[Revise the text of 4.1 as follows:]

Intelligent Mail barcodes and POSTNET (Postal Numeric Encoding Technique) barcodes are USPS-developed methods to encode ZIP Code information on mail that can be read for sorting by automated machines. Intelligent Mail barcodes also encode other tracking information. POSTNET barcodes do not qualify for automation pricing.

* * * * *

We will publish an appropriate amendment to 39 CFR Part 111 to reflect these changes.

Stanley F. Mires,

Attorney, Legal Policy & Legislative Advice.

[FR Doc. 2012–10505 Filed 5–2–12; 8:45 am]

BILLING CODE 7710–12–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R9–IA–2008–0123; FXES111309F2120D2–123–FF09E22000]

RIN 1018–AI83

Endangered and Threatened Wildlife and Plants; Reclassifying the Wood Bison Under the Endangered Species Act as Threatened Throughout Its Range

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are reclassifying the wood bison (*Bison bison athabascae*) from endangered to threatened. This action is based on a review of the best available scientific and commercial data, which indicate that the primary threat that led to population decline, unregulated hunting, is no longer a threat and that recovery actions have led to a substantial increase in the number of herds that have a stable or increasing trend in population size. Critical habitat has not been designated because free-ranging wood bison only occur in Canada and we do not designate critical habitat in foreign countries.

DATES: This rule becomes effective June 4, 2012.

ADDRESSES: This final rule is available on the Internet at *http://www.regulations.gov* under Docket No. FWS–R9–IA–2008–0123 and at *http://alaska.fws.gov/fisheries/endangered/index.htm.* Comments and materials received, as well as supporting documentation used in the preparation of this rule, will be available for public inspection, by appointment, during normal business hours at: U.S. Fish and Wildlife Service, Alaska Regional Office, 1011 East Tudor Road, Anchorage, AK 99503; 907–786–3856.

FOR FURTHER INFORMATION CONTACT: Marilyn Myers at U.S. Fish and Wildlife Service, Fisheries and Ecological Services, 1011 E. Tudor Road, Anchorage, AK 99503; or telephone at 907–786–3559; or facsimile at 907–786–3848. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. We listed the wood bison as endangered in 1970. Since listing, the status of wood bison has improved because enactment and enforcement of national and international laws and treaties have minimized the impacts of hunting and trade, and reintroduction of disease-free herds has increased the number of free-ranging herds in Canada from 1 population of 300 in 1978, to 7 populations totaling 4,414 bison in 2008. These free-ranging populations are stable or increasing. Therefore, we have determined that the wood bison no longer meets the definition of endangered under the Endangered Species Act.

This rule changes the listing of the wood bison from endangered to threatened.

Basis for our action. While we have determined that the wood bison no longer meets the definition of endangered under the Endangered Species Act, some threats to wood bison remain. Habitat loss has occurred in Canada from agricultural development, and we expect losses will continue in concert with human growth and expansion of agriculture, including commercial bison production. The presence of disease in Canada constrains herd growth, and regulatory mechanisms are inadequate to prevent disease transmission within Canada. However, the continued reintroduction of disease-free herds, the ongoing development and updating of management plans, the active management of herds, the ongoing research, and the protections provided by laws and protected lands provide compelling evidence that recovery actions have been successful in reducing the risk of extinction associated with the threats identified. Therefore, we are reclassifying the wood bison from endangered to threatened.

The majority of comments we received support this action. The majority of comments (13 of 19) supported downlisting. A subset of these comments (7 of the 13) asserted that the Service should delist the species immediately. Three comments stated that wood bison should remain listed as endangered. The peer review comments provided very specific corrections to details about two of the wood bison herds in Canada, and we have updated our information in this rule accordingly, but these changes do not alter our finding.

Background

Previous Federal Actions

The listing history for wood bison is extensive and was described in the proposed rule published on February 8, 2011 (76 FR 6734). Please refer to that proposed rule for the complete listing history. Here we present only the most pertinent facts.

The wood bison became listed in the United States under the 1969 Endangered Species Conservation Act when it was included on the first List of Endangered Foreign Fish and Wildlife, which was published in the **Federal Register** on June 2, 1970 (35 FR 8491). In 1974, the first list of federally protected species under the 1973 Endangered Species Act (Act; 16 U.S.C. 1531 *et seq.*) appeared in the Code of Federal Regulations (CFR), and the wood bison appeared on this list based on its inclusion on the original 1969 list. Because the wood bison was listed under the 1969 Endangered Species Conservation Act and grandfathered in for protection under the Act, there is not a separate **Federal Register** notice that defined the population(s) and their range or analyzed threats to the species. The wood bison was classified as endangered and has retained that designation since the original listing.

On May 14, 1998, the Service received a petition from a private individual requesting that the Service remove the wood bison from the List of Endangered and Threatened Wildlife, primarily because it had been downgraded from an Appendix I to an Appendix II species under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). In a 90-day finding published on November 25, 1998 (63 FR 65164), we found that the petitioner did not provide substantial

information to indicate that the delisting may be warranted.

On November 26, 2007, we received a petition from the co-chairs of Canada's National Wood Bison Recovery Team, requesting that we reclassify the wood bison from endangered to threatened. On February 3, 2009, we published a 90-day finding (74 FR 5908) acknowledging that the petition provided sufficient information to indicate that reclassification may be warranted and that we would initiate a status review. On February 8, 2011, we announced the completion of our status review of the species, which also constituted our 5-year review under section 4(c)(2) of the Act, and issued a proposed rule to reclassify the wood bison from an endangered species to a threatened species (76 FR 6734). This document is our final rule to reclassify the wood bison from endangered to threatened.

Species Information

Taxonomy and Species Description

Wood bison (*Bison bison athabascae*) belongs to the family Bovidae, which also includes cattle, sheep, and goats. Debate over the generic name *Bison* continues with some authorities using *Bos* and others using *Bison* depending on the methodology used to determine relationships among members of the tribe Bovini (Asian water buffalo, African buffalo, cattle and their wild relatives, and bison) (Boyd *et al.* 2010, pp. 13–15). In this discussion, we will use *Bison,* which is consistent with ''Wild Mammals of North America'' (Reynolds *et al.* 2003, p. 1010), ''Mammal Species of the World'' (Wilson and Reeder 2005, p. 689), and the Wood Bison Recovery Team (Gates *et al.* 2001, p. 25). Wood bison was first described as a subspecies in 1897 (Rhoads 1897, pp. 498–500). One other extant bison subspecies, the plains bison (*B. b. bison*), occurs in the United States and Canada. Based on the historical physical separation and quantifiable behavioral, morphological, and phenological (appearance) differences between the two subspecies, the scientific evidence indicates that subspecific designation is appropriate (van Zyll de Jong *et al.* 1995, p. 403; FEAP 1990, p. 24; Reynolds *et al.* 2003, p. 1010; Gates *et al.* 2010, pp. 15–17).

Wood bison is the largest native extant terrestrial mammal in North America (Reynolds *et al.* 2003, p. 1015). Average weight of mature males (age 8) is 910 kilograms (kg) (2,006 pounds (lb)) and the average weight of mature females (age 13) is 440 kg (970 lb) (Reynolds *et al.* 2003, p. 1015). They have a large triangular head, a thin beard and rudimentary throat mane, and a poorly demarcated cape (Boyd *et al.* 2010, p. 16). In addition, the highest point of their hump is forward of their front legs; they have reduced chaps on their front legs; and their horns usually extend above the hair on their head (Boyd *et al.* 2010, p. 16). These physical characteristics distinguish them from the plains bison (Reynolds *et al.* 2003, p. 1015; Boyd *et al.* 2010, p. 16).

Distribution

The exact extent of the original range of wood bison cannot be determined with certainty based on available information, but was limited to North America (Gates *et al.* 2001, p. 11). However, historically, the range of the wood bison was generally north of that occupied by the plains bison and included most boreal regions of northern Alberta, northeastern British Columbia east of Cordillera, a small portion of northwestern Saskatchewan, the western Northwest Territories south and west of Great Slave Lake, the Mackenzie River Valley, most of The Yukon Territory, and much of interior Alaska (Reynolds *et al.* 2003, pp. 1011–1012). Skinner and Kaisen (1947, pp. 158, 164) suggested that the prehistorical U.S. range extended from Alaska to Colorado, and Stephenson *et al.* (2001, p. 140) concluded that wood bison were present within the boundaries of what is now defined as Alaska until their disappearance during the last few hundred years. Currently, there is a wild population neither in Alaska nor in the continental United States (Harper and Gates 2000, p. 917; Stephenson *et al.* 2001, p. 140).

During the early 1800s, wood bison numbers were estimated at 168,000, but by the late 1800s, the subspecies was nearly eliminated, with only a few hundred remaining (Gates *et al.* 2001, p. 11). In the words of Soper (1941, p. 362), wood ''bison appear to have been practically exterminated,'' and based on the fate of plains bison, in which 40 to 60 million animals were reduced to just over 1,000 animals in less than 100 years (Hornaday 1889; Wilson and Strobeck 1998, p. 180), overharvest may have been the cause for the decline (Harper and Gates 2000, p. 915). The fact that populations began to rebound once protection was in place and enforced supports this idea (Soper 1941, pp. 362–363). In 1922, Wood Buffalo National Park (WBNP) was set aside for the protection of the last remnant population of wood bison. Since that time, several additional herds have been established (Table 1).

TABLE 1—SIZES OF WOOD BISON HERDS IN CANADA FROM 1978 TO 2008 (DATA PROVIDED BY CANADIAN WILDLIFE SERVICE)

Herd category and name	1978	1988	2000	2002	2004	2006	2008
Free-ranging, disease-free herds:							
Mackenzie	300	1,718	1,908	2,000	2,000	~ 2,000	1,600
Nahanni	.....	30	160	170	399	400	400
Aishihik	.....	.....	500	530	550	700	1,100
Hay-Zama	.....	.....	130	234	350	600	750
Nordquist	.....	.....	50	60	112	140	140
Etthithun	.....	.....	.....	43	70	124	124
Chitek Lake	.....	.....	70	100	150	225	300
Free-ranging, diseased herds:							
Wood Buffalo [1] National Park	.....	.....	2,178	4,050	[2] 4,947	[3] 5,641	[4] 4,639

[1] Excluding adjacent diseased Wentzel, Wabasca, and Slave River Lowlands herds.
[2] Population estimate for year 2003.
[3] Population estimate for year 2005.
[4] Population estimate for year 2007.

Another factor that is thought to have played a role in the decline in wood bison is a gradual loss of meadow habitat through forest encroachment (Stephenson *et al.* 2001, p. 143; Quinlan *et al.* 2003, p. 343; Strong and Gates

2009, p. 439). Although not quantified, it is likely that because of fire suppression, and subsequent forest encroachment on meadows, there was a net loss of suitable open meadow habitat for wood bison throughout their range through about 1990. More intensive fire management began in Canada in the early 1900s with the philosophy that fire was destructive and should be eliminated to protect property and permit proper forest management (Stocks *et al.* 2003, p. 2). However, wildfire is an integral component of boreal forest ecology (Weber and Flannigan 1997, p. 146; Rupp *et al.* 2004, p. 213; Soja *et al.* 2007, p. 277). Without fire, trees encroach on meadows and eventually the meadow habitat is lost and replaced by forest.

Habitat

The foraging habitats most favored by wood bison are grass and sedge meadows occurring on alkaline soils. These meadows are typically interspersed among tracts of coniferous forest, stands of poplar or aspen, bogs, fens, and shrublands. Meadows typically represent 5 to 20 percent of the landscape occupied by wood bison (Larter and Gates 1991a, p. 2682; Gates *et al.* 2001, p. 23). Wet meadows are rarely used in the summer, probably because of the energy required to maneuver through the mud, but they are used in late summer when they become drier, and in the winter when they freeze (Larter and Gates 1991b, pp. 133, 135; Strong and Gates 2009, p. 438).

Biology

Because wood bison can thrive on coarse grasses and sedges, they occupy a niche within the boreal forest that is not utilized by other northern herbivores such as moose or caribou (Gates *et al.* 2001, p. 25). Several studies indicate that wood bison prefer sedges (*Carex* spp.), which can comprise up to 98 percent of the winter diet (Reynolds *et al.* 1978, p. 586; Smith 1990, p. 88; Larter and Gates 1991a, p. 2679; Fortin *et al.* 2003, pp. 224–225). Seasonally, other important diet items include grasses, willow, and lichen (Reynolds *et al.* 1978, p. 586; Smith 1990, p. 88; Larter and Gates 1991a, pp. 2680–2681; Fortin *et al.* 2003, pp. 224–225).

Free-ranging wood bison roam extensively with annual maximum traveling distance from each individual's center-of-activity averaging from 45 to 50 kilometers (km) (28 to 31 miles (mi)) (Chen and Morley 2005, p. 430). However, some captive animals released into the wild have traveled over 250 km (155 mi) (Gates *et al.* 1992, pp. 151–152). Herds are fluid, and individuals interchange freely (Fuller 1960, p. 15; Wilson *et al.* 2002, p. 1545). Wood bison travel between favored foraging habitats along direct routes including established trails, roads, river corridors, and transmission lines (Reynolds *et al.* 1978, p. 587; Mitchell 2002, p. 50). Bison are also powerful swimmers and will cross even large rivers such as the Peace, Slave, Liard, and Nahanni to reach forage, provided that there are low banks for entry and exit (Fuller 1960, p. 5; Mitchell 2002, pp. 32, 50; Larter *et al.* 2003, pp. 408–412).

The wood bison's breeding season is from July to October. The age of first reproduction depends on nutritional condition and disease status, and is therefore variable (Gates *et al.* 2010, p. 49). Females typically produce their first calf when they are 3 years old and may be reproductively successful up to age 20 (Wilson *et al.* 2002, p. 1545). Although capable of reproduction at age 2, males typically do not participate in the rut until they are 5 or 6, and reproductive success is at its maximum between ages 7 and 14 (Wilson *et al.* 2002, pp. 1538, 1544). Bison have a polygynous mating system, in which one male mates with several females (Wilson *et al.* 2002, p. 1538). When habitat is adequate and there are no other limiting factors such as disease and predation, wood bison populations have expanded exponentially (FEAP 1990, pp. 34–35; Gates and Larter 1990, p. 233). Consequently, newly introduced populations have the capacity to grow quickly, as demonstrated by the Mackenzie herd (Gates and Larter 1990, p. 235).

Wood bison are susceptible to a variety of diseases that may affect their population dynamics. The most important are anthrax, bovine brucellosis, and bovine tuberculosis, none of which are endemic to wood bison (Gates *et al.* 2010, pp. 28–32). Anthrax is an infectious bacterial disease that is transmitted through the inhalation or ingestion of endospores (Gates *et al.* 2010, p. 28). The disease is rapidly fatal, with death usually occurring within several days once the clinical signs appear (Dragon *et al.* 1999, p. 209). Between 1962 and 1993, nine outbreaks were recorded in northern Canada, killing at least 1,309 bison (Dragon *et al.* 1999, p. 209). Additional outbreaks continued to occur through at least 2010 (GNT 2010, p. 9). Factors associated with outbreaks are high ambient temperatures, high densities of insects, and high densities of bison as they congregate in areas of diminishing forage and water (Dragon *et al.* 1999, p. 212). Sexually mature males are more susceptible than cows, juveniles, or calves, perhaps because of elevated levels of testosterone (Dragon *et al.* 1999, p. 211). Anthrax is not treatable in free-ranging wildlife, but captive bison can be vaccinated effectively and treated with antibiotics (Gates *et al.* 2001, p. 22)

Bovine brucellosis is caused by the bacterium *Brucella abortus* (Tessaro 1989, p. 416). Although the primary hosts are bovids, other ungulates such as elk can be infected. The disease is primarily transmitted through oral contact with aborted fetuses, contaminated placentas, and uterine discharges. Greater than 90 percent of infected female bison abort during their first pregnancy (Gates *et al.* 2010, p. 30). Naturally acquired immunity reduces the abortion rate with subsequent pregnancies (Aune and Gates 2010, p. 30). Male bison experience inflammation of their reproductive organs and, in advanced cases, sterility. Both sexes are susceptible to bursitis and arthritis caused by concentrations of the bacterium in the joints, which may make them more susceptible to predation (Joly 2001, pp. 97–98). Two vaccines, S19 and SR B51, have been developed in an attempt to prevent bovine brucellosis (Aune and Gates 2010, pp. 30–31); however, brucellosis remains extremely difficult to eradicate in ungulates. The combined use of quarantine protocols, serum testing, slaughter, and vaccination is being explored as a means of controlling the disease (Nishi *et al.* 2002, pp. 230–233; Bienen and Tabor 2006, pp. 324–325; Aune and Gates 2010, p. 31).

Bovine tuberculosis is a chronic infectious disease caused by the bacterium *Mycobacterium bovis* (Tessaro 1989, p. 417). Historical evidence indicates that bovine tuberculosis did not occur in bison prior to contact with infected domestic cattle (Tessaro 1989, p. 416). Wood bison were infected in the 1920s, when plains bison were introduced into the range of wood bison (Tessaro 1989, p. 417). Currently, the disease is concentrated in bison in and near WBNP (Wabasca, Wentzel, and Slave River Lowlands herds). The disease is primarily transmitted by inhalation and ingestion of the bacterium, but may also pass to offspring through the placenta or contaminated milk (FEAP 1990, p. 11). Bovine tuberculosis is a chronic disease that progressively becomes debilitating; advanced cases are fatal. There is not an effective vaccine for immunization against tuberculosis (FEAP 1990, p. 2).

Wood bison herds in and around WBNP, Alberta and the Northwest Territories, Canada, are infected with brucellosis and bovine tuberculosis.

These diseased herds account for about half of the free-ranging wood bison and are the only known reservoirs of tuberculosis and brucellosis among the herds (Gates *et al.* 2010, pp. 4, 35). Approximately 30 percent of the animals in these herds test positive for brucellosis, and 21 to 49 percent test positive for tuberculosis. The combined prevalence of the two diseases is 42 percent (Tessaro *et al.* 1990, p. 174; Gates *et al.* 2010, p. 35). Wood bison cows infected with both tuberculosis and brucellosis are less likely to be pregnant, and infected herds are more likely to have their populations regulated by wolf predation (Tessaro *et al.* 1990, p. 179; Joly and Messier 2004, p. 1173; Joly and Messier 2005, p. 549). Unlike anthrax, which occurs in outbreaks in which many animals die at one time, brucellosis and tuberculosis are chronic diseases that weaken animals over time.

Conservation Status

In Canada, the Committee on the Status of Endangered Wildlife in Canada (COSEWIC) was established in 1977, to assess species' status and evaluate their risk of extinction. In 1978, the COSEWIC designated wood bison as endangered, based primarily on the fact that there were only about 400 disease-free wood bison: 100 in a captive herd and 300 in a free-ranging herd. In 1988, wood bison was downlisted to threatened in Canada because of data presented in a status report prepared by the National Wood Bison Recovery Team that documented progress towards recovery (Gates *et al.* 2001, p. 28; Gates *et al.* 2010, p. 65). A review by the COSEWIC in 2000 confirmed that ''threatened'' was the appropriate designation at that time (Gates *et al.* 2010, p. 65).

The wood bison was listed in Appendix I of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) on July 1, 1975, when the treaty first went into effect. On September 18, 1997, it was transferred to Appendix II, based on a proposal from Canada that described progress in implementation of the Canadian recovery plan (Government of Canada 1997, entire). CITES Appendix-II species are not necessarily considered to be threatened with extinction now but may become so unless trade in the species is regulated. The United States supported this change.

Recovery Actions

Section 4(f) of the Act directs us to develop and implement recovery plans for the conservation and survival of endangered and threatened species, unless the Director determines that such a plan will not promote the conservation of the species. The Service has not developed a recovery plan for wood bison, because no wild populations of wood bison currently exist in the United States. In Canada, the National Wood Bison Recovery Team published a national recovery plan in 2001 (Gates *et al.* 2001), and is currently preparing a revision to the plan. The purpose of the recovery plan is to advance the recovery of the wood bison; specific criteria for delisting under Canada's Species at Risk Act (SARA) were not specified. Management plans for the provinces support the goals and objectives of the National Recovery Plan (e.g., Harper and Gates 2000, p. 917; GNT 2010, p. 1). Four goals were established to advance the recovery of wood bison (Gates *et al.* 2001):

(1) To reestablish at least four discrete, free-ranging, disease-free, and viable populations of 400 or more wood bison in Canada, emphasizing recovery in their original range, thereby enhancing the prospects for survival of the subspecies and contributing to the maintenance of ecological processes and biological diversity.

(2) To foster the restoration of wood bison in other parts of their original range and in suitable habitat elsewhere, thereby ensuring their long-term survival.

(3) To ensure that the genetic integrity of wood bison is maintained without further loss as a consequence of human intervention.

(4) To restore disease-free wood bison herds, thereby contributing to the aesthetic, cultural, economic, and social well-being of local communities and society in general.

Revisions to the U.S. List of Endangered and Threatened Wildlife (adding, removing, or reclassifying a species) must reflect determinations made in accordance with sections 4(a)(1) and 4(b) of the Act. Section 4(a)(1) requires that the Secretary determine whether a species is endangered or threatened, as defined by the Act, because of one or more of the five factors outlined in section 4(a)(1). In other words, an analysis of the five factors under 4(a)(1) can result in a determination that a species is no longer endangered or threatened. Section 4(b) requires that the determination made under section 4(a)(1) be based on the best scientific and commercial data available and after taking into account those efforts, if any, being made by any State or foreign nation to protect such species. Here, we rely on the five-factor analysis to determine if it is appropriate to reclassify wood bison. We also take into consideration the conservation actions that have occurred, are ongoing, and are planned.

In 1978, there was one free-ranging, disease-free herd with 300 individuals: the MacKenzie herd (see Table 1, above). By 2000, when the last Canadian status review was conducted, the number of disease-free herds had grown to 6, with a total of approximately 2,800 individuals (see Table 1, above). Since 2000, an additional herd has been established bringing the total number to 7, and the number of disease-free, free-ranging bison has increased to approximately 4,400 (see Table 1, above). Four of the herds have a population of 400 or more, meeting recovery goal number 1 (see Table 1, above). The free-ranging, disease-free herds are discussed in detail below.

Free-Ranging, Disease-Free Herds

The Mackenzie bison herd was established in 1963, with the translocation of 18 wood bison that were originally captured in an isolated area of WBNP. This herd is currently the largest free-ranging, disease-free herd of wood bison, with approximately 1,600 to 2,000 animals (Reynolds *et al.* 2004, p. 7). The Mackenzie Bison Sanctuary was established in 1979, and encompasses an area of 6,300 km^2 (2,432 mi^2) northwest of Great Slave Lake. The current range of the Mackenzie bison herd (12,000 km^2 (4,633 mi^2)) extends well beyond the boundaries of the sanctuary. In 2010, the Government of Northwest Territories released the final Wood Bison Management Strategy. It indicates that there is sufficient habitat in the Northwest Territories to support expanding bison populations (GNWT 2010, p. 9). Habitat protection within the range of the Mackenzie bison herd is facilitated through the Species at Risk Act (SARA), Canada's equivalent to the Act, and the Mackenzie Valley Resource Management Act of 1998. Although the Mackenzie Valley Resource Management Act does not specifically provide protection to wood bison, it did create a Land and Water Board (LWB), which is given the power to regulate the use of land and water, including the issuance of land use permits and water licenses. Under current management, an annual harvest is allowed (described under Factor B below), and the Mackenzie herd size has been greater than the recovery target of 400 since 1987, with approximately 1,600 to 2,000 animals (Gates and Larter 1999, p. 233; see Table 1, above). Thus, the

Mackenzie herd contributes to recovery goals 1 and 4.

Five releases of wood bison totaling 170 animals from 1988 to 1991 established the Aishihik herd in southwestern Yukon, in a remote area west of Whitehorse, Canada. Herd size has totaled over 400 since 1999 (Gates *et al.* 2001, p. 14; see Table 1, above). With a current population of approximately 1,100 animals, it is the second-largest herd. The herd inhabits approximately 9,000 km^2 (3,475 mi^2) of largely undeveloped habitat near the community of Haines Junction, adjacent to Kluane National Park. Less than 5 percent of the range of the Aishihik herd is on private lands (First Nation Settlement Lands), and these landowners participate in a management planning team specifically for this herd. The remainder of the herd's range is owned by the Government of Canada, and there are no threats to habitat in this area (Reynolds *et al.* 2004, p. 9). The herd has room to expand or shift its range, because there are no large-scale developments east, west, or north of the present range for several hundred kilometers. Small-scale agricultural development to the south of the present range, however, could restrict range expansion in that direction (Reynolds *et al.* 2004, p. 9). Regulated hunting occurs on this herd (described under Factor B below). Other than regulated harvest, no other limiting factors have been identified (Reynolds *et al.* 2004, p. 17). The Aishihik herd contributes to recovery goals 1, 2, and 4.

The Hay-Zama herd was established in 1984, when 29 wood bison were transferred from Elk Island National Park to the holding corral site near Hay-Zama Lakes, Alberta (Gates *et al.* 2001, p. 17). A herd of 48 wood bison became free-ranging when portions of the corral they were being held in collapsed in 1993 (Gates *et al.* 2001, p. 17). Since then, the free-ranging herd has grown to approximately 750 animals (Table 1), thus contributing to recovery goals 1, 2, and 4. In 1995, the Government of Alberta established a 36,000 km^2 (13,900 mi^2) Bison Management Area around the Hay-Zama herd in the northwestern corner of the province. In this area, all wood bison are legally protected from hunting under Alberta's Wildlife Act; outside of the area they are not protected. Collisions with vehicles are the largest source of known mortality for individuals in this herd (Mitchell and Gates 2002, p. 9).

The Nahanni herd, established in 1980 with the release of 28 wood bison, occurs primarily in the Northwest Territories and extends into southeast Yukon and northeast British Columbia. The population was bolstered by two supplemental releases in 1989 and 1998, of 12 and 59 animals, respectively (Larter and Allaire 2007, p. 3). Population size has been approximately 400 animals or more since 2006, and, based on surveys, was estimated at 413 in 2010 (Larter, GNWT, 2010, pers. comm.). There is currently sufficient habitat to support the expanding population (GNT 2010, p. 9).

The Nordquist herd was established in 1995, near the Laird River in northeastern British Columbia (see Table 1, above). Because the majority of the herd occupies habitat near the Alaska Highway, vehicle collisions are a source of mortality (Reynolds *et al.* 2009, p. 6). It is anticipated that the Nordquist and Nahanni herds will eventually coalesce into one herd because of their close proximity and the presence of river corridors that provide travel corridors (Gates *et al.* 2001, p. 18). Although it has not yet occurred, combination of the two herds would create a herd with numbers that exceed the recovery criterion of 400 (see Table 1, above).

The Etthithun herd was established in 2002, near Etthithun Lake, British Columbia. Factors limiting the size of this herd include the amount and location of suitable habitat, conflicts with humans and industrial development, and potential contact with commercial plains bison (BC MOE, pers. comm., 2010). Current population size is approximately 124 (see Table 1, above); consequently, this herd does not currently meet the recovery criterion of 400 individuals. However, it does contribute to recovery goals 2 and 4.

The Chitek Lake herd was established in 1991, in Manitoba, Canada. The Chitek Lake Wood Bison Management Committee plans to maintain the herd at approximately 300 animals to keep the herd within carrying capacity of the habitat. The 100,300-hectare (ha) (25,452-acre (ac)) Chitek Lake Park Reserve provides habitat protection for the core range of the herd. Limiting factors for the herd include accidental mortality from drowning, starvation in bad winters, and predation from wolves (Manitoba Conservation, pers. comm., 2010). Although outside of the historic range of wood bison, Chitek Lake herd plays an important role in wood bison conservation because it is an isolated, disease-free herd and, consequently, provides security to the species through population redundancy, thus contributing to recovery goal 2.

Captive, Disease-Free Herds

In addition to the free-ranging wood bison herds discussed above, four captive herds have been established, although only three are currently viable. The Elk Island National Park herd in Alberta, Canada, was established in 1965, from wood bison transferred from an isolated portion of WBNP. It is the national conservation herd and has provided disease-free stock for six of the free-ranging populations and several captive breeding herds in zoos and private commercial ranches (Gates *et al.* 1992, p. 153). Carrying capacity at Elk Island National Park is approximately 350 animals; animals above this number are regarded as surplus and are removed to establish and supplement free-roaming populations in former areas of their historic range (Parks Canada 2009a, unpaginated). Although the herd is fenced, the animals are semi-wild and spend the majority of their time roaming the 65 km^2 (25 mi^2) enclosure, interacting with the environment in a largely natural manner (Gates *et al.* 2001, p. 18). The herd is rounded up annually to test for disease and to vaccinate for common cattle diseases. The age, sex, and condition of all the individuals are determined to inform management decisions. Using this information, individuals are selected for sale, donation, or the establishment of new herds, which also controls the population size of the herd (Parks Canada 2009b, unpaginated). This conservation herd contributes to recovery goals 2, 3, and 4.

The Hook Lake Wood Bison Recovery Project was initiated to establish a captive, disease-free herd from a wild herd infected with brucellosis and tuberculosis. The overall objective of the project was to determine the feasibility of genetic salvage from a diseased herd (Nishi *et al.* 2002, p. 230). Specific objectives of the project were to conserve the genetic integrity of the wild herd by capturing an adequate number of calves, provide intensive veterinary and preventative drug treatment to eliminate disease from the calves, and raise a disease-free herd from the salvaged calves (Nishi *et al.* 2002, p. 229). From 1996 to 1998, 62 calves were captured. The disease eradication protocol included orphaning newborn, wild-caught calves to minimize their exposure to *B. abortus* and *M. bovis;* testing calves for antibodies to brucellosis prior to inclusion in the new herd; treating with antimycobacterial and anti-*Brucella* drugs; and intensive, whole-herd testing for both diseases (Nishi *et al.* 2002, p. 229). By 2002, the herd size was 122. In

2006, after 9 years of intensive management, the herd was destroyed because bovine tuberculosis was discovered in 2005 in 2 founding animals and 10 captive-born animals, even though all animals initially tested disease-free. The herd provided valuable information on genetic salvage, genetic management, captive breeding for conservation, disease testing, and the difficulties involved in eradicating disease (Wilson *et al.* 2003, pp. 24–35). The Hook Lake Herd contributed to recovery goal 3.

In April 2006, 30 wood bison calves were transferred from Elk Island National Park to Lenski Stolby Nature Park near Yakutsk, Sahka Republic (Yakutia), Russia. An additional 30 head were transferred in 2011. Although outside the historical range, this was an opportunity to create another geographically separate population that provides added security to the species through population redundancy, thereby contributing to recovery goal 2. Transfer of wood bison to Russia was specifically mentioned in the recovery plan because it would contribute to the global security of the species (Gates *et al.,* 2001, p. 14).

In June 2008, 53 disease-free wood bison were transferred from Elk Island National Park to the Alaska Wildlife Conservation Center in Portage, Alaska. Consequently, this captive herd currently contributes to recovery goal number 2 through population redundancy. Ultimately, the Alaska Department of Fish and Game (ADFG) plans to restore wood bison populations in one to three areas in interior Alaska, with potential herd size of 500 to 2,000 or more depending on the location (ADF&G 2007, p. 79). Environmental analysis of the project is currently under review. The National Wood Bison Recovery Team in Canada recommended establishing one or more populations in Alaska in areas that can support 400 or more animals (Gates *et al.* 2001, p. 31). Establishment of one or more herds in Alaska would be a significant contribution to increasing the number of secure, disease-free, free-roaming herds.

Summary of Progress Toward Recovery

In summary, since 1978, the number of free-ranging, disease-free herds has increased from 1 to 7, and the number of wood bison has increased from approximately 400 to over 4,000. The first recovery goal of establishing 4 free-ranging, disease-free herds with 400 or more animals has been met, and planning is underway to create one or more herds in Alaska. Although the number of herds needed to meet recovery goal 2 was not specified, progress has been made on the second goal with the establishment of disease-free herds in Russia; Manitoba, Canada; and Alaska. The Hook Lake Bison Recovery Project was a well-planned, science-based attempt to conserve the genetic diversity of a diseased herd and would have contributed greatly to recovery goal 3. Although ultimately the project was unsuccessful, a great deal of knowledge was gained (Wilson *et al.* 2003, pp. 62–67). The wood bison recovery team is very aware of the need to maintain genetic diversity in the herds and establishes new herds with the goal of maintaining genetic diversity through multiple introductions (i.e., the Aishihik herd, Nahanni, and Hook Lake herds). The establishment of six additional herds on the landscape since 1978 contributes to recovery goal 4. In addition, the captive population at Elk Island National Park has provided disease-free stock for those six additional herds and two captive herds. It is clear that there is active management of the herds, and multiple avenues of research are being funded and pursued regarding the biology and management of wood bison. Progress towards the recovery goals outlined in the national recovery plan, published by the National Wood Bison Recovery Team, is moving forward steadily.

Summary of Comments and Recommendations

In the proposed rule published on February 8, 2011 (76 FR 6734), we requested that all interested parties submit written comments on the proposal by April 11, 2011. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. We did not receive any requests for a public hearing.

During the comment period for the proposed rule, we received 19 comment letters directly addressing the proposed listing of wood bison with threatened status. All substantive information provided during the comment period has either been incorporated directly into this final determination or addressed below. Several of the comments included opinions or information not directly related to the proposed rule, such as views relating to the reintroduction of wood bison into Alaska. We do not address those comments as they do not have bearing on the reclassification of wood bison.

Peer Review

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), we solicited expert opinion from three knowledgeable individuals with scientific expertise that included familiarity with wood bison and its habitat, biological needs, recovery efforts, and threats. We received a response from one of the peer reviewers.

We reviewed all comments received for substantive issues and new information regarding the listing of wood bison. The majority of comments (13 of 19) supported downlisting. A subset of these commenters (7 of the 13) thought the Service should delist the species immediately. Three commenters felt that wood bison should remain listed as endangered. The peer reviewer comments are addressed in the following summary and incorporated into the final rule as appropriate.

Peer Reviewer Comments

(1) *Comment:* The peer reviewer provided very specific corrections to details about two of the wood bison herds in Canada, the Nahanni and Mackenzie.

Our Response: As the reviewer noted, and we agree, the changes do not alter our finding. We have incorporated the details and updates for the Canadian herds provided by the reviewer into this final rule.

Comments From State of Alaska

Comments received from the State of Alaska regarding the proposal to reclassify the wood bison are addressed below.

(2) *Comment:* The State agrees that ''endangered'' is not the appropriate designation for wood bison but states that the species should be removed from the List of Endangered and Threatened Wildlife (delisted), not reclassified as threatened. Several other commenters came to the same conclusion. They argue that recovery efforts in Canada have been successful enough that delisting is warranted.

Our Response: We agree that conservation efforts in Canada have led to significant increases in the number of herds and herd size. However, we also recognize that threats to the species, in particular disease, loss of habitat, and hybridization with plains bison, persist, and delisting is therefore not yet appropriate. We will continue to follow the progress of conservation efforts, and we will propose to delist wood bison if and when appropriate.

(3) *Comment:* The State and several commenters argued that listing under the Act provides no conservation benefits for the species in the United States, and may in fact be impeding conservation by making it more difficult to reintroduce wood bison into Alaska.

Our Response: Under section 4(b)(1)(A) of the Act, the Service must base a status determination solely on the best scientific and commercial data available. Thus, we cannot and did not base the decision to reclassify the wood bison under the Act on the efficacy of this action to conserve the species. Nevertheless, we disagree that listing is impeding conservation by making it more difficult to reintroduce the species to Alaska. Under the provisions of the Act's section 10(j), wood bison could be reintroduced into Alaska as an experimental, nonessential population. We have been working with the Alaska Department of Fish and Game on such a proposal, and both agencies agree that this approach may be a viable method for the reintroduction. Designating wood bison as an experimental, nonessential population would not only provide the means for reintroducing the animals, it would also provide assurances that conflicts with potential development would be minimal. Critical habitat is not designated for experimental, nonessential populations.

(4) *Comment:* The State commented that the only real impact from listing was to deny sportsmen the opportunity to import legally harvested wood bison trophies from Canada.

Our Response: We recognize that regulated hunting is an important component of Canada's recovery plan for the species; however, as explained above, listing determinations are based on evaluation of the factors affecting the species under section 4(a)(1) of the Act, using the best scientific and commercial information available. It is important to note that, under section 9(c)(2) of the Act, when the wood bison is reclassified to threatened status (see **DATES**, above), importation into the United States of sport-hunted trophies taken from Canada would not require a permit under 50 CFR 17.32, provided that a CITES Appendix-II export permit issued by the Canadian government accompanies the trophy when it arrives into the United States.

Federal Agency (Canada) Comments

(5) *Comment:* We received two responses from the Northwest Territories. Both included specific minor corrections regarding herds, and both supported downlisting.

Our Response: The commenters stated, and we agree, that none of the corrections were significant in terms of the finding. We have incorporated the details and updates for the Canadian herds provided by the reviewers in this final rule.

Public Comments

(6) *Comment:* A few commenters argued that wood bison should remain listed as endangered. In summary, the reasoning presented was that the populations were too small, there is not enough habitat available, and hunting should not be allowed because of the small population sizes.

Our Response: The Canada's National Wood Bison Recovery Team and recovery plan set forth the reasoning for maintaining a minimum population (herd) size of 400 (Gates *et al.* 2001, p. 32). At this point, there are more than 4,000 disease-free wood bison in 7 herds and an additional 4,000 animals in WBNP that are subject to disease but have a stable population. Four separate disease-free populations have 400 or more animals (see Table 1, above). In addition, it has been demonstrated that wood bison, like plains bison and cattle, are relatively easy to breed and their populations can be managed for growth either in the wild (given adequate resources) or in captivity.

Although we agree that there has been a loss of suitable habitat, there has been enough suitable and available habitat for the reintroduction of six herds within their historical range in Canada. All of the herds that have been established in the wild have expanded in size and are self-sustaining (see Table 1, above). Regulations prevent excess harvest on the free-ranging herds. Regardless of classification type (endangered or threatened), regulation of hunting in Canada is outside the jurisdiction of the Act. Currently, Canada uses hunting of wood bison as a management tool for population control and to minimize the chances that disease will spread from one population to another. We found no evidence that hunting, as it is currently managed, is a threat to the species. For these reasons, we have concluded that wood bison are no longer on the brink of extinction and are, therefore, not endangered; rather, they are progressing steadily towards recovery.

(7) *Comment:* One commenter argued that wood bison should remain listed as endangered because Alaska is a significant portion of the wood bison's range. Because wood bison are extinct in Alaska, they should remain endangered until they are successfully introduced back into Alaska.

Our Response: The Service disagrees that the wood bison's historical range, which includes Alaska, constitutes a significant portion of the range such that the endangered classification under the Act must be retained because of the species' extirpation in that portion of the historical range. The text of the Act supports our conclusion that we cannot base this determination on the status of the species in lost historical range. As defined by the Act, a species is endangered only if it ''is in danger of extinction'' in all or a significant portion of its range. The phrase ''is in danger'' denotes a present-tense condition of being at risk of a current (or future) undesired event. Hence, to say a species ''is in danger'' in an area where it no longer exists—i.e., in its historical range where it has been extirpated—is inconsistent with common usage. Thus, we consider ''range'' within the definition of an ''endangered species'' to mean current range, not historical. In addition, in determining whether a species is an endangered species, the Act requires the Secretary to consider ''present'' or ''threatened'' (i.e., future), rather than past, ''destruction, modification, or curtailment'' of a species' habitat or range (16 U.S.C. 1533(a)(1)(A)). Furthermore, additional support for this conclusion is found in the Act's requirement that a summary of a proposed listing regulation be published in a newspaper ''in each area of the United States in which the species is believed to occur'' (16 U.S.C. 1533(b)(5)(D)). There is no requirement to such notice in areas where the species no longer occurs. For these reasons, Alaska cannot be a significant portion of the wood bison's range.

(8) *Comment:* One commenter felt that the proposed rule was deficient because we did not address the status of wood bison in Alaska and only looked at where wood bison currently exists. Thus, we should have included Alaska in our analysis as part of wood bison's historical range.

Our Response: As explained above in our response to Comment 7, a species' listing determination cannot be based on the status of the species within its lost historical range. Nevertheless, we did consider the effect of the loss of the wood bison's historical range on the viability of the species throughout all or a significant portion of its current range. Although the species has been extirpated from Alaska for quite some time and the historic population in Alaska is unknown, we conclude that the loss of species' historic range in Alaska does not place the species in danger of extinction throughout all or a significant portion of the range. As detailed more fully in our final determination, the wood bison populations in Canada have stabilized or are increasing, and are self-sustaining in the absence of a population in Alaska.

(9) *Comment:* Two commenters argued that wood bison is not a valid

subspecies and that they should not be listed for that reason. One commenter stated that differences between wood and plains bison are only phenotypic (they look different), and that all wood bison are hybrids with plains bison. The commenter cites the work of Douglas *et al.* 2011, which concludes that based on mitochondrial sequences, wood and plains bison should not be considered separate subspecies.

Our Response: In the proposed rule (76 FR 6734), we outlined our reasoning for concluding that wood bison are a valid subspecies. We also acknowledged that because of the introduction of plains bison into WBNP there had been some introgression of plains bison genetic material into the wood bison genome. However, based on the historical physical separation, and quantifiable behavioral, morphological, and phenological (appearance) differences between the two subspecies, the scientific evidence indicates that subspecific designation is appropriate (van Zyll de Jong *et al.* 1995, p. 403; FEAP 1990, p. 24; Reynolds *et al.* 2003, p. 1010; Gates *et al.* 2010, pp. 15–17).

Douglas *et al.* (2011, p. 167) included mitochondrial sequences from only two wood bison in their analysis. Considering the history of wood and plains bison on the landscape, two animals cannot accurately represent the range of genetic variation present between wood and plains bison, and it is not reasonable to conclude that the two subspecies should be considered as one, based on a sample size of two. In addition, the authors (Douglas *et al.* 2011, p. 173) include the important qualifying clause, ''with respect to their mitochondrial genomic sequences'' *B. b. bison* and *B. b. athabascae* should not be considered distinct subspecies. Mitochondrial DNA is maternally inherited and therefore presents only a partial picture of an animal's total genome. Mitochondrial DNA is used primarily to look at the more recent divergence between species. Differences in nuclear DNA sequences (which represent contributions from both the male and female) are used to determine differences that originate further back in time. Unless a peer-reviewed revision of the phylogeny of the subfamily Bovinae occurs that indicates wood and plains bison do not vary enough genetically to be considered distinct subspecies, and that revision is accepted by the scientific community, we will continue to acknowledge the two subspecies of bison.

(10) *Comment:* One commenter stated that we did not provide a convincing argument that the threats to wood bison rise to the level that the species is likely to become endangered in the foreseeable future. The commenter states, ''[t]he Proposed Rule does not show that these risks are both sufficiently severe and likely to justify the ''threatened'' classification.''

Our Response: In the proposed rule (76 FR 6734), we identified threats under Factors A, C, D, and E. Although we did not identify an individual factor that might be responsible for the extinction of wood bison in the future, the combination of these threats are currently acting on the populations and will continue into the foreseeable future. The species is being actively managed in Canada to address these threats. Of these threats, disease is the most problematic for the species because there is not a clear path forward on how disease will be handled. No effective vaccines exist for brucellosis, tuberculosis, or anthrax for free-ranging populations and developing new disease-free herds is very challenging. In addition, although recommendations for the management of the diseased herds in and around WBNP have been suggested (FEAP 1990, p. 2), they have not yet been implemented, it is unknown if they will be implemented, and it is unknown how implementation of the recommendations would affect the status of the subspecies. It is possible many animals could be purposefully euthanized if disease spreads to currently uninfected herds that are in proximity to commercial cattle and bison operations, or as a solution to the diseased herds found in and around WBNP. As described in the proposed rule, the Hook Lake Herd, which was initiated as a disease-free herd, was eliminated when disease was detected. We also know that Canada has not yet made the decision to delist the species under SARA. We will continue to evaluate the status of wood bison and propose to delist the species when appropriate.

(11) *Comment:* One commenter said that the Service cannot conclude that the wood bison remains threatened without establishing a timeframe for the foreseeable future.

Our Response: We disagree. In some listings we have used very specific timeframes for our threats analysis (e.g., polar bear, see 73 FR 28212, May 15, 2008), especially when we are using models that are projecting into the future for a specific amount of time. In the case of wood bison, we are not relying on modeling to describe or understand the threats into the future. In analyzing how threats will affect the status of this species, we assessed the foreseeable future for the wood bison in terms of the threats that are currently operating on the populations as well as those we could reliably expect to continue to affect the populations.

(12) *Comment:* One commenter states that bison are inherently social creatures and are subject to rules of group behavior. As the size of herds changes, so too do their actions and lifestyles. There is simply not enough data from small herds over a few decades about wood bison sociology to make any confident predictions about the future. They argue that there are too few wood bison to contemplate easing protections on the species at this time.

Our Response: We agree that wood bison are social animals and that new herds have been established for a relatively short time. However, the growth of the herds gives ample evidence that when suitable habitat is present the herds will grow until controlled. In reality, the protections provided to a species listed as threatened do not differ significantly from the protections provided to an endangered species. Wood bison will continue to be protected under the Act as a threatened species.

(13) *Comment:* One commenter argued that *B. b. athabascae* is present in Yellowstone National Park (YNP) and it is endangered there.

Our Response: Peer-reviewed published papers present a compelling opposing view to this comment. The published literature indicates that the only place where free-ranging wood bison occur, or have occurred in the recent past (last several hundred years), is in Canada and Alaska (Skinner and Kaisen 1947, p. 164; Stephenson *et al.* 2001, pp. 137, 146; Wilson and Strobeck 1998, p. 186). We disagree that wood bison currently persists in YNP and that it is endangered there.

Summary of Changes From Proposed Rule

We reanalyzed the data from the United Nations Environment Programme—World Conservation Monitoring Center CITES Trade Database and, for clarity, reported data in specimens rather than shipments. However, this change did not alter our finding. We have not made any substantive changes in this final rule based on the comments we received. Although many commenters thought that wood bison no longer need the protections provided by the Act and should be delisted, no new or compelling information was provided to support such a recommendation. We recognize that conservation actions are continuing and that the status of wood bison is improving. However, because of the threats that are still present,

delisting is premature. Therefore, just as we proposed, we are changing the listing of the wood bison from endangered to threatened.

Summary of Factors Affecting the Subspecies

Section 4 of the Act and implementing regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. Changes in the Lists can be initiated by the Service or through the public petition process. Under section 4(a)(1) of the Act, a species may be determined to be endangered or threatened based on any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of Its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

We must consider these same factors in downlisting a species. For species that are already listed as endangered or threatened, we evaluate both the threats currently facing the species and the threats that are reasonably likely to affect the species in the foreseeable future following the delisting or downlisting and the removal or reduction of the Act's protections.

Under section 3 of the Act, a species is ''endangered'' if it is in danger of extinction throughout all or a significant portion of its range and is ''threatened'' if it is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. ''Foreseeable future'' is determined by the Service on a case-by-case basis, taking into consideration a variety of species-specific factors such as lifespan, genetics, breeding behavior, demography, threat projections timeframes, and environmental variability. The word ''range'' in the phrase ''significant portion of its range'' (SPR) refers to the range in which the species currently exists, and the word ''significant'' refers to the value of that portion of the range being considered to the conservation of the species.

For the purposes of this analysis, we will evaluate all five factors currently affecting, or that are likely to affect, the wood bison to determine whether the currently listed species is endangered or threatened.

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Loss of Foraging Habitat

Fire Suppression

Wood bison depend on a landscape that includes sufficient grasslands and meadows for foraging habitat (Larter and Gates 1991b, p. 133). It appears that primarily through fire suppression, there was an overall loss of meadow habitat in Canada through the 1900s. More intensive fire management began in Canada in the early 1900s, with the philosophy that fire was destructive and should be eliminated to protect property and permit proper forest management (Stocks *et al.* 2003, p. 2). However, wildfire is an integral component of boreal forest ecology (Weber and Flannigan 1997, p. 146; Rupp *et al.* 2004, p. 213; Soja *et al.* 2007, p. 277). Without fire, trees encroach on meadows and eventually the meadow habitat is lost and replaced by forest.

Fire alone, or in combination with grazing, can facilitate the conversion and maintenance of grasslands (Lewis 1982, p. 24; Chowns *et al.* 1997, p. 205; Schwarz and Wein 1997, p. 1369). Burning by Native groups within the range of wood bison was apparently a common practice through the 1940s outside WBNP but ended within the park when it was established in 1922 (Lewis 1982, pp. 22–31; Schwarz and Wein 1997, p. 1369). An examination of aerial photographs taken at WBNP over time showed that a semi-open grassland that covered about 85 ha (210 ac) in 1928 supported a grassland of only 3 ha (7.4 ac) in 1982 (Schwarz and Wein 1997, p. 1369). In addition, a number of sites previously identified as prairie are now dominated by trembling aspen (Schwarz and Wein 1997, p. 1369). Although not quantified, it is likely that because of fire suppression and forest encroachment on meadows, there was a net loss of suitable open meadow habitat for wood bison throughout their range through about 1990. More recently, several factors may be counteracting the loss of open meadow habitat including controlled burns, timber harvest, oil and gas development, agricultural development, and the effects of climate change, as discussed below.

Controlled Burns

Controlled burns have been implemented since 1992 in wood bison habitat in the Northwest Territories to increase meadow habitat (Chowns *et al.* 1997, p. 206). Approximately 4,400 to 26,900 ha (10,873 to 66,471 ac) were burned from 1992 to 1997, with some sites being burned up to three times (Chowns *et al.* 1997, pp. 206–207). In addition, lightning fires burned 300,000 ha (741,316 ac), or almost 20 percent of the wood bison range in this area, from 1994 to 1996 (Chowns *et al.* 1997, p. 209). Plants favored by bison were more abundant in unburned areas and in meadows that had burned only once (Quinlan *et al.* 2003, p. 348), indicating that prescribed burns must be used judiciously to be effective in creating foraging habitat for wood bison. A study of vegetation recovery and plains bison use after a wildfire near Farewell, Alaska (Campbell and Hinkes 1983, p. 18), showed that grass and sedge-dominated communities increased from 38 percent to approximately 97 percent of the study area. Plains bison use also increased in subsequent years after the fire, and winter distribution of the Farewell herd expanded due to fire-related habitat changes (Campbell and Hinkes 1983, pp. 18–19). Because sedges are important winter forage for wood bison, the amount of such habitat has a major influence on herd size. Newly created habitats will be used by wood bison when these habitats are contiguous with existing summer or winter ranges (Campbell and Hinkes 1983, p. 20).

In summary, studies that have looked at the exclusion of fire or the effect of wildfire on wood bison habitat have concluded that fire is a necessary component of the landscape to maintain clearings and create conditions that favor forage preferred by wood bison. Controlled burns can have the same effect as wildfire by creating openings in the forest. However, repeated burns in the same location can be detrimental to creating suitable forage.

Timber Harvest

The volume of timber logged in Canada rose 50 percent from 1970 to 1997; in Alberta, the logging rate increased 423 percent, from 3.4 to 17.8 million meters (m)^3 (120 to 628 million feet (ft)^3) per year during the same time (Timoney and Lee 2001, p. 394). These values are conservative because forests logged on private land and those harvested on government land after fire, insect outbreaks, or disease may go unrecorded (Timoney and Lee 2001, p. 395). The primary method of harvest is clearcutting (Timoney and Lee 2001, p. 394). Compared to a closed canopy forest, clearcuts improve the amount of suitable habitat available to wood bison because they create openings and increase the amount of summer forage available. However, the quantity and quality of forage is less than what is

found in preferred wood bison foraging habitats, and the increased productivity seen after a clearcut is not maintained, as woody vegetation becomes more dominant over time (Redburn *et al.* 2008, p. 2233). In addition, clearcuts do not provide adequate winter forage because wood bison's preferred food, sedges, typically do not colonize these areas. Clearcutting is not being used as a management tool to increase wood bison habitat currently, and whatever gains in habitat that have occurred from clearcutting are most likely low.

In summary, although timber harvest occurs throughout the range of wood bison, it is unclear to what extent it is creating suitable habitat. Clear cuts can increase summer forage, but they need to be in proximity to sedge meadows (wintering habitat) to increase the annual carrying capacity for wood bison, and the openings created by the clear cuts must be maintained over time. Although timber harvest has the potential to increase the amount of suitable habitat for wood bison, the amount that may have been created is most likely low and is undocumented.

Oil and Gas Development

Oil and gas exploration and production in Canada has increased in the last 20 years (Timoney and Lee 2001, pp. 397–398). Seismic mapping to determine the oil and gas reserves below the surface involves cutting paths 5 to 8 m (16.4 to 26 ft) wide across the landscape. The seismic lines become persistent features in the forested boreal landscape (Lee and Boutin 2006, p. 249). Approximately 70 percent of landscape disturbance for non-renewable resource extraction in Alberta is due to seismic lines (Timoney and Lee 2001, p. 397). There are an estimated 1.5 to 1.8 million km (932,000 to 1,100,000 mi) of seismic lines in Alberta (Timoney and Lee 2001, p. 397). Lee and Boutin (2006, p. 244) found that only 8.2 percent of seismic lines in Alberta's northeastern forested stands recovered to greater than 50 percent woody vegetative cover after 35 years, and 64 percent of these seismic lines maintained a cover of grasses and herbs. In terms of creating forest openings, more suitable foraging habitat, and linear paths, seismic lines may be beneficial for wood bison. However, because vehicular routes were established in 20 percent of the seismic lines, they also become corridors for off-road vehicles, recreationalists, and poachers (Trombulak and Frissell 2000, pp. 19–20; Timoney and Lee 2001, p. 400; Lee and Boutin 2006, p. 244). Although wood bison are known to occupy linear clearings such as roads, and seismic lines have increased dramatically within their range, potentially creating suitable habitat, we do not have documentation of wood bison use of this type of habitat.

Agricultural Development

The popularity of bison as an alternative to beef in human diets has led to a growth of commercial bison ranches in Canada and the United States (Gates *et al.* 1992, p. 155). Exports of bison meat from Canada doubled to over 2 million kilograms (2.3 tons) from 2001 to 2006 (Statistics Canada 2009a, unpaginated). Plains bison dominate agricultural production in Canada because commercial production of this subspecies has been in place much longer than it has been for wood bison (Gates *et al.* 1992, p. 156; Harper and Gates 2000, p. 919). Bison production in Canada is concentrated in the western provinces, within the historical range of wood bison. In 2006, there were 195,728 plains bison on 1,898 farms reporting in the Canadian National Census; this amounts to an increase of 35 percent from 2001 (Statistics Canada 2009b, unpaginated). Thus, plains bison represented approximately 95 percent of the total bison on the landscape in Canada in 2006. Existence and expansion of commercial plains bison production reduce the amount of land available for wild wood bison populations and increase the risk of hybridization when plains bison escape captivity (Harper and Gates 2000, p. 919; Gates *et al.* 2001, pp. 24, 29). Demand currently exceeds supply; therefore, expansion of commercial plains and wood bison operations is expected to continue (Gates *et al.* 2001, p. 24).

Escape of plains bison from fenced enclosures within the range of the wood bison in Canada poses a threat to the genetic integrity of wood bison (Gates *et al.* 1992, p. 156; Gates *et al.* 2001, p. 24). Because of their size, strength, and undomesticated nature, typical fences are insufficient to restrain bison (FEAP 1990, p. 29; Harper and Gates 2000, p. 919). Maintenance of fences can be a challenge in harsh environments where tree-fall, snow, ice, and frost heave can impair the integrity of the fence and necessitate frequent repairs. The import of plains bison to a private ranch near Pink Mountain, British Columbia, led to the establishment of a free-ranging herd of plains bison after they escaped their enclosure (Gates *et al.* 1992, p. 156).

In addition to commercial production, free-ranging, publicly managed plains bison herds have been established outside their historical range and within the historical range of wood bison in Alaska and Canada (Gates *et al.* 2010, p. 56). Because of the potential for hybridization, these herds limit where wood bison can be reintroduced. Five plains bison herds occur in Alaska and one occurs in British Columbia, Canada (Gates *et al.* 2010, p. 56). None of these plains bison herds occur in close proximity to free-ranging wood bison herds with the exception of one herd—the Pink Mountain herd, British Columbia—which also occupies habitat that could have been used for wood bison (Harper *et al.* 2000, p. 11). Preventing interbreeding between free-ranging plains bison and wood bison is a management objective in British Columbia and is accomplished by maintaining a large physical separation between the herds and having a management zone around the plains bison herd that allows harvest of plains bison within this zone (Harper *et al.* 2000, p. 23).

Agricultural development, including plains bison ranching, is the least compatible land use for wood bison recovery (Harper and Gates 2000, p. 921). Loss of habitat for agricultural production is a threat to wood bison because of the large areas involved. Agricultural development near Fort St. John and Fort Nelson, British Columbia, has reduced habitat for wood bison, and continuing expansion of agriculture in the north will further limit the ability to meet population recovery objectives (Harper and Gates 2000, p. 921). Based on a conservative estimate of historical habitat only in Canada, Gates *et al.* (1992, p. 154) estimated that human activities and development exclude wood bison from approximately 34 percent of their historic range. When an updated Canadian historical range (Stephenson *et al.* 2001, p. 136) and the Alaskan historical range are included in the calculation, the amount of compromised habitat drops to approximately 16.5 percent if only Canada is considered, and 13 percent if the historical habitat in Canada and Alaska are combined (Stephenson 2010, pers. comm.). Sanderson *et al.* (2002, pp. 894–896; 2008, p. 257) found that the level of human influence in the range occupied by wood bison to be extremely low (less than 10 percent). Although human development and influence is very low over the majority of range occupied by wood bison, we assume that because of human population growth, increased commercial production of plains bison, and increased agricultural production, there will be continued loss of suitable wood bison habitat into the foreseeable future.

Climate Change

Climate change models project that the largest temperature increases will occur in the upper latitudes of the northern hemisphere, and that there will be an increase in extreme climate events in these areas (IPCC 2007, p. 11.5.3.1). This area includes the boreal forest of Canada and Alaska in the range of wood bison. Some of the predicted outcomes of climate change are: An increase in temperature; an increase in insect outbreaks; an increase in wildfire severity, area burned, and fire season length with potential landscape-scale ecotype effects; and a shift northward of boreal forest (Hamann and Wang 2006, pp. 2780–2782; Soja *et al.* 2007, p. 277). These aspects of climate change have the potential to increase the amount of habitat suitable for wood bison over the next 100 years.

The mean annual temperature of interior Alaska and northern Canada has increased by 2 degrees Celsius (°C) (3.6 degrees Fahrenheit (°F)) in the last four decades (Serreze *et al.* 2000, p. 163). Warming has triggered bark beetle outbreaks in western North America, including south-central Alaska and British Columbia. In British Columbia, by the end of 2006, 130,000 km^2 (50,193 mi^2) of forested lands were affected (Kurz *et al.* 2008, p. 987). The outbreak in British Columbia was an order of magnitude greater in area and severity than all previous recorded outbreaks (Kurz *et al.* 2008, p. 987).

The effect of insect outbreaks on wood bison habitat includes a potential increase in suitable wood bison habitat, and an increase in susceptibility to fire. In insect-infested plots studied on the Kenai Peninsula, cover of bluejoint grass (*Calamagrostis canadensis*), a summer forage species, increased to more than 50 percent compared to uninfested forest stands (Werner *et al.* 2006, p. 198). These results indicate forests affected by beetle kill may become more suitable to wood bison by creating openings and changing the vegetative composition. This would be particularly true in areas where, because of climate change, there was a permanent change in landscape cover from forest to grassland (Rizzo and Wiken 1992, p. 53; Flannigan *et al.* 2000, pp. 226–227). Werber and Flannigan (1997, p. 157), and Malmström and Raffa (2000, p. 36), indicate that insect outbreaks increase an area's susceptibility to fire ignition and spread.

Since the mid-1980s, wildfire frequency in western forests has nearly quadrupled compared to the average frequency during the period 1970–1986. The total area burned is more than six and a half times the previous level (Westerling *et al.* 2006, p. 941). In addition, the average length of the fire season during 1987–2003 was 78 days longer compared to that during 1970–1986, and the average time between fire discovery and control was 29.6 days longer (Westerling *et al.* 2006, p. 941). In Alaska, the largest fire on record was in 2004, and the third largest was in 2003 (Soja *et al.* 2007, p. 281).

The area burned by forest fires in Canada has increased over the past four decades (Stocks *et al.* 2003, p. 2; Gillett *et al.* 2004, p. 4; Soja *et al.,* 2007, p. 281). In Canada, weather/climate is the most important natural factor influencing forest fires (Gillett *et al.* 2004, p. 2; Flannigan *et al.* 2005, p. 1). Projections based on the Canadian and Hadley General Circulation Models, which predict future carbon dioxide and temperature increases, indicate that the area burned in boreal forests of Canada will double by the end of the century (Flannigan *et al.* 2005, pp. 11–12), the area exhibiting high to extreme fire danger will increase substantially, and the length of the fire season will increase (Stocks *et al.* 1998, pp. 5–11).

In the absence of fire, vegetation changes would occur relatively slowly in response to relatively slow changes in the climate. Because of its immediate and large-scale effect, fire is seen as an agent of change that will hasten the modification of the landscape to a new equilibrium with climate. Area burned may overshadow the direct effects of climate change on plant species distribution and migration (Werber and Flannigan 1997, p. 157). The new fire regime is expected to affect the age class distribution, species composition, landscape mosaics, and boundaries, including a retraction of the southern boreal forest (Werber and Flannigan 1997, pp. 157, 160).

The increase in temperature, predicted by the Canadian and Hadley General Circulation Models described above, is expected to cause major shifts in ecosystems (Rizzo and Wiken 1992, p. 37; Hogg and Schwarz 1997, p. 527). The amount of grassland in Canada may increase by about 7 percent and shift northward (Rizzo and Wiken 1992, p. 52). Several modeling efforts suggest that boreal forests will shift northward into the area now characterized as subarctic (Rizzo and Wiken 1992, pp. 48–50; Rupp *et al.* 2002, p. 214). These changes may favor the expansion of suitable habitat for wood bison over the next century. Because one of the anticipated outcomes under climate change and the new fire regime is a retraction of the southern boreal forest and expansion of grasslands, we anticipate that habitat for wood bison, which require meadows intermixed with forest, will increase over the next century.

Summary of Factor A

Our analysis of habitat threats to wood bison under Factor A includes management actions that are being taken (controlled burns, timber harvest, oil and gas development), anticipated changes to the landscape based on climate change (increased insect outbreaks, increased fire, ecotype transition), and agricultural development. In summary, most likely there was loss of suitable meadow foraging habitat for wood bison from fire suppression in the 20th century. Several factors, including fire, timber harvest, oil and gas exploration, and insect infestations, could create more forest openings and grassland habitat. However, neither the loss nor potential gain in habitat from these sources has been quantified, and the suitability of habitat for wood bison created as a by-product of resource development is largely unknown. The primary loss of habitat for wood bison has occurred from agricultural development (including commercial production of plains bison). Although the current level of human influence in the range of wood bison is low, we anticipate human population growth will continue, and loss of suitable habitat from agricultural development is expected in the foreseeable future. In the short term, habitat loss is expected to outstrip gain because of the increasing demand and production of commercial bison. Based on model projections of the effects of climate change, it is anticipated that there will be increased insect infestations, increased fire frequency and area burned, and warmer temperatures, leading to shifts in ecosystems. In the long term, these changes will likely create more forest openings and landscapes in early successional stages and may increase the amount of suitable habitat available to wood bison. Whether the potential gain in habitat will offset the loss from development in the long term is unknown. Consequently, based on the best scientific and commercial data available, we conclude that loss of habitat remains a threat to wood bison in the foreseeable future.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Overharvesting for the fur trade and westward expansion by Europeans resulted in near extinction of wood bison by the late 1800s (Gates *et al.*

1992, pp. 143–145). Currently, the utilization of free-ranging, disease-free wood bison populations is closely regulated and managed for sustainability. Under the SARA, a species listed as threatened may not be killed on Federal lands such as National Parks or National Wildlife Areas, except where permitted under a national recovery strategy (GNT 2010, p. 10). Harvest is used as a recovery management tool to regulate herd size when other limiting factors, such as predation or disease, do not. Without harvest, herd size can expand beyond the carrying capacity of the landscape, may grow to the point where overlap with either plains bison or diseased herds is more likely, or may expand into areas such as highway rights-of-way. Regulated harvest is allowed from the disease-free Mackenzie herd, Nahanni herd (quota of two bison annually), the Aishihik herd, and the Hay-Zama herds under permit systems controlled by the respective territorial wildlife agencies, and is managed on a conservative sustained-yield basis. The regulated harvests for the Mackenzie, Aishihik, and Hay-Zama herds are described below.

Hunting of the Mackenzie wood bison herd is regulated under a quota system based on population size, with consideration given to Native community interests in subsistence hunting through a co-management process with the Fort Providence Resource Management Board. Regulated hunting was initiated in 1987. Non-resident hunting licenses were first issued for the winter hunt in 1992–1993. The quota for resident and non-residents has been adjusted over time based on herd size and community input. The allowable quota for harvest has never been taken and has ranged from 20 to 93.6 percent of the quota (Reynolds *et al.* 2004, p. 39). The current annual allowable harvest is 118 bison (*http://www.justice.gov.nt.ca/PDF/REGS/WILDLIFE/Big%20Game%20Hunting.pdf,* viewed January 23, 2012).

Sport hunting is the primary method of regulating the growth of the Aishihik herd because natural predation on the herd is low. The Yukon Wood Bison Technical Team provides advice on wood bison management that is sensitive to local conditions (i.e., to remove wood bison from highway rights-of-way, competition of bison with other native ungulates) and consistent with the National Wood Bison Recovery Plan (Yukon Environment 2009, p. 1). The annual allowable harvest is determined each year based on population size and calf recruitment rate. Harvest from 1999 to 2007–2008 winter season ranged from 65 to 75 animals. In the 2008–2009 winter season, the allowable harvest increased to 200 because the population continued to grow under the old quota. Increased harvest is expected to restrict the movement of wood bison away from their traditional range, address highway safety concerns, and achieve bison management objectives (Government of Yukon 2009, p. 1). Resident, non-resident, and First Nations hunters are required to have a permit to hunt wood bison. Harvest regulations are strictly enforced by Yukon Department of Environment conservation officers, often in collaboration with local First Nations Game Guardians.

Hunting in the Hay-Zama herd began in 2008. Hunting was initiated to regulate the population size, reduce wood bison conflicts with humans in the communities of Zama City and Chatey, reduce wood bison-vehicle collisions on two highways, and limit wood bison distribution eastward, preventing potential contact with diseased bison from WBNP (Government of Alberta 2010a, unpaginated). Harvest removed 128 and 155 animals in the 2008–2009 and 2009–2010 seasons, respectively (Government of Alberta 2010b, unpaginated). Three hundred licenses were issued each year, 200 to Aboriginal hunters and 100 to recreational hunters. Because the objectives of reducing herd size and human conflicts have been met, the total number of licenses has been reduced in the 2010–2011 season to 105 (Government of Canada 2010b, unpaginated). Based on the success rate of the past two seasons, approximately 50 animals will likely be harvested. It is estimated that a population objective of 400–600 wood bison can be sustained by harvesting approximately 60 to 70 animals per season (Government of Canada 2010b, unpaginated).

In addition to regulating herd size, harvest is also used to prevent the spread of bovine tuberculosis and brucellosis infection in wood bison. Under the Northwest Territories Big-Game Hunting Regulations, hunters may shoot any bison sighted within the Bison Control Area (BCA), an area located between the WBNP diseased herd and the Mackenzie and Nahanni disease-free herds. The goal is to reduce the risk of bovine tuberculosis and brucellosis infection of the Mackenzie and Nahanni herds by removing infected animals dispersing from WBNP (see discussion under Factor C, below). Thirteen bison were removed from the BCA in the mid-1990s (Nishi 2002, pp. 12–13). There is currently no authorized harvest of wood bison in British Columbia.

Under Canada's SARA, all collection of listed species such as wood bison for scientific purposes is closely regulated. Scientific research on disease, genetics, diet, and other aspects of wood bison life history can and has been done using animals that have been legally taken by hunters, animals that died through natural factors, or road kill (e.g., Tessaro *et al.* 1990, p. 175). Scientific research must relate to the conservation of the species and be conducted by qualified persons; the activity must benefit the species or enhance its chance of survival in the wild. In addition, activities affecting the species must be incidental to carrying out an otherwise lawful activity. Researchers must demonstrate awareness of the provisions of SARA, that measures are being taken to minimize harm to listed species, and that the most effective measures for minimizing harm are adopted.

Commercial harvest of free-ranging wood bison does not occur and only a small number of wood bison have been sporadically taken from disease-free herds for display in zoos or wildlife parks. This occurs only when surplus animals are available, and these surplus animals have typically come from Elk Island National Park (Gates *et al.* 2010, p. 81).

The wood bison was placed in Appendix I of CITES on July 1, 1975, when the treaty first went into effect. CITES is an international agreement between governments to ensure that the international trade of CITES-listed plant and animal species does not threaten their survival in the wild. There are currently 175 CITES Parties (member countries or signatories to the Convention). Under this treaty, CITES Parties regulate the import, export, and reexport of CITES-listed plant and animal species (also see discussion under Factor D, below). Trade must be authorized through a system of permits and certificates that are provided by the designated CITES Scientific and Management Authorities of each CITES Party (CITES 2010, unpaginated). Species included in CITES Appendix I are considered threatened with extinction, and international trade is permitted only under exceptional circumstances, which generally precludes commercial trade.

Beginning in 1993, the European Economic Community CITES Working Group authorized the import of wood bison trophies from the Mackenzie population, one of the disease-free herds with regulated harvest. On September 18, 1997, the wood bison was transferred to Appendix II of CITES

based on a proposal from Canada, which described progress made in recovery plan implementation (Government of Canada 1997, entire). The United States supported this change. Appendix II allows for regulated trade, including commercial trade, as long as the exporting country issues a CITES permit based on findings that the specimen was legally acquired and the export will not be detrimental to the survival of the species.

Data obtained from the United Nations Environment Programme–World Conservation Monitoring Center (UNEP–WCMC) CITES Trade Database show that, from July 1975, when the wood bison was listed in Appendix I, through 2009, a total of 23,344 specimens of this subspecies were reported to UNEP–WCMC as (gross) exports. Of those 23,344 specimens, 264 were live animals, 36 were skins, 10 were skin pieces, 5 were bodies, 26 were shoes, 21,300 were horn products, 461 were teeth, 46 were carvings, 5 were garments, 14 were leather products, 1,074 were scientific specimens, 31 were trophies, 59 were parts of trophies (horns, skulls, bones, feet, tails, and hair), and 13 were unspecified specimens. An additional 1,930 kilograms of meat were reported as exports.

In analyzing these data, it appears that several records may be over-counts due to slight differences in the manner in which the importing and exporting countries reported their trade. It is likely that the actual number of wood bison specimens in international trade during this period was 23,210, plus 1,074 kilograms of meat. Of the 23,210 specimens, 264 were live animals, 34 were skins, 10 were skin pieces, 5 were bodies, 26 were shoes, 21,300 were horn products, 461 were teeth, 46 were carvings, 4 were garments, 14 were leather products, 945 were scientific specimens, 30 were trophies, 58 were parts of trophies (horns, skulls, bones, feet, tails, and hair), and 13 were unspecified specimens.

With the information obtained from the UNEP–WCMC CITES Trade Database, 1,606 specimens and 1,910 kilograms of meat were reported in international trade since the wood bison was transferred from Appendix II to Appendix I in 1997. 1,398 of these specimens (87 percent) were reported as imported into the United States and 20 (1 percent) were reported as exported from the United States. Also, 1,900 of the total of 1,910 kilograms of meat (99 percent) were reported as imported into the United States. Of the 264 live wood bison reported in international trade between 1975 and 2009, 235 were traded since the subspecies was transferred from Appendix II to Appendix I in 1997. Of these 235 live specimens, 174 (74 percent) were reported as captive-bred or captive born, 13 (6 percent) were reported as ranched specimens, and 48 (20 percent) were reported as having been obtained from the wild. There has been no trade in live, wild wood bison since 2006.

As a species listed in Appendix II of CITES, commercial trade of wood bison is allowed. However, the Appendix-II listing requires that before an export can occur, a determination must be made that the specimens were legally obtained (in accordance with national laws) and that the export will not be detrimental to the survival of the species in the wild. Because CITES requires that all international shipments of wood bison must be legally obtained and not detrimental to the survival of the species, we believe that international trade controlled via valid CITES permits is not a threat to the species. Furthermore, we have no information indicating that illegal trade is a threat to this species.

Summary of Factor B

It is possible that, with the ongoing recovery actions, a status review of wood bison in Canada could lead to delisting under SARA within the next 10 years. If this were to happen, we expect that regulations for recreational hunting, import of wood bison trophies, and permitting would change. Our ability to predict how these changes would affect the status of the species is limited; consequently, we can only reliably project for a short time into the future.

Because harvest rates of free-ranging wood bison are based on sustainability, harvest is closely monitored and regulated, scientific collecting is tightly controlled, commercial harvest does not occur in wild populations, and import and export are controlled via CITES permits, we have determined that overutilization for commercial, recreational, scientific, or educational purposes is not a threat to wood bison now or in the foreseeable future.

C. Disease or Predation

Disease

In the early 1920s, 6,673 plains bison were introduced into WBNP, Alberta, Canada, where approximately 1,500 disease-free wood bison resided (FEAP 1990, p. 6; Gates *et al.* 1992, pp. 146–147). Although initially separated by fairly large distances, the plains bison eventually co-occurred and interbred with the wood bison and also transmitted bovine tuberculosis and brucellosis to them (FEAP 1990, p. 6; Gates *et al.* 1992, pp. 146–147). By the late 1940s and early 1950s, the population of wood bison in WBNP increased to between 12,500 and 15,000 animals (Fuller, 1950, p. 450). From that level, wood bison numbers began to decline from 11,000 in 1971, to approximately 2,300 by 1998 (Carbyn *et al.* 1998, p. 464). The reasons for the population decline are not known with certainty, but disease, predation by wolves, and habitat condition may all have played a role (Carbyn *et al.* 1998, pp. 467–468; Joly and Messier 2004, pp. 1165–1166). Population numbers at WBNP have stabilized at about 4,000 to 5,000 since 2002 (see Table 1, above).

Bovine tuberculosis and bovine brucellosis receive special attention because they cause production losses in domestic animals, can potentially infect humans, and are required to be reported under the Canadian Food and Inspection Agency's (CFIA) Health of Animals Act and Regulations (FEAP 1990, p. 7). Although wildlife is not under their jurisdiction, the CFIA recognizes the threat of reportable diseases to the commercial livestock industry and international trade. The CFIA follows a strict testing and eradication program for bovine tuberculosis and brucellosis in domestic animals, requiring that all infected animals and all exposed susceptible animals be destroyed (Canadian Food Inspection Agency 2002, unpaginated). Consequently, there is great concern from the Canadian cattle industry, which is currently recognized as disease-free, that disease will spread from wood bison to domestic cattle (GNT 2010, p. 8). The goal of the CFIA's National Bovine Tuberculosis/Brucellosis Eradication Program is to detect and eradicate tuberculosis and brucellosis in farmed animals in Canada in order to protect the health of food-producing and companion animals, safeguard human health, and safeguard the health of free-roaming wildlife. Canada recognizes an obligation to detect, identify, report, and contain important diseases in wildlife, especially those with the potential to impact biodiversity, human and livestock health, the environment, and the economy within and beyond their borders.

Wood bison in and around WBNP are a reservoir for bovine brucellosis and bovine tuberculosis. Because there is a risk that these diseases could spread to uninfected free-ranging bison herds or to commercial cattle and bison operations, limits are placed on herd expansion to minimize the chance that

the diseased animals come into contact with either free-ranging, disease-free herds, or with domestic cattle or bison operations. In addition, the diseased herds occupy suitable habitat that could be used for the establishment of disease-free herds of wood bison. Therefore, the existence of diseased bison herds in and around WBNP compromises further recovery of wood bison in northern Alberta, the Northwest Territories, and British Columbia (Gates *et al.* 2001, p. 29). The total area compromised by diseased herds is approximately 218,516 km^2 (84,369 mi^2) or about 12 percent of the original range of the wood bison in Canada (Gates *et al.* 2001, p. 24). As mentioned earlier, there are no effective vaccines for the treatment of animals in free-ranging populations.

The disease-free herds most at risk from infection from animals at WBNP are the Mackenzie, Hay-Zama, and Nahanni. Regulated harvest is allowed from the Mackenzie herd, Nahanni herd, and the Hay-Zama herd under permit systems (as described above under Factor B), in part to prevent overlap with the diseased herd. In addition, the Governments of the Northwest Territories, Alberta, and British Columbia have designated management zones to reduce the risk of dispersing animals transmitting disease to disease-free herds in their provinces. In 1987, the Government of the Northwest Territories implemented a program to reduce the risk of contact between infected bison in and around WBNP and disease-free bison in the Mackenzie and Nahanni herds by establishing a Bison Free Management Area (BFMA) (Nishi 2002, pp. 5–6). The BFMA (39,000 km^2 (15,058 mi^2)) encompasses the area between the Alberta–Northwest Territories border and southern shoreline of the Mackenzie River. In 1992, the Government of the Northwest Territories established the Nuisance Bison Control Regulations under the Northwest Territories Wildlife Regulations Act, permitting eligible hunters to legally shoot any bison sighted in the BFMA. All bison within this area are presumed disease carriers. The objectives of the program are to detect and remove any bison, and to prevent establishment of herds in the management area (Nishi 2002, p. 6). No bison were observed in the area during annual aerial surveys in the period 1988–2006, but 13 bison were killed in the mid-1990s (Nishi 2002, pp. 12–13; Hartop *et al.* 2009, p. 41). Aerial surveillance occurs annually.

In 1995, the Government of Alberta established a 36,000-km^2 (13,900-mi^2) bison management area around the Hay-Zama herd to protect all bison from hunting. Within this area, all wood bison are legally protected under Alberta's Wildlife Act; outside of the area they are not protected and can be hunted. The area outside of the protected management area creates a large buffer zone between the disease-free Hay-Zama herd and the diseased herds within WBNP (Gates *et al.* 2001, p. 38).

Control areas and buffer zones between diseased and non-diseased populations may not prevent disease transmission (Canadian Food Inspection Agency 2002, unpaginated) because they are sporadically patrolled and imperfectly enforced. As discussed earlier, fences are an ineffective method to contain herds long term, especially those in large areas (FEAP 1990, p. 29). Consequently, a long-term, more sustainable solution is needed to address this problem.

A Federal Environmental Assessment Panel (FEAP) was assembled to evaluate four courses of action to address the diseased herds at WBNP. These actions were initially proposed by the Bison Disease Task Force: (1) Do nothing; (2) fence WBNP to contain the diseased bison and prevent the spread of disease; (3) use a combination of strategically placed fences, buffer zones exterior to the Park from which all bison would be eliminated, and land-use restrictions on cattle grazing; and (4) phased elimination of the diseased herd and replacement with disease-free wood bison (FEAP 1990, p. 15). After public hearings, and consultation with technical experts, the panel recommended eradication of the existing diseased bison population to eliminate the risk of transmission of disease from bison in and around WBNP to domestic cattle, wood bison, and humans (FEAP 1990, p. 2). Public response to this recommendation was largely negative (Carbyn *et al.* 1998, p. 464). The recommendation was not implemented; consequently, control of disease spread currently depends on the buffer zones.

Annual examinations and serological studies of bison harvested from the Mackenzie herd indicate that the herd continues to be disease-free (Nishi 2002, p. 23). Over 220 samples were received from harvested bison from the Hay-Zama herd that could be tested for disease. All samples tested negative (Government of Canada 2010a, unpaginated). There is also no evidence of bovine brucellosis and bovine tuberculosis in reintroduced herds in the Yukon Territory, British Columbia, western Alberta, or Manitoba. Free-ranging, disease-free herds currently include approximately 4,414 wood bison (see Table 1, above). Because of their distance from WBNP, the Aishihik and Chitek Lake herds are the most secure from disease.

Recovery and conservation efforts for wood bison emphasize the importance of preventing the spread of tuberculosis and brucellosis to disease-free populations and eliminating diseases in infected populations (Gates *et al.* 2001, p. 30). The focus on disease prevention and control is consistent with the recovery goals of increasing the number of disease-free populations. Parks Canada, through Elk Island National Park, has worked with the recovery team and others to develop and maintain a disease-free, captive-breeding herd, which has provided healthy stock for several restoration projects (Gates *et al.* 2001, p. 18).

Because the northern latitudes are experiencing the greatest changes in climate, this area may also be at the greatest risk for the emergence of diseases and parasites that may threaten the stability of wildlife populations (Kutz *et al.* 2004, pp. 109, 114). Warming may be of particular concern for wildlife in northern regions because the life-history patterns of most hosts and parasites are currently constrained by climatic conditions (Kutz *et al.* 2004, p. 114). Researchers have hypothesized that climate change will accelerate pathogen development rates, lead to greater overwinter survival of pathogens, and modify host susceptibility to infection in such a way that the effects of disease will increase (Ytrehus *et al.* 2008, p. 214). Wood bison are susceptible to many diseases and parasites (Reynolds *et al.* 2003, pp. 1030–1032). How climate change may affect the number of animals infected, a pathogen's virulence, and, consequently, wood bison viability is unknown.

One potential effect of climate change may be an increase in anthrax outbreaks because of increased summer air temperatures. Between 1962 and 1993, nine anthrax outbreaks were recorded in northern Canada, killing at least 1,309 wood bison (Dragon *et al.* 1999, p. 209). Additional outbreaks continued to occur through at least 2010 (GNT 2010, p. 9). Wood bison appear most susceptible to outbreaks when they are stressed, including heat stress and high densities of biting insects (Dragon *et al.* 1999, p. 212; Gates *et al.* 2010, p. 28). In addition, if climate change leads to widespread or intense drought, there could be changes in the quality and availability of forage that may cause animals to concentrate around available food and water. These factors could contribute to stress levels and increase

susceptibility to anthrax (Dragon *et al.* 1999, p. 212; Gates *et al.* 2010, p. 28). Although isolated anthrax outbreaks occur currently, it is possible that outbreaks may become more frequent, become more widespread, or affect a greater number of animals in the future. Thus far, anthrax outbreaks have occurred sporadically when the necessary factors have come together to affect portions of one herd at a time. Anthrax is not currently having a population-level effect, and we do not have enough information to predict with confidence if anthrax will have a population-level effect on wood bison in the future as a result of climate change.

Predation

Wolf predation can be a significant limiting factor for diseased populations of wood bison (Reynolds *et al.* 1978, p. 581; Van Camp 1987, p. 25). Wood bison were the principle food of two wolf packs from 1975 to 1977 in the Slave River lowlands (Van Camp 1987, pp. 29, 32). Of the adult and subadult wood bison that died in 1976–1977, wolves killed 31 percent; however, hunters killed 39.3 percent (Van Camp 1987, p. 33). Joly and Messier (2004, p. 1173) found that productivity of the diseased WBNP herd was insufficient to offset losses to both predation and disease, but that in the absence of either factor, positive population growth was possible. Presence of disease likely increased the killing success of wolves through bison debilitation (Joly and Messier 2004, p. 1174). Wood bison evolved with wolves, and we have no data showing that predation by wolves is limiting the recovery of any of the disease-free herds or would cause the extirpation of a herd (ADF&G 2007, p. 98).

Summary of Factor C

The presence of disease and diseased herds is recognized as a factor limiting recovery (Mitchell and Gates 2002, p. 12). The effectiveness of current management actions such as maintaining spatial separation between diseased and disease-free herds by limiting herd size is yet to be determined over long timeframes. Research is continuing on creation of disease-free herds. No effective vaccines exist for brucellosis, tuberculosis, or anthrax for free-ranging populations. In addition, although recommendations for the management of the diseased herds in and around WBNP have been suggested (FEAP 1990, p. 2), they have not yet been implemented, it is unknown if they will be implemented, and it is unknown how implementation of the recommendations would affect the status of the subspecies.

Predation by wolves is a natural threat that will persist indefinitely into the future. Although diseased herds may be more susceptible to predation, healthy herds, which now represent approximately half of the free-ranging wood bison, are not. As long as wolves are present on the landscape, they will present an ongoing, low level of threat, especially to diseased herds.

The presence of disease in the largest potential donor population of wood bison (WBNP herd) has limited the number of animals available for establishing or augmenting herds throughout the wood bison's historical range and has removed otherwise optimal habitat from consideration for expansion of wild populations. The presence of reportable diseases will continue to lead to actions that impact conservation, in particular restriction of herd expansion and the reintroduction of herds in particular areas. Although brucellosis and tuberculosis may limit wood bison population growth and productivity in some herds, they are unlikely to cause extirpation of any population (Bradley and Wilmshurst 2005, p. 1204; Gates *et al.* 2010, p. 60), but when combined with predation, herd size can be limited. Anthrax outbreaks occur sporadically when critical factors come together. Climate change could affect the frequency of outbreaks if increased temperatures or drought cause increased levels of stress in the animals, especially during the rut. Because disease constrains and inhibits full recovery of the species, until a solution for the diseased animals at WBNP is found, or effective vaccines are discovered and used, disease will continue to be a threat to wood bison now and in the foreseeable future.

D. The Inadequacy of Existing Regulatory Mechanisms

Canada's Federal Regulatory Mechanisms

The first protective legislation for wood bison, making it illegal for anyone to molest the species, was passed by the Canadian Government in 1877, but not until the law was enforced beginning in 1897 did the population increase (Soper 1941, pp. 362–363; Gates *et al.* 2001, p. 12).

Canada's Species at Risk Act (SARA), enacted on December 12, 2002, became fully effective on June 1, 2004, and is the Canadian counterpart to the U.S. Endangered Species Act. The purpose of SARA is to prevent listed wildlife species from becoming extinct or lost from the wild (extirpated); to help in the recovery of extirpated, endangered, or threatened species; and to ensure that species of special concern do not become endangered or threatened. The SARA also requires the development of recovery strategies and action plans for covered species. In the SARA, the COSEWIC was established as the scientific body that identifies and assesses a species' status; however, the government makes the final decision on whether to list a species.

Species such as wood bison that were designated as endangered or threatened by the COSEWIC before SARA was enacted had to be reassessed before being included on the official list of wildlife species under SARA. The wood bison is currently listed as a threatened species under Schedule 1 of SARA. The National Recovery Plan for wood bison was published in 2001 (Gates *et al.* 2001) and is currently under revision. As discussed in the Recovery Actions section above, many recovery actions have been implemented and more are in progress. As discussed under Factor B (above), SARA requires permits for all scientific collection of listed species.

The SARA covers all species on Federal lands such as national parks, national wildlife areas, Prairie Farm Rehabilitation Administration pastures, aboriginal reserve lands, and military training areas. It prohibits the killing, harming, harassing, or taking of extirpated, endangered, or threatened species, and the destruction of their residences (e.g., nest or den) on Federal lands, except where permitted under a national recovery strategy (GNT 2010, p. 10). Because the recovery strategy includes managing herd size for the health of the habitat and herds (Gates *et al.* 2001, pp. 35–39), bison hunting is allowed under a quota system in the Nahanni, MacKenzie, and Aishihik herds (described above under Factor B). The Northwest Territories *Big Game Hunting Regulations* consider bison in the Slave River Lowlands to be hybrids, which General Hunting License holders may hunt without limit or closed season. In the Yukon, the Aishihik herd size is managed through hunting. In Alberta, Hay-Zama herd size is managed by hunting to reduce the likelihood that the herd will come into contact with animals from WBNP (GNT 2010, p. 7).

Habitat protection within the range of the Mackenzie bison herd is facilitated through the SARA and the Mackenzie Valley Resource Management Act of 1998. Although the Mackenzie Valley Resource Management Act does not specifically provide protection to wood bison, it did create a Land and Water Board (LWB), which is given the power to regulate the use of land and water,

including the issuance of land use permits and water licenses. The LWB's Environmental Impact Review Board is the main instrument in the Mackenzie Valley for the examination of the environmental impact of proposed developments. The LWB's Land Use Planning Board is given the power to develop land use plans and to ensure that future use of lands is carried out in conformity with those plans.

As described below, several wood bison herds occur wholly or partially in National Parks, ecological reserves, or Provincial Parks (Table 2). In 1922, WBNP was established in Alberta and the Northwest Territories for the protection of wood bison. Habitat protection of 44,807 km^2 (17,300 mi^2) within WBNP occurs through the Canada National Parks Act, the purpose of which is to maintain or restore the ecological integrity of parks, through the protection of natural resources and natural processes. With respect to a park, ecological integrity means a condition characteristic of its natural region, including abiotic (nonliving) components and the composition and abundance of native species and biological communities. Renewable harvest activities can be regulated or prohibited, and is enforced through this legislation (Canada National Parks Act, 2000). National parks are protected by Federal legislation from all forms of extractive resource use such as mining, forestry, agriculture, and sport hunting. Only activities consistent with the protection of park resources are allowed. Efforts are directed at maintaining the physical environment in as natural a state as possible. Sport hunting is prohibited; however, traditional subsistence-level harvesting by First Nations is allowed in some areas as long as the resources are conserved (The Canadian Encyclopedia 2010a, unpaginated).

TABLE 2—FREE-RANGING WOOD BISON HERDS AND LAND MANAGEMENT UNITS THAT PROVIDE PROTECTION TO THEM

Herd category and name	Canadian province	Protected area
Free-ranging, disease-free herds:		
Mackenzie	Northwest Territories	Mackenzie Bison Sanctuary.
Aishihik	Yukon	None identified, but occupied habitat is government-owned.
Hay-Zama	Alberta	Wildlife Management Area.
Nahanni	Northwest Territories, southeast Yukon, northeast British Columbia.	None identified, but occupied habitat is government-owned.
Nordquist	British Columbia	Portage Brule Rapids Ecological Reserve, Smith River Ecological Reserve, Smith River Falls–Fort Halkett Park, Liard River Corridor Park, Liard River Hotsprings Park, Liard River West Corridor Park, Liard River Corridor Protected Area, Hyland River Park, Muncho Lake Park, and Milligan Hills Park.
Etthithun	British Columbia.	
Chitek Lake	Manitoba	Chitek Lake Reserve.
Free-ranging, diseased herds:		
Wood Buffalo National Park	Alberta, Northwest Territories	Wood Buffalo National Park.

Ecological reserves are established in part for the protection of rare and endangered plants and animals in their natural habitat; preservation of unique, rare, or outstanding botanical, zoological, or geological phenomena; and perpetuation of important genetic resources. Research and educational functions are the primary uses for ecological reserves, but are open to the public for non-consumptive, observational uses. Plans are developed by the Ministry of Environment to provide protection and management to ensure long-term maintenance. Resource use, such as tree cutting, hunting, fishing, mining, domestic grazing, camping, lighting of fires and removal of materials, plants or animals, and the use of motorized vehicles are prohibited (British Columbia 2010, unpaginated).

Although there are numerous parks and ecological reserves throughout the range of the wood bison, these areas do not necessarily encompass all of the individuals of a herd. Individuals frequently move into and out of these areas; therefore, wood bison herds are only afforded protection while within the boundaries of the park or ecological reserve.

The Federal Environmental Assessment and Review Process (EARP) was introduced in Canada in 1973. In 1995, the Canadian Environmental Assessment Act replaced EARP and strengthened the Environmental Impact Assessment (EIA). The Canadian Environmental Assessment Act outlines responsibilities and procedures for the EIA of projects for which the Canadian Government holds decision-making authority. The purposes of EIAs are to minimize or avoid adverse environmental effects before they occur and to incorporate environmental factors into decision making. All projects in National Parks must have an EIA. An EIA is also required under the law of the provinces and territories. Municipalities and corporations are subject to the EIA requirements of their respective provincial, territorial, or land claim jurisdictions, and are also subject to the Canadian Environmental Assessment Act if the Canadian Government holds some decision-making authority concerning the proposed development or the acceptability of its impacts. This legislation ensures that any projects conducted on Canada's government-owned lands, including National Parks, are carefully reviewed before Canadian authorities take action so that projects do not cause significant adverse environmental effects, including areas surrounding the project. It encourages Canadian authorities to take actions that promote sustainable development (Canadian Environmental Assessment Agency 2010, unpaginated). If a project is likely to cause significant adverse environmental effects that cannot be justified in the circumstances, even after taking into account appropriate mitigation measures, the project will not be carried out in whole or in part (Canadian Environmental Assessment Act (20)(b) and (37)(b)).

Canada's Provincial and Territorial Regulatory Mechanisms

Provincial and territorial governments within Canada can use the Wild Animal and Plant Protection and Regulation of International and Interprovincial Trade

Act (WAPPRIITA) to control transport of wood bison across their borders. This law applies to wood bison because it is on the CITES control list (CITES is discussed below, under ''International Regulatory Mechanisms''). The WAPPRIITA prohibits the import, export, and interprovincial transportation of CITES-listed species or any Canadian species whose capture, possession, and transportation are regulated by provincial or territorial laws, unless the specimens are accompanied by the appropriate documents (licenses, permits). In all cases, the WAPPRIITA applies to the animal, alive or dead, as well as to its parts and any derived products (Environment Canada 2010, p.1).

In addition to national-level legislation that provides protection to wood bison, there is also protection at the provincial level. Alberta, the Northwest Territories, British Columbia, Manitoba, and the Yukon Territory classify wood bison as wildlife, which is the property of the provincial or territorial government. In 1995, the Government of Alberta established a Wildlife Management Area to protect the Hay-Zama herd and listed the wood bison as endangered within the protected area under the Alberta Wildlife Act (Gates *et al.* 2010, p. 71). In this area, all wood bison are legally protected from hunting; outside of the area they are not protected.

The Northwest Territories Wildlife Act enables the Minister of Environment and Natural Resources to prohibit the importation of any wildlife into the Northwest Territories without a permit. This prohibits uncontrolled importation of plains bison. In May 1964, wood bison were declared in danger of becoming extinct under the Northwest Territories Act and are now designated as a protected species in the Northwest Territories. As such, sport hunting and subsistence hunting by aboriginal people may occur, but is regulated.

Wood bison are on British Columbia's Red List of species and subspecies that are candidates for legal designation as endangered or threatened under the Wildlife Act (Harper 2002, p. 3). Wood bison are an endangered species under the Yukon Act, a ''specially protected species'' under the Wildlife Act (Yukon legislation), and are listed as protected under Manitoba's Wildlife Act. Bison are considered domestic when held in captivity under permit or license for game farming purposes. If a wood bison escapes captivity, the provincial or territorial government acquires ownership of the animal, and it, therefore, becomes protected (Harper and Gates 2000, p. 919).

Other Canadian Regulatory Mechanisms

Although there is tight control over the transmission of disease across the Canadian border, control of disease within Canada is more challenging. As explained above (Factor C), there is a program to detect and eradicate tuberculosis and brucellosis in farmed animals in Canada in order to protect the health of food-producing and companion animals, safeguard human health, and safeguard the health of free-roaming wildlife. In addition, buffer zones in which dispersing animals may be harvested have been created around the diseased herds to reduce the risk of bovine tuberculosis and brucellosis infection of the Mackenzie and Nahanni herds, which are most at risk from infection from animals at WBNP. In addition, the Governments of the Northwest Territories, Alberta, and British Columbia have designated management zones to reduce the risk of dispersing animals transmitting disease to disease-free herds in their provinces. However, as noted above, buffer zones are not ideal for preventing the spread of disease because they are sporadically patrolled and imperfectly enforced. Existing regulations and policies address the transmission of disease within Canada, but it is impossible to regulate the movement of wild animals across a large, mostly uninhabited landscape. Thus, we conclude that regulatory mechanisms are in place to minimize the spread of disease but because of the difficulty in containing herds of wild animals, the mechanisms are inadequate to prevent the spread of disease.

Under Factor E, we conclude that loss of genetic integrity through hybridization is a threat to wood bison. Preventing hybridization between plains bison and free-roaming wood bison is a goal of the recovery plan and is important to the conservation of the subspecies (Gates *et al.* 2001, p. 33). There is one free-ranging plains bison herd in Canada, in British Columbia, which was established as a result of the plains bison escaping from their enclosure. Preventing interbreeding between free-ranging plains bison and wood bison is a management objective in British Columbia and is accomplished by maintaining a large physical separation between the herds and having a management zone around the plains bison herd that allows harvest of plains bison within this zone (Harper *et al.* 2000, p. 23).

As discussed earlier under Factor A, plains bison presence on the landscape is increasing and commercial plains bison operations in Canada are expanding. The presence of plains bison within the historical range of wood bison increases the probability that wood bison will come into contact with them. Ranchers are most likely highly motivated by economics to prevent the escape of their animals and to recapture them if they do escape. It is unlikely that additional government regulations would improve on this basic incentive; therefore, although there may not be specific regulations regarding how plains bison should be contained, such regulations are not viewed as necessary or effectual. As mentioned above, buffer zones are not ideal for preventing the movement of free-ranging bison. Thus, although regulations are in place by which the Pink Mountain plains bison herd (a free-ranging herd) can be managed, and there is no indication that they have not been effective, they may not be 100 percent effective in preventing hybridization in the future because of the difficulty of managing wild animals over large areas of forested landscape.

U.S. Regulatory Mechanisms

In the United States, as an endangered species under the Act, pure wood bison can be imported only by permit for scientific research or enhancement of propagation or survival of the species. Wood/plains bison hybrids, however, are not protected by the Act and can be imported if the required CITES Foreign Export Permits are obtained from Canada prior to the import. When the wood bison is reclassified to threatened (see **DATES**, above), import of trophies legally taken and properly permitted can also occur. Because of the regulations in place in Canada for all hunts and the permits required for import and export under CITES, we do not anticipate that reclassification will cause any increase in the number of animals killed or have any effect on the herds that are hunted.

International Regulatory Mechanisms

The wood bison is listed on Appendix II of CITES. CITES, an international treaty among 175 nations, including Canada and the United States, became effective in 1975. In the United States, CITES is implemented through the U.S. Endangered Species Act. The Secretary of the Interior has delegated the Department of the Interior's responsibility for CITES to the Director of the Service and established the CITES Scientific and Management Authorities to implement the treaty.

CITES provides varying degrees of protection to more than 32,000 species of animals and plants that are traded as whole specimens, parts, or products.

Under this treaty, member countries work together to ensure that international trade in animal and plant species is not detrimental to the survival of wild populations by regulating the import, export, and reexport of CITES-listed animal and plant species (USFWS 2010, unpaginated). Under CITES, a species is listed on an Appendix and receives varying levels of regulation of international trade through permit and certification requirements depending upon the particular Appendix in which the species is listed (CITES 2010b, unpaginated). CITES Appendix-II species are not necessarily considered to be threatened with extinction now but may become so unless trade in the species is regulated. Appendix II allows for regulated trade, including commercial trade, as long as the exporting country issues a CITES permit based on findings that the specimen was legally acquired and the export will not be detrimental to the survival of the species. As discussed above under Factor B, we do not consider international trade to be a threat impacting the wood bison. Therefore, protection under this treaty is an adequate regulatory mechanism.

Summary of Factor D

The wood bison is currently protected through a variety of regulatory mechanisms, and we anticipate those protections to continue. The wood bison and its habitat is protected by Canadian Federal, provincial, and territorial law. Internationally, its trade is regulated by CITES. International trade is limited to animals surplus to recovery needs in Canada, as determined under guidance of the National Wood Bison Recovery Team. In the United States, activities involving wood bison are regulated by the Endangered Species Act, and with reclassification, they will continue to be regulated. Federal agencies will need to consult with the Service on activities within the United States that may affect the species, and Federal permits will be required for scientific collection or any other form of take.

Disease and hybridization have been identified as threats to wood bison. Although buffer zones have been established and regulations implemented for the management of the buffer zones to minimize the potential of disease spread and hybridization, buffer zones have limitations and are an imperfect means by which to prevent animal movement. Therefore, we conclude that existing regulatory mechanisms are inadequate to completely protect wood bison from these threats.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

Accidental Mortality

Because bison follow linear landmarks and prefer open areas, vehicles on roads and other linear developments, such as railroad lines, present a hazard to wood bison. Collisions with vehicles are the largest source of known mortality for individuals in the Hay-Zama herd (Mitchell and Gates 2002, p. 9). For the Nordquist herd, vehicle collisions are a significant mortality factor (Wildlife Collision Prevention Program. 2010, pp. 22–23). The herd was established in the Nordquist Flats area, near the Liard River in northeastern British Columbia; however, individuals, and then the majority of the herd, moved to the Alaska Highway corridor. In January 2007, a limited aerial survey counted 97 wood bison, all of which were on the highway right-of-way, except for four bulls, which were observed within 500 m (1,640 ft) of the road (Reynolds *et al.* 2009, p. 6). Three of 15 wood bison introduced to the Etthithun Lake area in 1996 were killed in collisions with industrial road traffic during the first winter (Harper and Gates 2000, p. 921). The Yukon government has a ''bison-free'' policy in the vicinity of the Alaska Highway that includes deterrence, capture, and ultimately the destruction of problem animals (Yukon Fish and Wildlife Co-management undated, p. 1). During the growth phase of the Aishihik herd from 1988 to 1993, 49 wood bison were removed from the Alaska Highway right-of-way because of vehicle collisions and problem wildlife complaints (Boyd 2003, p. 187). Of these, 36 were captured and moved to a game farm, 8 were killed in collisions, and 5 were intentionally killed (Wildlife Collision Prevention Program 2010, unpaginated). From 1989 to 2007, collisions with vehicles killed from 1 to 30 wood bison annually from three herds combined in the Northwest Territories; fewer than 10 were killed annually in 11 of the 18 years (Wildlife Collision Prevention Program 2010, unpaginated).

Because of continued or increased resource development, tourism, and off-road vehicle use, it is anticipated that mortality from collisions with vehicles will be a source of individual mortality for several populations. Because mortality from road collisions represents a small portion of the total subspecies population, and efforts are made to reduce bison/highway conflicts, this source of mortality is not expected to have a significant impact at the subspecies population level.

Spring flooding in the Peace-Athabasca River Delta in 1958, 1961, and 1974 killed approximately 500, 1,100, and 3,000 wood bison, respectively (Reynolds *et al.* 2003, p. 1029). Autumn flooding in the same area in 1959 killed an estimated 3,000 wood bison (Reynolds *et al.* 2003, p. 1029). This region is within WBNP where the diseased herds reside. Most likely a small number of animals drown each year when caught by floods or when they break through ice (Soper 1941, p. 403; Larter *et al.* 2003, p. 411). Large drowning events have not been documented from other rivers, and no large mortality events have been documented in recent years. Drowning is also recognized as a cause of mortality in the Chitek Lake, Mackenzie, and Nahanni herds (Larter *et al.* 2003, p. 411). Because mortality due to drowning typically affects only a portion of a herd and herd sizes are increasing (see Table 1, above), drowning does not appear to be having a population-level effect on wood bison.

Although wood bison are hardy and very cold tolerant (Gates *et al.* 2010, p. 24), above-average snowfall, long periods of sub-zero temperatures, and midwinter thaws followed by freezing can cause mortality. Such severe winter conditions reduce forage availability (Reynolds *et al.* 2003, p. 1030). Rain-on-snow events can also form an ice layer that creates a barrier to forage for herbivores (Putkonen 2009, p. 221). Freezing rain in autumn that causes ground-fast ice to form before snow cover accumulates, ice layering in the snow cover, crusting of the snow, and the formation of ground-fast ice in spring increase the energy required to obtain forage or make forage unobtainable (Gunn and Dragon 2002, p. 58). Soper (1941, pp. 403–404) recounts several stories in which excessive snowfall caused mass mortalities of wood bison, and Van Camp and Calef (1987, p. 23) report that 33 percent of the diseased wood bison herd in the Slave River lowlands was lost during the severe winter of 1974–1975. Starvation in bad winters is recognized as a source of mortality for wood bison in the Chitek Lake herd. We have no information indicating that starvation is having a population-level effect on any of the herds currently.

Rain-on-snow events may increase in the face of climate change (Rennert *et al.* 2009, p. 2312). A doubling of carbon dioxide is estimated to cause a 40 percent increase in the area impacted by rain-on-snow events in the Arctic by 2080 (Rennert *et al.* 2009, p. 2312). Rain-on-snow events may become more prevalent primarily in northwestern

Canada, Alaska, and eastern Russia (Rennert *et al.* 2009, p. 2312). We have no reports that rain-on-snow events have led to the deaths of bison, but they could be susceptible to starvation by such events.

Genetic Issues

Genetic diversity in wood bison has been reduced through the large historic reduction in overall population size and the starting of new populations with very few individuals (founder effect). Genetic diversity is the primary means by which organisms can adapt to changing environmental conditions over time. Low levels of genetic diversity can reduce the ability of a population to respond to environmental changes. Current wood bison herds were established from relatively few founders (Wilson and Strobeck 1999, pp. 484–486). For example, the Elk Island National Park herd was started from 11 individuals, and the Mackenzie herd was started from 16 (Gates *et al.* 1992, p. 150; Wilson and Strobeck 1999, p. 494). Inbreeding, the mating of related individuals, can lead to lower fecundity, increased abnormalities, reduced growth rates, and other issues. Although inbreeding is more likely to occur in small herds or in herds that are isolated, it has not been documented in wood bison. Starting new populations with multiple groups of animals is one way to avoid or minimize the founder effect as was done in the establishment of the Aishihik and Nahanni herds. Moving disease-free animals from one herd to another is another method to maintain genetic diversity. One of the wood bison recovery goals is to ensure that the genetic integrity of wood bison is maintained. Because no effects of inbreeding have been documented and management actions have been shown to be effective, we conclude that loss of genetic diversity is not a threat to wood bison now or in the foreseeable future.

Hybridization occurs when individuals from genetically distinct groups such as wood bison and plains bison interbreed. The introduction of plains bison to WBNP in the 1920s put the two distinct subspecies in contact with each other and threatened the genetic purity of wood bison (Gates *et al.* 2010, p. 17). The discovery of an isolated subpopulation of wood bison in 1957, and subsequent translocation of individuals, created the Mackenzie and Elk Island National Park herds, which were thought to be pure wood bison. Genetic analysis has indicated that these bison did have limited contact with plains bison, but it was minimal enough that the animals exhibit predominantly wood bison traits and wood bison herds originating from these founders are genetically more similar to one another than they are to plains bison (van Zyll de Jong *et al.* 1995, pp. 401–404; Wilson and Strobeck 1999, p. 493). Although recovery actions emphasize maintaining the genetic integrity of wood bison (i.e., recovery goal number 3) (Gates *et al.* 2001, p. 33), as discussed earlier under Factor A, the presence of plains bison on the landscape is increasing. Commercial plains bison operations in Canada are expanding, and the Pink Mountain plains bison herd was established in British Columbia as a result of plains bison escaping from an enclosure. The commercial plains bison operations and plains bison herds remove potential habitat for wood bison, and the presence of plains bison within the historical range of wood bison increases the probability that wood bison will come into contact with them. For these reasons, loss of genetic integrity through hybridization is a threat to wood bison and will remain so in the foreseeable future.

Summary of Factor E

Accidental mortality typically occurs randomly and cannot be predicted. We expect accidents to continue at the same rate and scale as they have in the past, into the future, but only expect this to affect individuals and not be significant enough to affect the species as a whole. Relative to genetic diversity, inbreeding in wood bison has not been documented, and management actions are in place to prevent further loss of genetic diversity. The status of genetic issues relating to hybridization could change relatively rapidly, especially if plains bison were to escape from captivity in close proximity to a wood bison herd. Currently, free-ranging wood bison and plains bison herds are widely separated from one another, but as herd size grows, the separation shrinks, increasing the odds that they may come into contact with one another. Furthermore, bison are difficult animals to contain, they can travel long distances, and the wood and plains bison can readily interbreed.

In summary, accidental mortality will continue to occur regularly, primarily through collisions with vehicles and drowning. In addition, climate change may create localized weather conditions such as above-average snowfall, long periods of sub-zero temperatures, or ground-fast ice formation that can lead to winter mortality of portions of herds. Given the number of herds and their wide distribution across the landscape, we conclude that accidental mortality and starvation are not threats to wood bison now or in the foreseeable future. It is recognized that genetic diversity in wood bison is relatively low, and that the herds must be managed to maintain genetic diversity. Loss of genetic diversity is a factor that may limit the ability of wood bison to adapt to changing conditions in the future, but the magnitude of that limitation, if it exists, is unknown. Lack of genetic diversity is potentially limiting over the long term, depending on the magnitude of environmental change wood bison may face. Because no effects of inbreeding have been documented and management actions have been shown to be effective, we conclude that loss of genetic diversity is not a threat to wood bison now or in the foreseeable future. Hybridization with plains bison is a threat that most likely will increase in the future. Because of consumer demand for bison meat, we expect commercial bison production will continue to expand, removing suitable habitat for wood bison recovery herds, and increasing the probability that escaped plains bison will be free on the landscape. Hybridization is a threat to wood bison now and in the foreseeable future.

Finding

As required by the Act, we considered the five factors in assessing whether the wood bison is endangered or threatened throughout all or a significant portion of its range. We reviewed the petition, information available in our files, comments and information we received after the publication of our 90-day finding (74 FR 5908, February 3, 2009), comments and information we received after the publication of our proposed rule to reclassify wood bison (76 FR 6734, February 8, 2011), and other available published and unpublished information. We also consulted with recognized experts. We have carefully assessed the best available scientific and commercial data regarding the past, present, and future threats faced by wood bison. We found that threats to wood bison are still present in factors A, C, D, and E. Habitat loss has occurred from agricultural development, and we expect losses will continue in concert with human growth and expansion of agriculture, including commercial bison production. The presence of bovine brucellosis and bovine tuberculosis constrains herd growth as: Managers attempt to maintain physical separation between diseased and disease-free wood bison and cattle herds, the diseased herds are occupying habitat that could be restored with disease-free herds, and disease in the largest potential donor population (WBNP herd) prevents those animals from being used in

reintroduction projects. Plains bison are commercially produced in historical wood bison habitat. These operations remove potential habitat from wood bison recovery efforts, and the escape of plains bison poses a threat to wood bison because of hybridization and the loss of genetic integrity. Finally, we found that regulatory mechanisms are inadequate to prevent disease transmission and hybridization within Canada.

In addition to the five-factor analysis, we took into consideration the conservation actions that have occurred, are ongoing, and are planned. Since listing, the subspecies' status has improved as a result of the following:

- Enactment and enforcement of national and international laws and treaties have minimized the impacts of hunting and trade.
- Reintroduction of disease-free herds has increased the number of free-ranging herds from 1 population of 300 in 1978, to 7 populations totaling 4,414 bison in 2008.
- Diseased and disease-free, free-ranging populations are stable or increasing.

In sum, the continued reintroduction of disease-free herds, the ongoing development and updating of management plans, the active management of herds, the ongoing research, and the protections provided by laws and protected lands provide compelling evidence that recovery actions have been successful in reducing the risk of extinction associated with the threats identified. We anticipate that continued growth and expansion of the herds would further reduce the risk of extinction in the future.

The primary factor that led to the listing of the wood bison was the small number of free-ranging, disease-free animals on the landscape. However, the trend today is towards increasing numbers of disease-free herds and population sizes. We find that the threats identified under factors A, C, D, and E, when combined with the increase in number of herds and population sizes, ongoing active management, and protections provided by laws, are not of sufficient imminence, intensity, or magnitude to indicate that the wood bison is presently in danger of extinction. The wood bison therefore no longer meets the definition of endangered under the Act. However, threats to wood bison still exist and will likely continue into the foreseeable future. In particular, there are no easy solutions for dealing with the diseased animals. No effective vaccines exist for brucellosis, tuberculosis, or anthrax for free-ranging populations. In addition, although recommendations for the management of the diseased herds in and around WBNP have been suggested (FEAP 1990, p. 2), they have not yet been implemented, it is unknown if they will be implemented, and it is unknown how implementation of the recommendations would affect the status of the subspecies. Therefore, we have determined that the wood bison meets the definition of threatened under the Act. Consequently, we are reclassifying the wood bison's listing status from endangered to threatened with this rule.

In our February 8, 2011, proposed rule (76 FR 6734), we determined that the Aishihik and Chitek Lake herds are discrete under our Distinct Vertebrate Population Segment policy (61 FR 4722, February 7, 1996), but are not significant, and therefore, did not qualify as a distinct population segment. In that proposed rule, we also considered whether there is a significant portion of the range where the wood bison is in danger of extinction and did not identify any area or herd whose loss would result in a decrease in the ability to conserve the species as a whole. Consequently, as described in the proposed rule, we are not listing a distinct population segment of wood bison and we have not identified a portion of the range that is so significant to the species that threats there imperil the species as a whole.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and encourages and results in conservation actions by Federal governments, private agencies and groups, and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for all listed species. The protection measures required of Federal agencies and the prohibitions against certain activities are discussed, in part, below.

Section 7(a) of the Act, as amended, and as implemented by regulations at 50 CFR part 402, requires Federal agencies to evaluate their actions within the United States or on the high seas with respect to any species that is proposed or listed as endangered or threatened, and with respect to its critical habitat, if any is being designated. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. However, given that there are no wild populations of wood bison in the United States, critical habitat is not being designated for this species under section 4 of the Act.

Section 8(a) of the Act authorizes limited financial assistance for the development and management of programs that the Secretary of the Interior determines to be necessary or useful for the conservation of endangered and threatened species in foreign countries. Sections 8(b) and 8(c) of the Act authorize the Secretary to encourage conservation programs for foreign endangered species and to provide assistance for such programs in the form of personnel and the training of personnel.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered and threatened wildlife. As such, these prohibitions are, and will continue to be when this rule is effective (see **DATES**, above), applicable to the wood bison. These prohibitions, under 50 CFR 17.21 (50 CFR 17.31 for threatened wildlife species), make it illegal for any person subject to the jurisdiction of the United States to ''take'' (take includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, collect, or to attempt any of these) within the United States or upon the high seas, import or export, deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of a commercial activity, or to sell or offer for sale in interstate or foreign commerce, any endangered wildlife species. It also is illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken in violation of the Act. Certain exceptions apply to agents of the Service and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered and threatened wildlife species under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22 for endangered species, and at 50 CFR 17.32 for threatened species. With regard to endangered wildlife, a permit must be issued for the following purposes: for scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. For threatened species, a permit may be issued for the same activities, as well as zoological

exhibition, education, and special purposes consistent with the Act.

Effects of This Rule

This final rule revises 50 CFR 17.11(h) to reclassify the wood bison from endangered to threatened. This rule formally recognizes that this species is no longer presently in danger of extinction throughout all or a significant portion of its range. However, this reclassification does not significantly change the protection afforded this species under the Act. The regulatory protections of section 9 and section 7 of the Act remain in place. Anyone taking, attempting to take, or otherwise possessing a wood bison, or parts thereof, in violation of section 9 of the Act is still subject to a penalty under section 11 of the Act, unless their action is covered under a special rule under section 4(d) of the Act. We are not currently publishing a special rule under section 4(d) of the Act for the wood bison at this time. However, section 9(c)(2) of the ESA sets out an exemption to the general import prohibition for threatened, Appendix-II wildlife, both live and dead, when: (1) The taking and export meet all provisions of CITES; (2) all other import and reporting requirements under section 9 of the ESA are met; and (3) the import is not made in the course of a commercial activity. Since the wood bison is currently listed in Appendix II of CITES, upon the effective date of this publication, and the reclassification of the wood bison from endangered to threatened, this ESA exemption is generally applicable. Because a sport-hunted trophy is not a specimen obtained or imported in the course of a commercial activity, the section 9(c)(2) ESA exemption would typically apply to the import of sport-hunted trophies, provided that all other requirements of section 9(c)(2) of the ESA are met.

Under section 7 of the Act, Federal agencies must ensure that any actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of the wood bison. Because no free-ranging herds of wood bison occur in Alaska or any other State, we do not anticipate that there will be an additional regulatory responsibility because of this rule.

Required Determinations

Paperwork Reduction Act

This rule does not contain any new information collections or recordkeeping requirements for which Office of Management and Budget (OMB) approval is required under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). We may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

We have determined that we do not need to prepare an environmental assessment or environmental impact statement, as defined under the authority of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of the references cited is available at *http://www.regulations.gov* at Docket No. FWS–R9–IA–2008–0123 or upon request from the Alaska Regional Office (see **ADDRESSES**).

Author

The primary author of this rule is Marilyn Myers, Ph.D., Fisheries and Ecological Services, Alaska Regional Office, 1011 E. Tudor Road, Anchorage, AK 99503; 907–786–3559.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

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

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

■ 2. Amend § 17.11(h) by revising the entry for ''Bison, wood'' under MAMMALS in the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
MAMMALS							
*	*	*	*	*	*	*	
Bison, wood	*Bison bison athabascae*.	Canada, Alaska	Entire	T	3,803	NA	NA
*	*	*	*	*	*	*	

Dated: April 24, 2012.

Daniel M. Ashe,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2012–10635 Filed 5–2–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 111213751–2102–02]

RIN 0648–XC013

Fisheries of the Exclusive Economic Zone Off Alaska; Atka Mackerel in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Atka mackerel in the Central Aleutian district (CAI) of the Bering Sea and Aleutian Island management area (BSAI) by vessels participating in the BSAI trawl limited access fishery. This action is necessary to prevent exceeding the A season allowance of the 2012 Atka mackerel total allowable catch (TAC) in the CAI allocated to vessels participating in the BSAI trawl limited access fishery.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), April 30, 2012, through 1200 hrs, A.l.t., June 10, 2012.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7269.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The A season allowance of the 2012 Atka mackerel TAC, in the CAI, allocated to vessels participating in the BSAI trawl limited access fishery was established as a directed fishing allowance of 476 metric tons by the final 2012 and 2013 harvest specifications for groundfish in the BSAI (77 FR 10669, February 23, 2012).

In accordance with § 679.20(d)(1)(iii), the Administrator, Alaska Region, NMFS, finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Atka mackerel in the CAI by vessels participating in the BSAI trawl limited access fishery.

After the effective dates of this closure, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Acting Assistant Administrator for Fisheries, NOAA, (AA) finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such a requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of the Atka mackerel fishery in the CAI for vessels participating in the BSAI trawl limited access fishery. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of April 27, 2012. The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: April 30, 2012.

Emily H. Menashes,

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

[FR Doc. 2012–10682 Filed 4–30–12; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 77, No. 86
Thursday, May 3, 2012

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 11 and 25

RIN 3150–AJ00

[NRC–2011–0161]

Access Authorization Fees

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is proposing to amend its access authorization fees charged to licensees for work performed under the Material Access Authorization Program (MAAP) and the Information Access Authority Program (IAAP). The amended cost is due to an increase in the review time for each application for access authorization. The NRC's formula for calculating fees remains the same and is based on current Office of Personnel Management (OPM) billing rates for background investigations. The formula is designed to recover the full cost of processing a request for access authorization from an NRC licensee.

DATES: Submit comments by June 4, 2012. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may access information and comment submissions related to this proposed rule, which the NRC possesses and is publicly available, by searching on *http://www.regulations.gov* under Docket ID NRC–2011–0161. You may submit comments related to this proposed rule by the following methods:

- *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2011–0161. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

You may submit comments on the information collections by the methods described in the **SUPPLEMENTARY INFORMATION** section of this document, under the heading, ''Paperwork Reduction Act Statement.''

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Emily Robbins, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–492–3524, email: *Emily.Robbins@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2011–0161 when contacting the NRC about the availability of information for this proposed rule. You may access information related to this proposed rulemaking, which the NRC possesses and is publicly available, by the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2011–0161.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2011–0161 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS, and the NRC does not edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information in their comment submissions that they do not want to be publicly disclosed. Your request should state that the NRC will not edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

Procedural Background

Because the NRC considers this action noncontroversial and routine, the NRC is publishing this proposed rule concurrently as a direct final rule in the Rules and Regulations section of this **Federal Register**. The amendments make a routine adjustment to the access authorization fees and are of a minor and administrative nature. Adequate protection of public health and safety continues to be ensured. The direct final rule will become effective on June 22, 2012. However, if the NRC receives significant adverse comments on the direct final rule by June 4, 2012, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in response to the proposed revisions in a subsequent final rule. Absent significant

modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC staff to make a change (other than editorial) to the rule.

For additional procedural information, see the direct final rule published in the Rules and Regulations section of this **Federal Register**.

List of Subjects

10 CFR Part 11

Hazardous materials—transportation, Investigations, Nuclear materials, Reporting and recordkeeping requirements, Security measures, Special nuclear material.

10 CFR Part 25

Classified information, Criminal penalties, Investigations, Reporting and recordkeeping requirements, Security measures.

For the reasons set forth in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing the following amendments to Title 10 of the *Code of Federal Regulations* (10 CFR), Parts 11 and 25.

PART 11—CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO OR CONTROL OVER SPECIAL NUCLEAR MATERIAL

1. The authority citation for part 11 is revised to read as follows:

Authority: Atomic Energy Act sec. 161 (42 U.S.C. 2201); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note).

Section 11.15(e) also issued under Independent Offices Appropriations Act sec. 501, (31 U.S.C. 9701); Omnibus Reconciliation Act of 1990 sec. 6101 (42 U.S.C. 2214).

Federal Register Citation: October 10, 2003; 68 FR 58792, 58800.

2. In § 11.15:

i. Add paragraph (e) introductory text;

ii. Revise paragraphs (e)(1) and (e)(2);

iii. Redesignate paragraph (e)(3) as paragraph (e)(4); and

iv. Add a new paragraph (e)(3).

The revisions and addition read as follows:

§ 11.15 Application for special nuclear material access authorization.

* * * * *

(e) The Office of Personnel Management (OPM) bills the NRC for the cost of each background investigation conducted in support of an application for special nuclear material access authorization (application). The combined cost of the OPM investigation and the NRC's application processing overhead (NRC processing fee) are recovered through a material access authorization fee imposed on applicants for special nuclear material access authorization.

(1) Each application for a special nuclear material access authorization, renewal, or change in level must be accompanied by a remittance, payable to the U.S. Nuclear Regulatory Commission, which is equal to the NRC material access authorization fee. This fee must be determined using the following formula: the OPM investigation billing rates on the day of NRC receipt of the application + the NRC processing fee = the NRC material access authorization fee. The NRC processing fee is determined by multiplying the OPM investigation billing rate on the day of NRC receipt of the application by 55.8 percent (i.e., OPM rate × 55.8 percent).

(2) Updated OPM investigation billing rates are published periodically in a Federal Investigations Notice (FIN) issued by the OPM's Federal Investigative Services. Copies of the current OPM investigation billing rates schedule can be obtained by contacting the NRC's Personnel Security Branch, Division of Facilities Security, Office of Administration by email to *Licensee_Access_Authorization_Fee@nrc.gov.*

(3) The NRC's Material Access Authorization Program (MAAP) is considered reimbursable work representing services provided to an organization for which the NRC is entitled payment. The NRC is authorized to receive and retain fees from licensees for services performed. The NRC's Office of the Chief Financial Officer periodically reviews the fees charged for MAAP and makes recommendations on revising those charges to reflect costs incurred by the NRC in providing those services. The reviews are performed using cost analysis techniques to determine the direct and indirect costs. Based on this review the MAAP fees are adjusted to reflect the current cost for the program. Copies of the current NRC material access authorization fee may be obtained by contacting the NRC's Personnel Security Branch, Division of Facilities Security, Office of Administration by email to: *Licensee_Access_Authorization_Fee@nrc.gov.* Any change in the NRC's access authorization fees will be applicable to each access authorization request received on or after the effective date of the OPM's most recently published investigation billing rates schedule. Applicants shall calculate the access authorization fee according to the stated formula (i.e., OPM rate × 55.8 percent) and with reference to the following table:

The NRC application fee for an access authorization of type . . .	Is the sum of the current OPM investigation billing rate charged for an investigation of type . . .	Plus the NRC's processing fee (rounded to the nearest dollar), which is equal to the OPM investigation billing rate for the type of investigation referenced multiplied by . . .
i. NRC–R [1]	NACLC—National Agency Check with Law and Credit (Standard Service, Code C).	55.8%

The NRC application fee for an access authorization of type . . .	Is the sum of the current OPM investigation billing rate charged for an investigation of type . . .	Plus the NRC's processing fee (rounded to the nearest dollar), which is equal to the OPM investigation billing rate for the type of investigation referenced multiplied by . . .
ii. NRC–R Based on Certification of Comparable Investigation.[2]	No fee assessed for most applications	
iii. NRC–R renewal.[1]	NACLC—National Agency Check with Law and Credit (Standard Service, Code C).	55.8%
iv. NRC–U requiring single scope investigation	SSBI—Single Scope Background Investigation (Standard Service, Code C).	55.8%
v. NRC–U requiring single scope investigation (expedited processing).	SSBI—Single Scope Background Investigation (Priority Handling, Code A).	55.8%
vi. NRC–U based on certification of comparable investigation.[2]	No fee assessed for most applications	
vii. NRC–U renewal[2]	SSBI–PR—Periodic Reinvestigation for SSBI (Standard Service, Code C).	55.8%

[1] If the NRC, having reviewed the available data, deems it necessary to perform a single scope investigation, the appropriate NRC–U fee will be assessed before the conduct of the investigation.

[2] If the NRC determines, based on its review of available data, that a single scope investigation is necessary, the appropriate NRC–U fee will be assessed before the conduct of the investigation.

* * * * *

PART 25—ACCESS AUTHORIZATION

3. The authority citation for part 25 is revised to read as follows:

Authority: Atomic Energy Act secs. 145, 161, 223, 234 (42 U.S.C. 2165, 2201, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); E.O. 10865, as amended, 3 CFR 1959–1963 Comp., p. 398 (50 U.S.C. 401, note); E.O. 12829, 3 CFR, 1993 Comp., p. 570; E.O. 13526, 3 CFR 2010 Comp., pp. 298–327; E.O. 12968, 3 CFR, 1995 Comp., p. 396;

Section 25.17(f) and Appendix A also issued under 31 U.S.C. 9701; Omnibus Reconciliation Act of 1990 sec. 6101 (42 U.S.C. 2214).

Federal Register Citation: November 30, 2010; 75 FR 73935, 73941.

4. In § 25.17(f):

i. Add paragraph (f) introductory text;

ii. Revise paragraphs (f)(1) and (f)(2);

iii. Redesignate paragraph (f)(3) as paragraph (f)(4); and

iv. Add a new paragraph (f)(3).

The revisions and addition read as follows:

§ 25.17 Approval for processing applicants for access authorization.

* * * * *

(f) The Office of Personnel Management (OPM) bills the NRC for the cost of each background investigation conducted in support of an application for access authorization (application). The combined cost of the OPM investigation and the NRC's application processing overhead (NRC processing fee) are recovered through an access authorization fee imposed on applicants for access authorization.

(1) Each application for access authorization, renewal, or change in level must be accompanied by a remittance, payable to the U.S. Nuclear Regulatory Commission, which is equal to the NRC access authorization fee. This fee must be determined using the following formula: the OPM investigation billing rates on the day of NRC receipt of the application + the NRC processing fee = the NRC access authorization fee. The NRC processing fee is determined by multiplying the OPM investigation billing rate on the day of NRC receipt of the application by 55.8 percent (i.e., OPM rate × 55.8 percent).

(2) Updated OPM investigation billing rates are published periodically in a Federal Investigations Notice (FIN) issued by the OPM's Federal Investigative Services. Copies of the current OPM investigation billing rates schedule can be obtained by contacting the NRC's Personnel Security Branch, Division of Facilities Security, Office of Administration by email to *Licensee_Access_Authorization_Fee@nrc.gov*.

(3) The NRC's Information Access Authority Program (IAAP) is considered reimbursable work representing services provided to an organization for which the NRC is entitled payment. The NRC is authorized to receive and retain fees from licensees for services performed. The NRC's Office of the Chief Financial Officer periodically reviews the fees charged for IAAP and makes recommendations on revising those charges to reflect costs incurred by the NRC in providing those services. The reviews are performed using cost analysis techniques to determine the direct and indirect costs. Based on this review the IAAP fees are adjusted to reflect the current cost for the program. Copies of the current NRC access authorization fee may be obtained by contacting the NRC's Personnel Security Branch, Division of Facilities Security, Office of Administration by email to: *Licensee_Access_Authorization_Fee@nrc.gov*. Any change in the NRC's access authorization fee will be applicable to each access authorization request received on or after the effective date of the OPM's most recently published investigation billing rates schedule.

* * * * *

5. Appendix A to part 25 is revised to read as follows:

Appendix A to Part 25—Fees for NRC Access Authorization

The NRC application fee for an access authorization of type . . .	Is the sum of the current OPM investigation billing rate charged for an investigation of type . . .	Plus the NRC's processing fee (rounded to the nearest dollar), which is equal to the OPM investigation billing rate for the type of investigation referenced multiplied by . . .
Initial "L" access authorization[1]	ANACI—Access National Agency Check with Inquiries (Standard Service, Code C).	55.8%
Reinstatement of "L" access authorization[2]	No fee assessed for most applications	

The NRC application fee for an access authorization of type . . .	Is the sum of the current OPM investigation billing rate charged for an investigation of type . . .	Plus the NRC's processing fee (rounded to the nearest dollar), which is equal to the OPM investigation billing rate for the type of investigation referenced multiplied by . . .
Renewal of "L" access authorization [1]	NACLC—Access National Agency Check with Law and Credit (Standard Service, Code C).	55.8%
Initial "Q" access authorization	SSBI—Single Scope Background Investigation (Standard Service, Code C).	55.8%
Initial "Q" access authorization (expedited processing)	SSBI—Single Scope Background Investigation (Priority Handling, Code A).	55.8%
Reinstatement of "Q" access authorization [2]	No fee assessed for most applications	
Renewal of "Q" access authorization [1]	SSBI–PR—Periodic Reinvestigation for SSBI (Standard Service, Code C).	55.8%

[1] If the NRC determines, based on its review of available data, that a single scope investigation is necessary, the appropriate fee for an Initial "Q" access authorization will be assessed before the conduct of investigation.
[2] Full fee will only be charged if an investigation is required.

Dated at Rockville, Maryland, this 19th day of April 2012.

For the Nuclear Regulatory Commission.

R.W. Borchardt,

Executive Director for Operations.

[FR Doc. 2012–10710 Filed 5–2–12; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–0821; Directorate Identifier 2010–NE–30–AD]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede an existing airworthiness directive (AD) that applies to all Rolls-Royce plc (RR) RB211–Trent 875–17, RB211–Trent 877–17, RB211–Trent 884–17, RB211–Trent 884B–17, RB211–Trent 892–17, RB211–Trent 892B–17, and RB211–Trent 895–17 turbofan engines. The existing AD currently requires initial and repetitive ultrasonic inspections (UIs) of certain low-pressure (LP) compressor blades identified by serial number (S/N). This proposed AD would require the same actions but expands the population of blades. We are proposing this AD to prevent LP compressor blades from failing due to blade root cracks, which could lead to uncontained engine failure and damage to the airplane.

DATES: We must receive comments on this proposed AD by July 2, 2012.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ, telephone: 011–44–1332–242424; fax: 011–44–1332–245418, or email: *http://www.rolls-royce.com/contact/civil_team.jsp.* You may review copies of the referenced service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Alan Strom, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7143; fax: 781–238–7199; email: *alan.strom@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2010–0821; Directorate Identifier 2010–NE–30–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On March 20, 2012, we issued AD 2012–06–23, Amendment 39–17004 (77 FR 20508, April 5, 2012), for all RR RB211–Trent 875–17, RB211–Trent 877–17, RB211–Trent 884–17, RB211–Trent 884B–17, RB211–Trent 892–17, RB211–Trent 892B–17, and RB211–Trent 895–17 turbofan engines. That AD requires initial and repetitive UIs of certain LP compressor blades identified by S/N. That AD superseded AD 2011–08–07, Amendment 39–16657 (76 FR 24798, May 3, 2011) and resulted from RR concluding that additional blades affected must be inspected. We issued that AD to prevent LP compressor blades from failing due to blade root cracks, which could lead to uncontained

engine failure and damage to the airplane.

Actions Since Existing AD Was Issued

We issued AD 2012–06–23, Amendment 39–17004 (77 FR 20508, April 5, 2012), to ensure timely inspection of the listed blades in Appendices 3A through 3G of Rolls-Royce plc Alert Service Bulletin (ASB) No. RB.211–72–AG244, Revision 4, dated December 22, 2011. We now need AD action to add the inspection of the blades listed in Appendices 3H through 3L of that ASB.

Relevant Service Information

We reviewed Rolls-Royce plc ASB No. RB.211–72–AG244, Revision 4, dated December 22, 2011. The service information describes procedures for performing UIs of the LP compressor blades listed in Appendices 3A through 3L of that ASB.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would retain all of the requirements of AD 2012–06–23 (77 FR 20508, April 5, 2012). This proposed AD would require adding inspections of the blades listed in Appendices 3H through 3L of ASB No. RB.211–72–AG244, Revision 4, dated December 22, 2011. This proposed AD would also require accomplishing the actions specified in the service information described previously.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 158 engines installed on airplanes of U.S. registry. We also estimate that it would take about 3 hours per engine inspection, and six inspections per year. The average labor rate is $85 per work-hour. We estimate that one LP compressor blade per year would need replacement, at a cost of about $82,000. Based on these figures, we estimate the annual cost of the proposed AD on U.S. operators to be $323,740. Our cost estimate is exclusive of possible warranty coverage.

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),

(3) Will not affect intrastate aviation in Alaska, and

(4) 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.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, 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 FAA amends § 39.13 by removing airworthiness directive (AD) 2012–06–23, Amendment 39–17004 (77 FR 20508, April 5, 2012), and adding the following new AD:

Rolls-Royce plc: Docket No. FAA–2010–0821; Directorate Identifier 2010–NE–30–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by July 2, 2012.

(b) Affected ADs

This AD supersedes AD 2012–06–23, Amendment 39–17004 (77 FR 20508, April 5, 2012).

(c) Applicability

This AD applies to Rolls-Royce plc (RR) RB211–Trent 875–17, RB211–Trent 877–17, RB211–Trent 884–17, RB211–Trent 884B–17, RB211–Trent 892–17, RB211–Trent 892B–17, and RB211–Trent 895–17 turbofan engines.

(d) Unsafe Condition

This AD was prompted by the need to add the inspections of the low-pressure (LP) compressor blades listed by serial number (S/N) in Appendices 3H through 3L of Rolls-Royce plc Alert Service Bulletin (ASB) No. RB.211–72–AG244, Revision 4, dated December 22, 2011. We are issuing this AD to prevent LP compressor blades from failing due to blade root cracks, which could lead to uncontained engine failure and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Perform an initial ultrasonic inspection (UI) of the affected LP compressor blades identified by S/N in Appendices 3A through 3L of RR ASB No. RB.211–72–AG244, Revision 4, dated December 22, 2011. Use Table 1 of this AD to determine your initial inspection threshold.

TABLE 1—INITIAL INSPECTION THRESHOLDS

Appendix number of RR ASB No. RB.211–72–AG244, revision 4, that identifies affected LP compressor blades by S/N	Initial inspection threshold
3A and 3B	Within 70 flight cycles after the effective date of this AD.
3C	Within 10 months after the effective date of this AD.
3D	Within 22 months after the effective date of this AD.
3E	Within 34 months after the effective date of this AD.

TABLE 1—INITIAL INSPECTION THRESHOLDS—Continued

Appendix number of RR ASB No. RB.211–72–AG244, revision 4, that identifies affected LP compressor blades by S/N	Initial inspection threshold
3F	Within 46 months after the effective date of this AD.
3G	Within 58 months after the effective date of this AD.
3H	Within 70 months after the effective date of this AD.
3I	Within 82 months after the effective date of this AD.
3J	Within 94 months after the effective date of this AD.
3K	Within 106 months after the effective date of this AD.
3L	Within 118 months after the effective date of this AD.

(2) Thereafter, perform repetitive UIs of the affected LP compressor blades within every 100 flight cycles.

(3) Use paragraph 3.A.(2) of Accomplishment Instructions of RR ASB No. RB.211–72–AG244, Revision 4, dated December 22, 2011, and paragraphs 1. through 3.B. of Appendix 1 of that ASB, or paragraphs 3.B.(1) through 3.B.(3) of Accomplishment Instructions of RR ASB No. RB.211–72–AG244, Revision 4, dated December 22, 2011, and paragraphs 1. through 3.C. of Appendix 2 of that ASB, to perform the UIs.

(4) Do not return to service any engine with blades that failed the inspection required by this AD.

(5) For blades that are removed from the engine and pass inspection, re-apply dry film lubricant before re-installing the blades.

(6) After the effective date of this AD, do not install any affected LP compressor blade that has reached the initial inspection threshold in Table 1, unless it has passed the initial and repetitive UIs required by this AD.

(f) Credit for Actions Accomplished in Accordance With Previous Service Information

You may take credit for the initial inspection that is required by paragraph (e)(1) of this AD if you performed the initial inspection before the effective date of this AD using RR ASB No. RB.211–72–AG244, dated August 7, 2009; ASB No. RB.211–72–AG244, Revision 1, dated January 26, 2010; ASB No. RB.211–72–AG244, Revision 2, dated August 18, 2011; or ASB No. RB.211–72–AG244, Revision 3, dated December 13, 2011.

(g) Alternative Methods of Compliance

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(h) Related Information

(1) For more information about this AD, contact Alan Strom, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7143; fax: 781–238–7199; email: *alan.strom@faa.gov.*

(2) Refer to European Aviation Safety Agency AD 2012–0025, dated February 8, 2012, for related information.

(3) For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ, telephone: 011–44–1332–242424; fax: 011–44–1332–245418, or email: *http://www.rolls-royce.com/contact/civil_team.jsp.* You may review copies of the referenced service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on April 27, 2012.

Colleen M. D'Alessandro,

Assistant Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2012–10693 Filed 5–2–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5, 200, 207, and 232

[Docket No. FR–5465 P–01]

RIN–2502–AJ05

Federal Housing Administration (FHA): Section 232 Healthcare Facility Insurance Program-Strengthening Accountability and Regulatory Revisions Update

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Proposed rule.

SUMMARY: In 2010 through 2011, HUD commenced and completed the process of revising regulations applicable to, and closing documents used in, FHA insurance of multifamily rental projects, to reflect current policy and practices in the multifamily mortgage market. The multifamily rental project regulations and closing documents had not been updated in more than 20 years. Through this proposed rule, HUD commences a similar process for its regulations governing insurance of healthcare facilities under section 232 of the National Housing Act, and the closing documents used in such transactions. HUD's Section 232 program insures mortgage loans to facilitate the construction, substantial rehabilitation, purchase, and refinancing of nursing homes, intermediate care facilities, board and care homes, and assisted-living facilities. This rule proposes amendments to update HUD's Section 232 regulations, to reflect current policy and practices, and to improve accountability and strengthen risk management.

DATES: Comment Due Date: July 2, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule. *No Facsimile Comments.* Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 1–800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Michael B. Vaughn, Director, Office of Residential Care Facilities, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6264, Washington, DC 20410–8000; telephone number 202–708–0599 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The American population is undergoing a significant demographic change as an increasing portion is age 65 or older or approaching 65.[1] As several governmental and private organizations have reported, the growing number of older adults is placing increased demands on the public health system and on medical and social services.[2] These demands include greater need for nursing homes, long-term care facilities, and assisted living arrangements. Further, although options for long-term care and assisted living have expanded, nursing homes will likely retain a major role in caring for the most severely impaired and vulnerable populations.[3] Moreover, nursing homes are increasingly offering medical services similar to those offered in hospitals after surgery, illness, or other sudden medical problems. In those situations, older adults in particular need a higher level of care because hospital stays are shorter than previously.[4]

The Section 232 Program

Section 232 of the National Housing Act (12 U.S.C. 1715w) (Section 232) authorizes FHA to insure mortgages made by private lenders to finance the development of nursing homes, intermediate care facilities, board and care homes, and assisted living facilities (collectively, residential healthcare facilities). The Section 232 program allows for long-term, fixed-rate financing for new and rehabilitated properties for up to 40 years. Existing properties without rehabilitation can be financed with or without Ginnie Mae[5] Mortgage Backed Securities for up to 35 years.

Eligible borrowers under the Section 232 program include investors, builders, developers, public entities (nursing homes), and private nonprofit corporations and associations. For nursing homes only, applicants may be public agencies that are licensed or regulated by a state to care for convalescents and people who need nursing or intermediate care. The documents executed at loan closing provide that the borrower entity may not engage in any other business or activity.

Facilities covered by an FHA-insured mortgage under the Section 232 program must accommodate 20 or more residents who require skilled nursing care and related medical services, or those who, while not in need of nursing home care, are in need of minimum but continuous care provided by licensed or trained personnel. Assisted living facilities, nursing homes, intermediate care facilities, and board and care homes may be combined in the same facility covered by an insured mortgage or may be in separate facilities. Insured mortgages may include the cost of major movable equipment, daycare facilities, and the installation of fire safety equipment. Assisted living facilities, nursing homes, intermediate care homes, and board and care homes must be licensed or regulated by the appropriate state agency, municipality, or other political subdivision where the facility is located.

The maximum amount of the loan for new construction and substantial rehabilitation is equal to 90 percent (95 percent for nonprofit organization sponsors) of the estimated value of physical improvements and major movable equipment. For existing projects, the maximum is 85 percent (90 percent for nonprofit organization sponsors) of the estimated value of the physical improvements and major movable equipment.

As the need for residential care facilities has expanded, requests to FHA to make mortgage insurance available for such facilities has also expanded. As with any program expansion, FHA seeks to ensure that program requirements currently in place are sufficient to meet increased demand, and prevent mortgage defaults that not only impose a risk to the FHA insurance fund but also jeopardize residents of Section 232 facilities.

The Need for Regulatory Update

HUD's regulations governing the Section 232 program are codified in 24 CFR part 232. These regulations were promulgated in 1971, with some revisions made in the 1970s and the 1980s. Two regulatory updates were issued in the 1990s. On November 29, 1994, HUD issued a final rule that amended the Section 232 regulations to implement statutory authority to insure assisted living facilities for the care of frail elderly persons, as authorized by section 511 of the Housing and Community Development Act of 1992 (Pub. L. 102–550, approved October 28, 1992). (See 59 FR 61228.) On April 1, 1996, HUD issued a final rule to comply with the then-Administration's regulatory review initiative to streamline regulations, including by removing obsolete ones. (See 63 FR 14396.) The preamble to that final rule stated that the only changes being made to the Section 232 regulations were to remove the regulatory provisions concerning lender eligibility and to provide a cross-reference to 24 CFR part 200, subpart A, which addressed the general eligibility requirements to be approved as an FHA-approved lender. (See 63 FR 14397.) The 1996 rule was the last time that HUD amended the Section 232 regulations. Given the far greater demand today for nursing homes, and long-term care and assisted living facilities, and the changes, over the years, in how these facilities offer services to an aging population, as discussed above, HUD's Section 232 regulations need to be revised and updated.

In the 1970s, regulations governing FHA-insured transactions were generally structured so that details pertaining to the duties and obligations of parties involved in the transaction were primarily addressed in contractual documents, and that has been the case as well for the Section 232 regulations.

[1] See *http://www.aoa.gov/aoaroot/aging_statistics/index.aspx.*

[2] See *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5206a2.htm.*

[3] Bercovitz, Anita, Decker, Frederic H., Jones, Adrienne, Remsburg, Robin, *End of Life Care in Nursing Homes: 2004 National Nursing Home Survey,* National Health Statistics Reports, No. 9, October 8, 2008, pages 1 and 2.

[4] See *http://www.healthinaging.org/aginginthenow/chapters_print_ch_trial.asp?ch=15.*

[5] Ginnie Mae is a registered service mark of the Government National Mortgage Association; See *http://www.ginniemae.gov/.*

This approach has offered FHA and the parties to a transaction the necessary flexibility to adjust requirements as may be appropriate given the specifics of a given transaction, and HUD believes they should be retained for certain transaction aspects. After 16 years, however, certain policy and practices have developed that are not unique to certain parties and transactions and should be reflected in regulation. For example, since the operating revenues of the healthcare facility determine the financial health of the project and the FHA insurance fund, it has become clear that oversight by FHA of such revenues is vital.

II. This Proposed Rule

Through this rule, and similar to HUD's recent update of multifamily rental project regulations and closing documents, HUD proposes to update its Section 232 regulations and related closing documents. Notice of the publication of the documents is provided separately in the **Federal Register** through Notice FR–5623–N–01, Federal Housing Administration (FHA) Healthcare Facility Documents: Proposed Revisions and Updates and Notice of Information Collection. Through this proposed rule, HUD updates terminology and makes amendments to reflect current policy and practices. The specific amendments proposed to update HUD's Section 232 regulations by this rule follow. The update includes amendments to 24 CFR parts 5, 200, 207, and 232 dealing with, respectively, Uniform Reporting Standards, Real Estate Assessment Center (REAC) inspections, Multifamily Mortgage Insurance contract requirements, and strengthening of the eligibility and oversight provisions of the healthcare programs. As the most significant proposals are in 24 CFR part 232, these are addressed first in this part of the preamble.

A. Mortgage Insurance for Nursing Homes, Intermediate Care Facilities, Board and Care Homes, and Assisted Living Facilities (Part 232)

Nomenclature Change

In its review of the regulations in 24 CFR part 232, HUD noted that the regulations use both the term ''borrower'' and ''mortgagor.'' These terms have the same meaning, and to avoid any misunderstanding that they have different meanings, this proposed rule would substitute the term ''borrower'' for ''mortgagor'' throughout the part 232 regulations. Closing documents for the Section 232 program may sometimes refer to the borrower as the ''mortgagor,'' ''lessor,'' and/or the ''owner.''

Eligibility Requirements (Subpart A)

Subpart A of the part 232 regulations, entitled ''Eligibility Requirements,'' would be revised as follows:

The rule would revise eligibility requirements under § 232.1 to establish an exception from the multifamily program requirements for eligible borrowers. Eligible borrowers for multifamily projects are addressed in 24 CFR 200.5.

A new § 232.3 is added to part 232 to provide an appropriate definition of an eligible borrower for healthcare facilities. In a Section 232 transaction, HUD maintains a relationship with the borrower, and the borrower assumes a responsibility to ensure the appropriate maintenance and use of project assets. Given the importance of this relationship, the proposed rule would include a new definition of eligible borrower in § 232.3. This revised definition would conform to current legal changes in the forms of commercial property ownership. HUD notes that the single asset entity form of ownership has become the standard form of ownership for commercial real estate transactions. The revised definition, therefore, provides that the borrower shall be a single asset borrower entity acceptable to the Federal Housing Commissioner (Commissioner) and shall possess the power necessary and incidental to operating the project. The regulation provides that the Commissioner may approve an exception to this single asset requirement in limited circumstances based upon such criteria as may be specified by the Commissioner.

The rule would redesignate existing eligibility requirements presently contained in current § 232.3. That section presently establishes the standards for healthcare facility bathroom and resident ratios and access. Moving this section to § 232.7 would merely restructure the sequence of the eligibility requirements in the regulations.

The rule would add a new § 232.9 to define mortgaged property. Mortgaged property would be defined to include all of the borrower's interest in any property, real, personal, or mixed, covered by the mortgage or mortgages securing the note endorsed for insurance or held by the Secretary. This definition is consistent with the definition of mortgaged property currently in the Security Agreement, used in Section 232 transactions, and as used in the revised Borrower's Security Instrument.

The rule would add § 232.11 to require borrowers to establish at final closing and maintain throughout the term of the mortgage loan a long-term debt service reserve account. Given the complexities of, and volatility of both funding for and market demand for residential care facilities, such reserve account is important for improved risk management. The reserve account may be financed from mortgage proceeds, provided that the loan remains within the loan to value ratio. (See § 232.903, discussed below.) The amount required to be initially placed in the borrower's long-term debt service reserve account, and the minimum long-term balance to be *maintained* in that account, will be determined during underwriting and separately identified in the firm commitment. Although HUD may, under certain circumstances, permit the balance to fall below the required minimum long-term balance, the owner may not take any distribution except when both the long-term debt service reserve account is funded at the minimal long-term level and such distribution is otherwise permissible. The proposed establishment of the long-term debt service reserve account is in conjunction with the proposals governing the use and distribution of project funds, which is discussed below. This long-term reserve account would be required for new loans and refinancings.

Contract Rights and Obligations (Subpart B)

Subpart B of the part 232 regulations addresses contract rights and obligations to which all section 232 transactions are subject unless otherwise specified in another regulatory section in part 232.

Section 232.251, entitled ''Cross-Reference,'' would be retitled ''Other Applicable Regulations'' and would continue to include the regulations cross-referenced in existing § 232.251, but also clarify the applicability of the new provisions included in subpart B.

The rule would add a new § 232.254 to provide that borrowers may, to the extent allowed in their transactional loan documents and applicable law, make and take distributions of mortgaged property. Although previously the borrower could take distributions only annually (or, in limited circumstances, semi-annually), the proposed rule would allow borrowers to take distributions more frequently, provided that, upon making a calculation of borrower surplus cash, no less frequently than semi-annually, they can demonstrate positive surplus cash in their semi-annual financial reports or repay any distributions made

during the fiscal period to the extent that they are not in a positive surplus cash position at the end of the fiscal period in which distributions are made. HUD has included language in the proposed regulation to clarify that it does not intend to override existing transactional agreements.

The proposed rule provides that upon each calculation of borrower surplus cash, the borrower must demonstrate positive surplus cash, or, to the extent that surplus cash is negative, the borrower must repay any distributions taken during such calculation period within 30 days or within such shorter period as may be required by HUD. The borrower shall be deemed to have taken distributions to the extent that surplus cash is negative unless, in conjunction with the calculation of surplus cash, the borrower provides to HUD documentation evidencing, to HUD's reasonable satisfaction, a lesser amount of total distributions.

New § 232.254 would also include a definition of borrower surplus cash, which would be defined in the Borrower Regulatory Agreement.

The rule would add a new § 232.256 to require that a borrower may not lease any portion of the project, or enter into any agreement with an operator without HUD's prior written consent.

The rule would revise the introductory paragraph of § 232.903, relating to the § 232/223(f) program, by amending the maximum mortgage amounts to provide that the new debt service reserve account may be considered part of the cost of financing. No such amendment is necessary for any § 232 programs other than § 232/223(f), since, for other programs, funding of the debt service reserve is an eligible cost that may be funded from mortgage proceeds to the extent that the insured loan remains below the maximum loan to value ratio.

Eligible Operators and Facilities and Restrictions on Fund Distributions (New Subpart F)

This proposed rule would add to part 232 a new subpart F entitled, ''Eligible Operators and Facilities and Restrictions on Fund Distributions.'' As noted earlier in this preamble, operators carry out significant day-to-day duties in the administration of healthcare facilities. HUD finds that this important role needs to be explicitly addressed in regulation, by providing for the requisite accountability by such entities. The proposed new provisions recognize that a borrower may share its responsibility over the project with another entity. However, the fact that a borrower chooses to contract with a separate entity to operate the project does not relieve the borrower of its obligation to safeguard and ensure the proper use of all project assets, or of its obligation to ensure that acts of the operator do not cause the borrower to be in noncompliance with the borrower's own obligations. Instead, these new provisions are directed to ensuring that an operator, which may be an entity separate from the borrower, is also required to safeguard and ensure the proper use of all project assets.

New § 232.1001 would advise that the scope of this new subpart is to establish the requirements applicable to the operator of a residential care facility under the Section 232 regulations.

New § 232.1003 would define several key terms used in a Section 232 transaction. Section 232.1003 would define ''project,'' ''identity of interest projects,'' ''management agent,'' ''operator,'' and ''owner operator''.

New § 232.1005 would address commingling of funds and direct that an operator must not, without HUD's prior approval, allow funds attributable to an FHA-insured or HUD-held healthcare facility to be commingled with funds attributable to another healthcare facility or business.

New § 232.1007 would provide that payments from operating funds for goods and services must be reasonable and not exceed amounts normally paid for such goods or services in the geographic area where the services are rendered or the goods are furnished, unless otherwise approved by HUD.

New § 232.1009 provides that no principal of the borrower entity may receive a salary or any payment of funds derived from operation of the project, other than from permissible distributions, without HUD's prior approval.

Violations of these requirements on the use of project assets and income would be subject to double damages, in addition to HUD's other remedies, pursuant to statutory amendments, described hereinafter, enacted in 2004. Section 421 of the Housing and Community Development Act of 1987 (12 U.S.C. 1715z–4a), entitled ''Double damages remedy for unauthorized use of multifamily housing project assets and income,'' was amended by section 220 of Title II of Division I of the Consolidated Appropriations Act, 2005 (Public Law 108–447, 118 Stat. 2809, approved December 8, 2004), to expressly provide that a violation by ''any person'' of a regulatory agreement that applies to ''a nursing home, intermediate care facility, board and care home, assisted living facility, or hospital whose mortgage is or, at the time of the violations, was insured or held by the Secretary under title II of the National Housing Act'' is subject to the double damages provisions of 12 U.S.C. 1715z–4a (See 118 Stat. 3320, and 12 U.S.C. 1715z–4a(a)(1)(A).) Section 220 further amended section 421 to include as ''any person'' subject to double damages ''any nursing home lessee or operator'' and to permit an action for double damages ''to recover any assets or income used by a person in violation of * * * any applicable regulation.'' (See 12 U.S.C. 1715z–4a(a)(2)(D) and 12 U.S.C. 1715z–4a(a)(1)(D).) Any assets or income used in violation of these regulatory requirements would be subject to double damages under section 421, as well as to all other remedies available to HUD, in the same way that use of assets or income in violation of a regulatory agreement is subject to such double damages and other remedies.

New § 232.1011 would address financial statements, which are also discussed in the proposed amendment to 24 CFR 5.801 below. This new section provides that, within 90 days following the end of each fiscal year, the owner must provide HUD with audited financial statements. These audited financial statements must be prepared and certified in accordance with the requirements of 24 CFR 5.801 and 200.36. The operator must provide HUD with complete quarterly and year-to-date financial reports based on an examination of the books and records of the operator's operations with respect to the healthcare facility.

New § 232.1013 would address leases and would provide that, except as provided in residential agreements in the normal course of business, an operator may not lease or sublease any portion of the project without HUD's prior written approval.

New § 232.1015 would address the role of management agents in a Section 232 project and would provide that an operator may, with the prior written approval of HUD, execute a management agent agreement setting forth the duties and procedures for managing matters related to the project. However, both the management agent and the management agent agreement must be acceptable to HUD and approved in writing by HUD. New § 232.1015 also provides that an operator may not enter into any agreement that provides for a management agent to have rights to or claims on funds owed to the operator.

New § 232.1015 would also address fees paid by an operator or borrower to a management agent. This section provides that management agent agreements and the fees set forth therein

must be approved by HUD, and that the fee may not be renegotiated without HUD's approval once the management agent agreement has been executed. New § 232.1015 also provides that HUD may approve an identity-of-interest management agent to be a management agent only if amounts paid to the identity-of-interest agent for goods and services provided to the healthcare facility are not in excess of amounts that would be charged by an independent agent and only if all goods and services benefit the project.

New § 232.1017 would address treatment of project revenue. New § 232.1017(a) directs that an operator must deposit in a separate segregated account in the project's name all revenue the operator receives operating the healthcare facility, and that the account must be with a financial institution whose deposits are insured by an agency of the Federal Government, provided that, in order to minimize risk to the insurance fund, where balances are likely to exceed federal limits on insurance of such deposits, funds must be in depository institutions acceptable to Ginnie Mae.

New § 232.1017(b) provides that operators, whether owner-operators or non-owner operators, must ensure that the healthcare facility maintain positive working capital at all times. If a quarterly financial statement demonstrates negative working capital, the operator must cure such violation or HUD may declare a default of the operator's regulatory agreement and pursue remedies.

New § 232.1019 reflects recognition of the highly regulated environment in which many Section 232 projects operate, and would require operators, unless HUD determines otherwise, to promptly notify the owner, mortgagee, and HUD of certain matters placing the facility's viable operation, and thus the mortgage security, at substantial risk. These matters include violations of permits and approvals, imposition of civil money penalties, or governmental investigations or inquiries involving fraud. HUD has determined that, given the responsibilities of servicing lenders with respect to risk mitigation of their residential care facility portfolio, it is appropriate that the lenders are timely provided with the same financial, census, and performance data (of the owner entity, as well as operator entity) that HUD is requiring borrowers and operators to routinely provide to HUD. Accordingly, this regulatory section provides that, concurrently with submitting to HUD financial data and census and performance data, the borrower and operator also provide this data to the servicing lender.

In addition to the amendments made to the Section 232 regulations, HUD makes the following conforming amendments to 24 CFR parts 5, 200, and 207.

B. Uniform Financial Reporting Standards (24 CFR Part 5; § 5.801)

This proposed rule would amend the reporting requirements of 24 CFR 5.801 to include operators of projects with mortgages insured or held by HUD under the Section 232 program as entities that must submit financial reports. Borrowers are currently subject to this regulatory reporting requirement. HUD has determined that the audited financial statements of a borrower/owner are not sufficient to assess the financial status of a Section 232 project, because the viability of the project is heavily dependent on the operator's financial performance. HUD must also receive and review the financial statements of the operator, as may be applicable, for an accurate assessment of the project's financial status.

This proposed rule would, therefore, require owners to submit audited financial statements on an annual basis and would require operators to submit financial statements quarterly, covering separately the most recent quarter and the fiscal year to date. Quarterly and year-to-date financial statements are appropriate for operators for a number of reasons. First, they provide much more timely notice of operator financial weaknesses and trends than annual statements would provide. The timeliness is further enhanced in that the operator statements may be operator-certified rather than audited, allowing the operator to provide them much more promptly at the end of a reporting period. With respect to the skilled nursing facilities (of which a large portion of HUD's residential care facility portfolio is comprised), much of the information is also furnished in Medicare and Medicaid Cost Reports to fulfill other government obligations and serve as a basis for reimbursement, a practice that provides an additional check on accuracy.

This proposed rule also amends the reporting requirements with respect to facilities insured under Section 232, by specifying that the financial statements being submitted to HUD must be concurrently submitted to the servicing lender. Given the servicing lenders' responsibilities with respect to risk mitigation of their residential care facility portfolio, and given the difficulty that some lenders have in obtaining financial data related to the facility, it is appropriate that the lenders be timely provided the same financial data (of the owner entity, as well as the operator entity) that HUD is requiring borrowers and operators to routinely provide to HUD. Both owner and operator financial reporting requirements would apply beginning with the year in which the final rule following this proposed rule becomes effective.

C. Introduction to FHA Programs: Physical Condition of Multifamily Properties (Part 200, Subpart P)

Section 200.855(c) of HUD's regulations (24 CFR 200.855(c)), which addresses timing of inspections, would narrow and streamline the scope of Section 232 facilities that are routinely inspected by the Real Estate Assessment Center (REAC). In particular, facilities such as assisted living facilities and board and care facilities would be subject to routine REAC inspections unless the state or local government had a reliable and adequate inspection system in place. The remainder of the Section 232 properties, and properties that are routinely surveyed pursuant to regulations of the Centers for Medicare and Medicaid Services, would be inspected only when and if HUD determined, on a case-by-case basis and on the basis of information received, that inspection of such facility is needed to assure protection of residents or the adequate preservation of the project. This amendment would help assure that facilities surveyed frequently by state regulatory agencies, for physical condition matters related to resident care and safety, are not subject to duplicative inspections. HUD- and FHA-approved mortgagees now have ready electronic access to the results of state agency inspections conducted pursuant to requirements of the Centers for Medicare and Medicaid Services.

D. Multifamily Housing Mortgage Insurance (Part 207)

Contract Rights and Obligations (Subpart B)

Subpart B of the part 232 regulations addresses contract rights and obligations and the rights and duties of the mortgagee under the contract of insurance.

HUD is taking this opportunity to make changes to HUD's regulations in this subpart affecting the Section 232 programs. These proposed changes alter several of the amendments to the multifamily regulations adopted last spring. (See 76 FR 24363 May 11, 2011, HUD Multifamily Rental Projects: Regulatory Revisions.)

Section 207.255, ''Defaults for purposes of insurance claim,'' includes language defining the date of defaults. This proposed rule revises § 207.255(a)(4) by clarifying the dates on which certain monetary and other defaults occur.

This proposed rule modifies § 207.258, ''Insurance claim requirements,'' by deleting in paragraph (a)(2) a parenthetical expression.

This proposed rule also modifies § 207.258(b)(1)(i) by clarifying the time period within which a mortgagee may elect to assign a mortgage to the Commissioner.

E. Costs and Benefits of Proposed Revisions to the Section 232 Program Regulations

As discussed in this preamble, this proposed rule updates HUD's Section 232 program regulations similar to the 2011 updates that were made to HUD's multifamily rental project regulations and accompanying closing documents. The revisions proposed by this rule update the Section 232 regulations to reflect existing practices in financing and refinancing healthcare facilities, and to decrease risk to the program due to outdated regulations and the need for greater accountability by healthcare facility operators. Key changes highlighted in the preamble include requiring borrowers to establish a long term debt-service reserve account, requiring operators to submit quarterly and year-to-date self-certified financial reports, and reducing duplicative physical inspections.

The valued benefits from fewer physical inspections, and the costs from increased financial reporting and the opportunity cost of the debt service reserve fund, each total less than $1 million. Unvalued benefits include uninterrupted services of healthcare facilities, which otherwise would close due to foreclosure. Transfers from avoided claim payments total $13 million. The total costs, benefits, and transfers of this rule will not in any year exceed the $100 million threshold set by Executive Order 12866 (Regulatory Planning and Review). Therefore, the rule is not economically significant.

The risk mitigation requirements proposed by this rule are necessary due to the combination of two particular risks facing healthcare facilities. First, similar to multifamily residential properties, the owner usually relies on a separate entity to operate the facility. The performance of the operator is crucial to the mortgagor's ability to repay the mortgage. Since the operator may not be known to FHA at the time of underwriting, or may change during the term of the mortgage, the risk of operator deficiency is difficult to assess. Second, unlike residential or other commercial properties, the value of a poorly maintained and operated facility can decrease dramatically because the building was designed specifically for healthcare use and may not retain the mortgaged value at resale due to a lack of alternative uses. Thus, FHA may face more uncertainty when selling foreclosed healthcare properties than foreclosed residential properties. This rule therefore proposes requirements intended to identify operator deficiencies earlier and ensure that funds are available if financial problems arise.

The rule also proposes to require the borrower to establish a long-term debt service reserve fund. Although FHA currently requires owners of new construction projects to maintain a reserve fund until sustainable occupancy is reached, usually one to two years, this new requirement would require a reserve fund to be maintained throughout the life of the mortgage and used in case of operator deficiency. Of the 30 insurance claims from 2009 to mid-2011, operator deficiencies played a role in the property's performance demise in 23. Further, these claims were distributed widely over age of loan, not simply in the first few years, indicating the need for a reserve fund over the life of the mortgage. The maintenance of a reserve is to decrease the number of nonperforming mortgages by providing additional time to resolve operator deficiencies.

Based on FHA's experience, a reserve fund can be an important source for debt service payments during a period of instability. Thus, the reserve can delay the point at which a lender finds it necessary to file a claim, providing extra time for the parties to restructure and stabilize a project and avoid a claim to HUD. FHA has accepted claims where borrowers were pursuing workouts, but stability could not be achieved prior to the lenders' expenses becoming too burdensome to sustain. The extra time afforded by a debt service reserve makes avoiding a claim more likely under such scenarios. In its analysis of 2009, 2010, and early 2011 claims, HUD found that 5 out of 30 projects brought to claim may have benefited from the additional time provided by a debt service reserve. Finally, as an additional offset for borrowers to the added requirement of debt service reserve, the rule also provides greater flexibility to borrowers in the making of distributions and use of surplus cash. Assuming that, as a result of the rule, 2 fewer claims were paid annually, FHA would save $13 million per year, if projected based on the average unpaid balance (UPB) of assigned Section 232 mortgages from 2009–2011, which was $6.5 million. In the absence of these claim payments, FHA could pass these savings on to its mortgagors and thus such savings are best viewed as a transfer between borrowers.

The amount of funds required to be initially placed in the debt service reserve fund, and the minimum long-term balance, will be determined during underwriting. FHA estimates that on average, a borrower's monthly debt service will increase by approximately 1.5 percent. Based on an expected average of $3.4 billion annually in the value of new mortgage endorsements, borrowers would be required, in aggregate, to place and maintain $51 million in the fund. The cost to borrowers is the lower return from restricting this amount to the reserve fund compared to other investment options. This opportunity cost of holding these funds in a reserve account is, therefore, calculated as the difference between the average market rate of return and the risk-free interest rate. The average market rate is represented by the real annualized return of the S&P 500 between 1990 and 2011, which equals 5.37 percent. The risk-free interest rate is the average 10-year Treasury rate between 1990 and 2011, which equals 2.6 percent. The opportunity cost of holding the estimated funds in a reserve fund totals $141,270.

This rule also requires operators to submit annual and year-to-date financial reports. Currently, the borrower, but not the operator, is required to provide audited financial statements. Although submission of the operator's financial reports is a new requirement, the expense of such reports is mitigated by allowing the operator to submit self-certified, rather than audited statements. Moreover, the required operator financial information is data that operators need to maintain in the normal course of business in order to monitor and manage their own operations effectively. FHA estimates this will require approximately 10,000 employee hours annually to prepare and submit these reports (2,500 respondents, 4 reports per year and 1 hour to generate each report). The median wage of the employees who prepare these reports is approximately $75 per hour. Thus, the total cost of complying with this requirement would be $750,000.

Finally, this rule exempts facilities from FHA physical inspection requirements if they are inspected by

state or local agencies in order to eliminate duplicative inspections. FHA estimates that, as a result, approximately 1,391 inspections would be avoided per year. The estimated cost per inspection totals $475, which would mean a total annual inspection savings of $660,725.

In addition to the valued benefits, this rule also provides benefits that are less easily quantified. As explained above, HUD expects the reserve fund and financial reporting requirements to decrease the number of claims paid. While some troubled facilities may be stabilized and continue operating, at this stage of delinquency, they are often forced to close. Thus, there is a disruption of healthcare services to the community and costs to moving residents from one facility to another. In smaller communities, there are fewer alternatives for facility residents, and the benefits of avoiding foreclosure are greater as residents may be without needed services for a long period. In larger cities, existing facilities may be able to absorb the additional demand fairly quickly. In both of these cases, however, residents bear costs associated with transferring between facilities. Although the avoided loss or interruption of services is difficult to quantify and varies by city, the avoided loss or interruption of services is an important benefit that this rule is trying to achieve.

SUMMARY OF VALUED ANNUAL BENEFITS, COSTS, AND TRANSFERS

	Benefits	Costs	Transfers
Debt Service Reserve Fund	$660,725	$141,270	$13,000,000
Financial Reporting	.....	750,000	.....
Physical Inspections.			
Total	660,725	891,270	13,000,000

III. Findings and Certifications

Executive Order 13563, Regulatory Review

The President's Executive Order (EO) 13563, entitled ''Improving Regulation and Regulatory Review,'' was signed by the President on January 18, 2011, and published on January 21, 2011, at 76 FR 3821. This EO requires executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' Section 4 of the EO, entitled ''Flexible Approaches,'' provides, in relevant part, that where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. As discussed earlier in this preamble, the Section 232 regulations have not been updated since 1996. HUD submits that the changes proposed by this rule to the Section 232 regulations are consistent with the EO's directions. As the preceding section discussed, the changes proposed by this rule will modernize the Section 232 program, reduce burden by eliminating duplicative physical inspections, providing flexibility to borrowers in the making of distributions and use of surplus cash, and increasing accountability to strengthen the program, thereby helping it ensure that it remains viable for the financing of healthcare facilities.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

This rule is directed to creating transparency in HUD's Section 232 program by, codifying existing and longstanding provisions imposed on a Section 232 borrower, and strengthening this program through stronger risk management practices, such as making operators more accountable for their role in administering Section 232 healthcare facilities. As noted under the discussion of EO 13563, this rule proposes amendments that will enhance HUD's oversight ability, while minimizing the burdens on private actors, to the benefit of participants and facility clients. Additionally, by clarifying and codifying existing requirements, the rule makes it easier for borrowers and operators to comply with their legal obligations. Through this rule, the viability of the Section 232 program and HUD's enforcement authority are increased, and waste, fraud, and abuse are reduced.

Approximately 3,343 of the anticipated annual participants in the Section 232 program are small entities, including approximately 2,500 entities involved in nursing homes, 725 entities involved in assisted living facilities, and 70 other entities. (The total figure exceeds the number of facilities involved, because a single transaction many involve distinct legal entities serving as the operator and owner.) The changes required by this rule do not impose significant economic impacts on these small entities or otherwise adversely disproportionately burden such small entities. The reporting requirements of this rule have been tailored to complement normal business accounting practices. Accordingly, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Notwithstanding HUD's determination that this rule will not have a significant effect on a substantial number of small entities, HUD specifically invites comments regarding any less burdensome alternatives to this rule that will meet HUD's objectives as described in this preamble.

Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made, in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). That finding is available for public inspection between the hours of 8 a.m. and 5 p.m. weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the finding by calling the Regulations Division at 202–402–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this

number via TTY by calling the Federal Relay Service at 800–877–8339.

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either: (1) Imposes substantial direct compliance costs on state and local governments and is not required by statute, or (2) preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This rule will not have federalism implications and would not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. This proposed rule does not impose any federal mandates on any state, local, or tribal governments, or on the private sector, within the meaning of UMRA.

Information Collection Requirements

The information collection requirements contained in this proposed rule have been submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number.

The burden of the information collections in this proposed rule is estimated as follows:

REPORTING AND RECORDKEEPING BURDEN

Section reference	Number of respondents	Number of responses per respondent	Estimated average time for requirement (in hours)	Estimated annual burden (in hours)
24 CFR 5.801(c)(4) Financial information	2,500	4	1	10,000
24 CFR 232.11 HUD written approval	100	1	1	100
24 CFR 232.1005 HUD written approval	25	1	1	25
24 CFR 232.1007 HUD approval	25	1	1	25
24 CFR 232.1009 HUD written approval	50	1	1	50
24 CFR 232.1011 Financial statement	2,500	1	60	150,000
24 CFR 232.1013 Specifications for lease agreement, HUD written approval	25	1	1	25
24 CFR 232.1015 HUD written approval	25	1	1	25
24 CFR 232.1017 HUD written approval	25	1	1	25
24 CFR 232.1019 HUD written approval	1,750	2	.50	1,750
Totals	7,025	14	68.5	162,025

In accordance with 5 CFR 1320.8(d)(1), HUD is soliciting comments from members of the public and affected agency concerning this collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of HUD, including whether the information will have practical utility;

(2) Evaluate the accuracy of HUD's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology; e.g., permitting electronic submission of responses.

Interested persons are invited to submit comments regarding the information collection requirements in this rule. Comments must refer to the proposal by name and docket number (FR–5465–P–01) and must be sent to:

HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503. Fax number: 202–395–6947. and

Reports Liaison Officer, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room 9116, Washington, DC 20410–8000.

Interested persons may submit comments regarding the information collection requirements electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *http://www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

List of Subjects

24 CFR Part 5

Administrative practice and procedure, Aged, Claims, Grant programs—housing and community development, Individuals with disabilities, Intergovernmental relations, Loan programs—housing and community development, Low and moderate income housing, Mortgage insurance, Penalties, Pets, Public housing, Rent subsidies, Reporting and recordkeeping requirements, Social Security, Unemployment compensation, Wages.

24 CFR Part 200

Administrative practice and procedure, Claims, Equal employment opportunity, Fair housing, Home improvement, Housing standards, Lead poisoning, Loan programs—housing and community development, Mortgage insurance, Organization and functions (Government agencies), Penalties, Reporting and recordkeeping.

24 CFR Part 207

Mortgage insurance—Nursing homes, Intermediate care facilities, Board and

care homes, and Assisted living facilities.

24 CFR Part 232

Fire prevention, Health facilities, Loan programs—health, Loan programs—housing and community development, Mortgage insurance, Nursing homes, Reporting and recordkeeping requirements.

Accordingly, parts 5, 200, 207, and 232 of title 24 of the Code of Federal Regulations are proposed to be amended as follows:

PART 5—GENERAL HUD PROGRAM REQUIREMENTS; WAIVERS

1. The authority citation for 24 CFR part 5 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437d, 1437f, 1437n, 3535(d), and Sec. 327, Pub. L. 109–115, 119 Stat. 2936.

2. Amend § 5.801 to:

a. Add paragraph (a)(6),

b. Revise the first sentence of the introductory text of paragraph (b),

c. Add paragraph (b)(4),

d. Revise the heading of paragraph (c),

e. Add paragraph (c)(4), and

f. Add paragraph (d)(4) to read as follows:

§ 5.801 Uniform financial reporting standards.

(a) * * *

(6) Operators of projects with mortgages insured or held by HUD under section 232 of the Act (Mortgage Insurance for Nursing Homes, Intermediate Care Facilities, Board and Care Homes).

(b) Entities (or individuals) to which this subpart is applicable must provide to HUD such financial information as required by HUD. Such information must be provided on an annual basis, except as required more frequently under paragraph (c)(4) of this section. * * *

* * * * *

(4) With respect to financial reports relating to properties insured under Section 232 of the Act, concurrently with submitting the information to HUD, this information must also be submitted to the mortgagee in a format and manner prescribed by the Secretary.

(c) *Filing of financial reports.* * * * * * *

(4) For entities listed in paragraph (a)(6) of this section, the financial information to be submitted to HUD in accordance with paragraph (b) of this section must be submitted to HUD on a quarterly and fiscal-year-to-date basis, within 30 days of the end of each quarterly reporting period. The financial statements submitted pursuant to paragraph (a)(6) of this section may, at the operator's option, be operator-certified rather than audited, provided, however, that if the operator is also the borrower, then that entity's obligation to submit an annual audited financial statement within 90 days of its fiscal year end (in addition to its obligation as an operator to submit financial information on a quarterly and year-to-date basis) remains and is not obviated. Additionally, if HUD has reason to believe that a particular operator's operator-certified statements may be unreliable or are presented in a manner that is inconsistent with Generally Accepted Accounting Principles, HUD may, on a case-by-case basis, require audited financial statements from the operator. Additionally, with respect to facilities with FHA-insured or HUD-held Section 232 mortgages, HUD may request more frequent financial statements from the borrower, as specified under (a)(4)(x), and/or the operator on a case-by-case basis when the circumstances warrant. Nothing in the regulations in this section limits HUD's ability to obtain further or more frequent information when appropriate pursuant to the applicable regulatory agreement.

(d) * * *

(4) Entities described in paragraph (a)(6) of this section must comply with the requirements of this section with respect to fiscal years ending [*a date of one year after the effective date of the final rule to be inserted at the final rule stage*] and later.

* * * * *

PART 200—INTRODUCTION TO FHA PROGRAMS

3. The authority citation for part 200 continues to read as follows:

Authority: 12 U.S.C. 1702–1715–z–21; 42 U.S.C. 3535(d).

4. In 200.855, add a new paragraph (c)(5) to read as follows:

§ 200.855 Physical condition standards and physical inspection requirements.

* * * * *

(c) * * *

(5)(i) For Assisted Living Facilities and Board and Care Facilities, the initial inspection required under this subpart will be conducted within the same time restrictions set forth in paragraph 200.855(c)(4) immediately above, and any further inspections will be conducted at a frequency determined consistent with § 200.857, and

(ii) For any other Section 232 facilities, the inspection will be conducted only when and if HUD determines, on the basis of information received, such as through a complaint, site inspection, or referral by a state agency, on a case-by-case basis, that inspection of a particular facility is needed to assure protection of the residents or the adequate preservation of the project.

PART 207—MULTIFAMILY HOUSING MORTGAGE INSURANCE

5. The authority citation for part 207 continues to read as follows:

Authority: 12 U.S.C. 1701z–11(e), 1713, and 1715b; 42 U.S.C. 3535(d).

6. In § 207.255(a)(4) introductory text, remove the reference to ''paragraph (b)'' and add in its place a reference to ''paragraph (a)''.

7. In § 207.258 revise paragraphs (a)(2) introductory text and (b)(1)(i) to read as follows:

§ 207.258 Insurance claim requirements.

(a) * * *

(2) For mortgages funded with the proceeds of state or local bonds, GNMA mortgage-backed securities, participation certificates, or other bond obligations specified by the Commissioner (such as an agreement under which the insured mortgagee has obtained the mortgage funds from third-party investors and has agreed in writing to repay such investors at a stated interest rate and in accordance with a fixed repayment schedule), any of which contains a lock-out or prepayment premium, the mortgagee must, in the event of a default during the term of the prepayment lock-out or prepayment premium:

* * * * *

(b) * * *

(1) * * *

(i) If the mortgagee elects to assign the mortgage to the Commissioner, the mortgagee shall, at any time within 30 days after the date HUD acknowledges the notice of election, file its application for insurance benefits and assign to the Commissioner, in such manner as the Commissioner may require, any applicable credit instrument and the realty and chattel security instruments.

* * * * *

PART 232—MORTGAGE INSURANCE FOR NURSING HOMES, INTERMEDIATE CARE FACILITIES, BOARD AND CARE HOMES, AND ASSISTED LIVING FACILITIES

8. The authority citation for 24 CFR part 232 continues to read as follows:

Authority: 12 U.S.C. 1715b, 1715w; 42 U.S.C. 3535(d).

9. Throughout part 232, the word ''mortgagor'' is revised to read ''borrower'' wherever it appears.

10. Revise § 232.1 to read as follows:

§ 232.1 Eligibility requirements.

All of the requirements, except § 200.5, set forth in 24 CFR part 200 subpart A, apply to project mortgages insured under Section 232 of the National Housing Act (12 U.S.C. 1715w), as amended.

11. Redesignate § 232.3 as § 232.7 and add a new § 232.3 to read as follows:

§ 232.3 Eligible borrower.

For mortgages originated after *[a date of one year after the effective date of the final rule to be inserted at the final rule stage*], the borrower shall be a single asset entity acceptable to the Commissioner, as limited by the applicable section of the Act, and shall possess the powers necessary and incidental to operating the project, except that the Commissioner may approve a non-single asset borrower entity under such circumstances, terms, and conditions determined and specified as acceptable to the Commissioner.

12. Add new §§ 232.9 and 232.11 to read as follows:

§ 232.9 Mortgaged property.

Mortgaged property includes all of Borrower's interests in property, real, personal, or mixed, covered by the mortgage or mortgages securing the note endorsed for insurance or held by the Secretary, as further defined in the mortgage documents.

§ 232.11 Establishment and maintenance of long-term debt service reserve account.

To be eligible for insurance under this part, and except with respect to Supplemental Loans to Finance Purchase and Installation of Fire Safety Equipment (subpart C of this part), the borrower must establish at final closing and maintain throughout the term of the mortgage a long-term debt service reserve account. This long-term debt service reserve account may be financed as part of the initial mortgage amount, provided that the maximum mortgage amount as otherwise calculated is not thereby exceeded. The amount required to be initially placed in the long-term debt service reserve account and the minimum long-term balance to be maintained in that account will be determined during underwriting and separately identified in the firm commitment. Although HUD may, when appropriate to avert a mortgage insurance claim, permit the balance to fall below the required minimum long-term balance, the borrower may not take any distribution of mortgaged property except when both the long-term debt service reserve account is funded at the minimal long-term level and such distribution is otherwise permissible.

Subpart B—Contract Rights and Obligations

13. Revise § 232.251 to read as follows:

§ 232.251 Other applicable regulations.

(a) *Cross-reference.* (1) All of the provisions, except § 207.258b, of 24 CFR part 207, subpart B, relating to mortgages insured under section 207 of the National Housing Act, apply to mortgages insured under section 232 of the Act.

(2) For the purposes of this subpart, all references in 24 CFR part 207 to section 207 of the Act shall be construed to refer to section 232 of the Act.

(3) Unless otherwise specified in this part, the regulations in this subpart B apply to all mortgages insured under section 232 of the Act.

(b) [Reserved]

14. Add new §§ 232.254 and 232.256, to read as follows:

§ 232.254 Withdrawal of project funds, including for repayments of advances from the borrower, operator, or management agent.

(a) *General.* Borrower may make and take distributions of mortgaged property, as set forth in the mortgage loan transactional documents, to the extent and as permitted by the law of the applicable jurisdiction, provided that, upon each calculation of borrower surplus cash, which calculation shall be made no less frequently than semi-annually, borrower must demonstrate positive surplus cash, or to the extent surplus cash is negative, repay any distributions taken during such calculation period within 30 days or within such shorter period as may be required by HUD. Borrower shall be deemed to have taken distributions to the extent that surplus cash is negative unless, in conjunction with the calculation of surplus cash, borrower provides to HUD documentation evidencing, to HUD's reasonable satisfaction, a lesser amount of total distributions. To the extent that the provisions of this paragraph (a) are inconsistent with the provisions in a borrower's existing transactional loan documents, including without limitation any HUD-required regulatory agreement, the provisions of the transactional loan documents shall apply.

(b) *Definition.* Borrower surplus cash means any cash remaining in the Borrower's accounts after:

(1) The payment of:

(i) All sums due or currently required to be paid under the terms of any mortgage or note insured or held by the Secretary;

(ii) All amounts required to be deposited in the project's reserve fund for replacements, long-term debt service reserve account, or residual receipts account; and

(iii) All project obligations of the borrower other than the insured mortgage, unless funds for payment are set aside or deferment of payment has been approved by the Secretary; and

(2) The segregation of:

(i) An amount equal to the aggregate of all special funds required to be maintained by the project, including the long-term debt service escrow account;

(ii) Any tenant security deposits held; and

(iii) All other accrued items payable by borrower within 30 days after the end of the annual or semi-annual fiscal period for which surplus cash is calculated.

§ 232.256 Leases.

A borrower may not lease any portion of the project or enter into any other agreement with an operator without HUD's prior written consent.

15. Revise the introductory text of § 232.903, and § 232.903(c) and (d) to read as follows:

§ 232.903 Maximum mortgage limitations.

Notwithstanding the maximum mortgage limitations set forth in § 200.15 of this chapter, a mortgage within the limits set forth in this section shall be eligible for insurance under this subpart.

* * * * *

(c) *Project to be refinanced—additional limit.* (1) In addition to meeting the requirements of paragraphs (a) and (b) of this section, if the Project is to be refinanced by the insured mortgage, the maximum mortgage amount must not exceed the cost to refinance the existing indebtedness. For the purposes of this requirement:

(i) The Project shall not have changed ownership, or

(ii) The Project shall have been sold to a purchaser who has an identity of interest with the seller (as defined by the Commissioner).

(2) The existing indebtedness will consist of the following items, the eligibility and amounts of which must be determined by the Commissioner:

(i) The amount required to pay off the existing indebtedness;

(ii) The amount of the initial deposit for the reserve fund for replacements;

(iii) Reasonable and customary legal, organization, title, and recording expenses, including mortgagee fees under § 232.15;

(iv) The estimated repair costs, if any;

(v) Architect's and engineer's fees, municipal inspection fees, and any other required professional or inspection fees;

(vi) The amount of any debt service reserve account required by the Commissioner.

(d) *Project to be acquired—additional limit.* In addition to meeting the requirements of paragraphs (a) and (b) of this section, if the project is to be acquired by the borrower and the purchase price is to be financed with the insured mortgage, the maximum amount must not exceed 85 percent for a profit-motivated borrower and 90 percent for a private nonprofit borrower of the cost of acquisition as determined by the Commissioner. The cost of acquisition shall consist of the following items, to the extent that each item (except for item numbered (1)) is paid by the purchaser separately from the purchase price. The eligibility and amounts of these items must be determined in accordance with standards established by the Commissioner.

(1) Purchase price is indicated in the purchase agreement;

(2) An amount for the initial deposit to the reserve fund for replacements;

(3) Reasonable and customary legal, organizational, title, and recording expenses, including mortgagee fees under § 232.15;

(4) The estimated repair cost, if any;

(5) Architect's and engineer's fees, municipal inspection fees, and any other required professional or inspection fees;

(6) The amount of any debt service reserve account required by the Commissioner.

16. Add new subpart F to read as follows:

Subpart F—Eligible Operators and Facilities and Restrictions on Fund Distributions

Sec.

232.1001 Scope.
232.1003 Definitions.
232.1005 Treatment of project operating accounts.
232.1007 Operating expenses.
232.1009 Payments to borrower principals prohibited.
232.1011 Financial reports.
232.1013 Leases.
232.1015 Management agents.
232.1017 Restrictions on deposit, withdrawal, and distribution of funds, and repayment of advances.
232.1019 Prompt notification to HUD and mortgagee of circumstances placing the value of the security at risk.

Subpart F—Eligible Operators and Facilities and Restrictions on Fund Distributions

§ 232.1001 Scope.

This subpart establishes requirements applicable to the operators of healthcare facilities and the facilities under this part.

§ 232.1003 Definitions.

The following definitions apply throughout this part.

Identity-of-interest projects refers to those projects that are operated by a licensed operator and/or managed by a management agent who shares an identity of interest with the ownership entity.

Management agent means an entity that, pursuant to a contract with the operator or borrower, manages matters related to the project, subject to limitations set forth in § 232.1015.

Operator means a single asset entity acceptable to the Commissioner, and shall possess the powers necessary and incidental to operating the healthcare facility, except that the Commissioner may approve a non-single asset entity under such circumstances, terms, and conditions determined and specified as acceptable to the Commissioner.

Owner operator means an owner who operates its own project and does not lease the project or otherwise contract with an eligible operator. In that instance, the borrower entity and the operating entity are the exact same legal entity, and the owner operator must comply with regulatory provisions governing the use of funds for both operators and borrowers in § 232.254, § 232.1005, and § 232.1017.

Project means any and all assets of whatever nature or wherever situated related to the insured mortgage loan, including without limitation the mortgaged property, any site improvements, and any collateral owned by operators securing the insured mortgage loan.

§ 232.1005 Treatment of project operating accounts.

(a) All accounts deriving from the operation of the property, including operator accounts and including all funds received from any source or derived from the operation of the facility, are project assets subject to control under the insured mortgage loan's transactional documents, including, without limitation, the operator's regulatory agreement. Funds generated by the operation of the healthcare facility shall be deposited into a federally insured bank account in the name of the single asset operator of the facility, provided that an account held in an institution acceptable to the Government National Mortgage Association may have a balance that exceeds the amount to which such insurance is limited. If the borrower is not also the operator, any of owner's project-related funds shall be deposited into a federally insured bank account in the name of the single asset borrower.

(b) An operator must not allow funds attributable to the healthcare facility to be commingled with funds attributable to another healthcare facility or any other business unless approved by HUD. Any centralized accounting system involving project funds must have prior HUD approval and must clearly delineate which portion of the funds in an account are attributable to the particular facility.

(c) Except to the extent that the healthcare facility maintains positive working capital, an operator may not advance or otherwise use funds attributable to the operator's business at a project under this part to pay expenses attributable to any other project or business without the advance written approval of HUD.

§ 232.1007 Operating expenses.

Goods and services purchased or acquired in connection with the Project shall be reasonable and necessary for the operation or maintenance of the Project, and the costs of such goods and services incurred by the borrower or operator shall not exceed amounts normally paid for such goods or services in the area where the services are rendered or the goods are furnished, except as otherwise approved by HUD.

§ 232.1009 Payments to borrower principals prohibited.

No principal of the borrower entity may receive a salary or any payment of funds derived from operation of the project, other than from permissible distributions, except as approved by HUD.

§ 232.1011 Financial reports.

Within 90 days following the end of each entity's fiscal year, the borrower must provide HUD an audited annual financial report based on an examination of its books and records, in such form and substance required by HUD in accordance with 24 CFR 5.801 and 200.36. Operators must submit financial statements quarterly within 30 days of the date of the end of each fiscal quarter, setting forth both quarterly and

fiscal year-to-date information in accordance with 24 CFR 5.801(c)(4).

§ 232.1013 Leases.

Except to enter into resident agreements in the standard course of operating the healthcare facility, an operator may not lease or sublease any portion of the project without HUD's prior written approval.

§ 232.1015 Management agents.

(a) An operator or borrower may, with the prior written approval of HUD, execute a management agent agreement setting forth the duties and procedures for matters related to the management of the project. Both the management agent and the management agent agreement must be acceptable to HUD and approved in writing by HUD.

(b) An operator or borrower may not enter into any agreement that provides for a management agent to have rights to or claims on funds owed to the operator.

(c) Management agent fees may not be renegotiated without HUD's written approval once the management agent agreement has been executed.

(d) HUD may approve an identity of interest between a management agent and a borrower or operator only to the extent that the goods and services provided benefit the project and if the operator clearly establishes that the amounts paid to the identity-of-interest management agent for goods and services provided to the healthcare facility are not in excess of amounts that would be charged by an independent management agent.

§ 232.1017 Restrictions on deposit, withdrawal, and distribution of funds, and repayment of advances.

(a) *Deposit of funds.* An operator must deposit all revenue the operator receives directly or indirectly in connection with the operation of the healthcare facility in a separate, segregated account. The account must be with a financial institution whose deposits are insured by an agency of the Federal Government, *provided* that an account held in an institution acceptable to the Government National Mortgage Association may have a balance that exceeds the amount to which such insurance is limited.

(b) *Withdrawals of funds.* Operators, whether or not an operator is also the borrower, shall at all times maintain positive working capital for the healthcare facility. If a quarterly financial statement, required pursuant to § 232.1011, demonstrates negative working capital for the healthcare facility, the operator must cure such violation or HUD may pursue such remedies as set forth in the insured mortgage loan's transactional documents.

§ 232.1019 Prompt notification to HUD and mortgagee of circumstances placing the value of the security at risk.

(a) HUD and the mortgagee shall be informed of any notification of any failure to comply with governmental requirements including the following:

(1) The licensed operator of a project shall promptly provide the mortgagee and HUD with a copy of any notification that has placed the licensure, a provider funding source, and/or the ability to admit new residents at risk, and any responses to those notices, provided that HUD may determine certain information to be exempt from this requirement based upon severity level. Such required information shall include, but is not limited to, the following types of notices and responses:

(i) The operator shall deliver to HUD and the mortgagee electronically, within 48 hours after the date of receipt, copies of any and all notices, reports, surveys, and other correspondence (regardless of form) received by the operator from any governmental authority that includes any statement, finding, or assertion that:

(A) The operator or the project is or may be in violation of (or default under) any of the permits and approvals or any governmental requirements applicable thereto;

(B) Any of the permits and approvals is to be terminated, limited in any way, or not renewed;

(C) Any civil money penalty (other than a de minimis amount) is being or may be imposed; or

(D) The operator or the project is subject to any governmental investigation or inquiry involving fraud.

(ii) The operator shall also deliver to HUD and the mortgagee, simultaneously with delivery to any governmental authority, any and all responses given by or on behalf of the operator to any of the foregoing and shall provide to HUD and the mortgagee, promptly upon request, such additional information relating to any of the foregoing as HUD or the mortgagee may request. The receipt by HUD and/or the mortgagee of notices, reports, surveys, correspondence, and other information shall not in any way impose any obligation or liability on HUD, the mortgagee, or their respective agents, representatives, or designees to take (or refrain from taking) any action; and HUD, the mortgagee, and their respective agents, representatives, and designees shall have no liability for any failure to act thereon or as a result thereof.

(2) The operator shall provide additional and ongoing information as requested by the borrower, mortgagee, or HUD pertaining to matters related to that risk. Controlling documents between or among any of the parties may provide further requirements with respect to such notification and communication.

(b) This section is applicable to all operators on the effective date of this regulation.

Dated: April 12, 2012.

Carol J. Galante,

Acting Assistant Secretary for Housing—Federal Housing Commissioner .

[FR Doc. 2012–10690 Filed 5–2–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Meloy Channel, U.S. Coast Guard Base Miami Beach, FL; Restricted Area

AGENCY: United States Army Corps of Engineers, Department of Defense.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The U.S. Army Corps of Engineers (Corps) is proposing to amend its regulations to establish a new restricted area in the waters surrounding the U.S. Coast Guard Base Miami Beach, Florida (Base Miami Beach). Base Miami Beach is composed of multiple U.S. Coast Guard (USCG) units, both land and waterside. The facility has one of the highest operational tempos in the USCG for both routine and emergency operations. The amendment to the regulations is necessary to enhance the USCG's ability to secure their shoreline to counter postulated threats against their personnel, equipment, cutters and facilities by providing stand-off corridors encompassing the waters immediately contiguous to Base Miami Beach. The amendment will also serve to protect the general public from injury or property damage during routine and emergency USCG operations and provide an explosive safety arc buffer during periodic transfer of ammunitions between units, including cutters.

DATES: Written comments must be submitted on or before June 4, 2012.

ADDRESSES: You may submit comments, identified by docket number COE–2012–0009, by any of the following methods:

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

Email: david.b.olson@usace.army.mil. Include the docket number, COE–2012–0009, in the subject line of the message.

Mail: U.S. Army Corps of Engineers, Attn: CECW–CO (David B. Olson), 441 G Street NW., Washington, DC 20314–1000.

Hand Delivery/Courier: Due to security requirements, we cannot receive comments by hand delivery or courier.

Instructions: Direct your comments to docket number COE–2012–0009. 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 commenter indicates that 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 email. The regulations.gov web site is an anonymous access system, which means we will not know your identity or contact information unless you provide it in the body of your comment. If you send an email directly to the Corps without going through regulations.gov, your email 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, we recommend 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 we cannot read your comment because of technical difficulties and cannot contact you for clarification, we may not be able to consider your comment. Electronic comments should avoid the use of any special characters, any form of encryption, and be free of any defects or viruses.

Docket: For access to the docket to read background documents or comments received, go to *www.regulations.gov*. All documents in the docket are listed. Although listed in the index, some information is not publicly available, such as 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.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922 or Mr. Jon M. Griffin, U.S. Army Corps of Engineers, Jacksonville District, Regulatory Division, at 904–232–1680.

SUPPLEMENTARY INFORMATION:

Executive Summary

The purpose of this regulatory action is to establish a restricted area in the waters surrounding the U.S. Coast Guard Base Miami Beach, Florida to counter postulated threats against their personnel, equipment, cutters and facilities by providing stand-off corridors encompassing the waters immediately contiguous to Base Miami Beach.

The Corps authority to establish this restricted area is Section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3).

Background

Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat 892; 33 U.S.C. 3) the Corps is proposing to amend the regulations at 33 CFR part 334 by establishing a new restricted area in the waters near Meloy Channel, Government Cut Channel, and Miami Main Channel surrounding Base Miami Beach. The proposed amendment to this regulation will allow the Base Commander, U.S. Coast Guard Base Miami Beach to restrict passage of persons, watercraft, and vessels in waters contiguous to this Command, thereby providing greater security to the personnel, equipment, cutters, and facilities housed at the site.

Procedural Requirements

a. *Review Under Executive Order 12866.* The proposed rule is issued with respect to a military function of the Department of Defense and the provisions of Executive Order 12866 do not apply.

b. *Review Under the Regulatory Flexibility Act.* The proposed rule has been reviewed under the Regulatory Flexibility Act (Pub. L. 96–354) which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (i.e., small businesses and small governments). Unless information is obtained to the contrary during the comment period, the Corps expects that the proposed rule would have practically no economic impact on the public, or result in no anticipated navigational hazard or interference with existing waterway traffic. This proposed rule, if adopted, will have no significant economic impact on small entities.

c. *Review Under the National Environmental Policy Act.* Due to the administrative nature of this action and because there is no intended change in the use of the area, the Corps expects that this regulation, if adopted, will not have a significant impact on the quality of the human environment and, therefore, preparation of an environmental impact statement will not be required. An environmental assessment will be prepared after the public notice period is closed and all comments have been received and considered.

d. *Unfunded Mandates Act.* This proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Therefore, this proposed rule is not subject to the requirements of Sections 202 and 205 of the Unfunded Mandates Reform Act (UMRA). The proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. Therefore, the proposed rule is not subject to the requirements of Section 203 of UMRA.

List of Subjects in 33 CFR Part 334

Danger zones, Navigation (water), Restricted areas, Waterways.

For the reasons set out in the preamble, the Corps proposes to amend 33 CFR part 334 as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

1. The authority citation for part 334 continues to read as follows:

Authority: 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

2. Add § 334.605 to read as follows:

§ 334.605 Meloy Channel, U.S. Coast Guard Base Miami Beach, Florida; restricted area.

(a) *The area.* The restricted area shall encompass all navigable waters of the United States as defined at 33 CFR part 329, within the area bounded by a line connecting the following coordinates: Commencing from the shoreline at latitude 25°46′20.07″ N, longitude 080°08′50.94″ W; thence to latitude 25°46′22.69″ N, longitude 080°08′44.01″ W; thence to latitude 25°46′22.02″ N, longitude 080°08′42.14″ W; thence to latitude 25°46′12.23″ N, longitude 080°08′35.33″ W; thence to latitude

25°46′09.13″ N, longitude 080°08′40.74″ W; thence to latitude 25°46′11.63″ N, longitude 080°08′43.36″ W; thence to latitude 25°46′17.22″ N, longitude 080°08′47.17″ W; thence to latitude 25°46′17.15″ N, longitude 080°08′47.62″ W; thence to latitude 25°46′17.63″ N, longitude 080°08′49.33″ W; thence to latitude 25°46′18.91″ N, longitude 080°08′50.24″ W; thence proceed directly to a point on the shoreline at latitude 25°46′18.76″ N, longitude 080°08′50.71″ W thence following the mean high water line to the point of beginning.

(b) *The regulations.* (1) The restricted area described in paragraph (a) of this section is only open to U.S. Government vessels. U.S. Government vessels include, but are not limited to, U.S. Coast Guard and Coast Guard Auxiliary vessels, Department of Defense vessels, state and local law enforcement and emergency services vessels, and vessels under contract with the U.S. Government. Warning signs notifying individuals of the restricted area boundary and prohibiting all unauthorized entry into the area will be posted along the property boundary and, as appropriate, on the piers of the MacArthur Causeway Bridge adjacent to the restricted area.

(2) All persons, vessels, and other craft are prohibited from entering, transiting, drifting, dredging, or anchoring within the restricted area described in paragraph (a) of this section without prior approval from the Base Commander, U.S. Coast Guard Base Miami Beach or his/her designated representative.

(3) Fishing, trawling, net-fishing, and other aquatic activities are prohibited in the restricted area without prior approval from the Base Commander, U.S. Coast Guard Base Miami Beach or his/her designated representative.

(4) The restrictions described in paragraph (b) of this section are in effect 24 hours a day, 7 days a week.

(c) *Enforcement.* The regulations in this section shall be enforced by the Base Commander, U.S. Coast Guard Base Miami Beach and/or such persons or agencies as he/she may designate.

Dated: April 25, 2012.

Richard C. Lockwood,

Chief, Operations and Regulatory, Directorate of Civil Works.

[FR Doc. 2012–10606 Filed 5–2–12; 8:45 am]

BILLING CODE 3720–58–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2011–0520; FRL–9667–2]

40 CFR Part 147

State of Tennessee; Underground Injection Control (UIC) Program Primacy

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of public comment period and of public hearing.

SUMMARY: The purpose of this notice is to announce that: 1 the EPA has received a complete application from the State of Tennessee requesting approval of its Underground Injection Control program; 2 the EPA has determined the application contains all the required elements; 3 the application is available for inspection and copying at the address appearing below; 4 public comments are requested; and (5) a public hearing will be held.

DATES: Requests for a public hearing and/or to present oral testimony must be received by May 31, 2012; if determined to be warranted, the Public Hearing will be held on June 7, 2012 at 1:00 p.m. Requests to testify may be mailed to Fred McManus, Chief, Ground Water and SDWA Enforcement Section, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303. If it is determined that a hearing is warranted, it will be held on the 17th Floor Conference Room B, L&C Tower, 401 Church Street, Nashville, Tennessee 37243. Comments will be accepted until June 14, 2012. The EPA will determine by June 4, 2012, whether there is sufficient interest to warrant a public hearing. Contact Nancy H. Marsh to determine if a hearing is warranted (see the **FOR FURTHER INFORMATION CONTACT** section).

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2011–0520, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: marsh.nancy@epa.gov.*
- *Fax:* (404) 562–9439.
- *Mail:* State of Tennessee; Underground Injection Control (UIC) Program Primacy, U.S. Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Hand Delivery: Water Docket, EPA Docket Center (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. 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–OW–2011–0520. 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 email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov,* your email 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, the 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 the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the 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 the EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm* of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the following locations:

U.S. Environmental Protection Agency, Region 4, Library, 9th Floor, 61 Forsyth Street SW., Atlanta, Georgia 30303. The Library is open from

Friday, excluding legal holidays. The telephone number for the Library is (404) 562–8190.

Tennessee Department of Environment and Conservation, 6th Floor, 401 Church Street, Nashville, Tennessee 32743, The Library is open from 9:00 a.m.–4:00 p.m. Monday through Friday, excluding legal holidays. The telephone number for the Library is (615) 532–0191.

State of Tennessee; Underground Injection Control (UIC) Program Primacy Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m.–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 OW Docket is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: Nancy H. Marsh, Safe Drinking Water Branch, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303; telephone number: 404–562–9450. Fax number: 404–562–9439; email address: *marsh.nancy@epa.gov.* Comments should also be sent to this address.

SUPPLEMENTARY INFORMATION: The State of Tennessee has submitted an application to regulate Class I, II, III, IV and V injection wells in the State. The application was determined to be complete because it included all of the requirements of 40 CFR § 145.22(a): a letter from the Governor requesting program approval; a complete description of the State Underground Injection Control program; a statement of legal authority; a memorandum of agreement between the State of Tennessee and the EPA, Region 4; copies of all applicable rules and forms; and a showing of the State's public participation process prior to program submission.

Dated: April 19, 2012.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 2012–10619 Filed 5–2–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 430, 431, 435, 436, 440, 441, and 447

[CMS–2249–CN]

RIN 0938–AO53

Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Setting Requirements for Community First Choice; Correction

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

ACTION: Proposed rule; correction.

SUMMARY: This document corrects a technical error that appeared in the proposed rule published elsewhere in this **Federal Register** entitled ''Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Setting Requirements for Community First Choice.'' The proposed rule was intended to carry a 60-day comment period, but was submitted with a 30-day comment period. This document corrects that error.

DATES: The comment close date for the proposed rule under the same heading published elsewhere in this issue is correctly extended to July 2, 2012.

FOR FURTHER INFORMATION CONTACT: Annette Brewer, (410) 786–6580.

SUPPLEMENTARY INFORMATION:

I. Background

In the proposed rule that is published elsewhere in this **Federal Register**, there was a technical error that is identified and corrected in the Correction of Errors section below. The provisions in this correction document are effective as if they had been included in the document that is published elsewhere in this **Federal Register**.

II. Summary of Errors

In the **DATES** section of the proposed rule, we inadvertently stated that the comment period would close on June 4, 2012 allowing a 30-day comment period. This notice is being issued to correct that error and to allow a 60-day comment period.

III. Waiver of Proposed Rulemaking

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 this notice and comment procedure 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 notice. We are not issuing additional rulemaking at this time since this notice extends the comment period for the proposed rule to 60 days to allow the public additional time to submit comments.

IV. Correction of Errors

In proposed rule that is published elsewhere in this **Federal Register**, make the following corrections:

In the **DATES** section, the date ''June 4, 2012'' is corrected to read ''July 2, 2012''.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: April 30, 2012.

Jennifer M. Cannistra

Executive Secretary to the Department.

[FR Doc. 2012–10677 Filed 5–1–12; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 2, 22, and 52

[FAR Case 2011–028; Docket 2011–0028; Sequence 1]

RIN 9000–AM21

Federal Acquisition Regulation; Nondisplacement of Qualified Workers Under Service Contracts

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement an Executive order for nondisplacement of qualified workers under service contracts, as implemented in Department of Labor regulations.

DATES: Interested parties should submit written comments to the Regulatory

Secretariat at one of the addressees shown below on or before July 2, 2012 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAR Case 2011–028 by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching ''FAR Case 2011–028''. Select the link ''Submit a Comment'' that corresponds with ''FAR Case 2011–028.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''FAR Case 2011–028'' on your attached document.
- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), ATTN: Hada Flowers, 1275 First Street NE., 7th Floor, Washington, DC 20417.

Instructions: Please submit comments only and cite FAR Case 2011–028, in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Edward Loeb, Procurement Analyst, at 202–501–0650, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite FAR Case 2011–028.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA are proposing to amend the FAR to implement Executive Order (E.O.) 13495, Nondisplacement of Qualified Workers Under Service Contracts, dated January 30, 2009, published in the **Federal Register** at 74 FR 6103 on February 4, 2009, and the Department of Labor (DOL) implementing regulations, published in the **Federal Register** at 76 FR 53720, August 29, 2011, with an effective date to be established later. The E.O. revoked E.O. 13204 of February 17, 2001, which had resulted in the deletion of FAR subpart 22.12 in its entirety. This proposed rule would amend the FAR to add subpart 22.12 and a new clause at FAR 52.222–XX, providing the policy of the Federal Government, as expressed in E.O. 13495, to require service contractors and their subcontractors under successor contracts to offer employees of the predecessor contractor and its subcontractors a right of first refusal of employment for positions for which they are qualified. The E.O. provides a clause for service contracts that will succeed service contracts for performance of the same or similar work at the same location.

Executive Order 13495 specifically excludes service contracts and subcontracts in the following categories:

- Under the simplified acquisition threshold;
- Awarded through the AbilityOne Program pursuant to the rules of the Committee for Purchase From People Who Are Blind or Severely Disabled (41 U.S.C. chapter 85);
- Guard, elevator operator, messenger, or custodial services provided to the Federal Government by sheltered workshops employing the ''severely handicapped'' as described in 40 U.S.C. 593;
- Vending facility agreements entered into under the Randolph-Sheppard Act; and
- Employees who were hired to work under a Federal service contract and one or more nonfederal service contracts as part of a single job, provided that the employees were not deployed in a manner that was designed to avoid the purposes of E.O. 13495.

The E.O. and DOL regulations provide (see 29 CFR 9.1(b)) that nothing in either document can be used as a reason for failure to comply with any provision of law or other E.O. With this policy, the E.O. and the DOL implementing regulations allow for compliance with (a) the HUBZone Program (15 U.S.C. 657a and 632(p) and FAR subpart 19.13), (b) Executive Order 11246 (Equal Employment Opportunity), and (c) the Vietnam Era Veterans' Readjustment Assistance Act of 1974 (38 U.S.C. 4212). For these reasons, the FAR proposed rule includes a paragraph regarding such compliance, at FAR 22.1202(b), Policy, and paragraph (b)(2) of the clause at FAR 52.222–XX, to be used in procurements where one of the offerors for the successor contract may have been certified by the Small Business Administration as a HUBZone small business concern.

In addition to the exemptions listed above, the E.O. provides, at section 4, the authority for the head of a contracting department or agency to waive the application of the E.O. to a contract, subcontract, or purchase order (or a class of contracts, subcontracts, or purchase orders) upon a determination that its application would impair the ability of the Government to procure services on an economical and efficient basis or would not serve the purposes of the E.O. (see also 29 CFR 9.4(d)). A decision to exempt a procurement or class of procurements from one or more provisions of the E.O. is a requirements decision, and the associated analysis, documentation, and other requirements necessary for an exemption are subject to 29 CFR part 9. However, the FAR puts contracting officials on notice that any waiver that is not completed in accordance with 29 CFR part 9 prior to the contract solicitation date automatically makes the agency waiver determination inoperative. Failure to comply will require resolicitation.

The E.O. tasked the Secretary of Labor with enforcement, authorized the Secretary of Labor, among other things, to issue final orders prescribing appropriate sanctions and remedies, and required the Secretary of Labor to issue regulations that implement the requirements of the E.O.

The E.O. required FAR regulations 180 days after the date of the E.O. FAR Case 2009–001 was opened February 5, 2009. However, that FAR case was closed and a new FAR case opened upon publication of the final DOL rule, which occurred on August 29, 2011.

II. Discussion and Analysis

This proposed rule would add FAR subpart 22.12, entitled Nondisplacement of Qualified Workers Under Service Contracts, and the associated clause at FAR 52.222–XX, entitled Nondisplacement of Qualified Workers. The requirements in FAR subpart 22.12 and the associated clause are taken directly from E.O. 13495 and the implementing regulations published August 29, 2011, by the Department of Labor at 29 CFR part 9 (see 76 FR 53720). However, the FAR does not repeat elements of the investigative methods, available reviews, or enforcement mechanisms established by the Department of Labor except as necessary to ensure that contracting officers and contractors, including subcontractors, are aware of their requirements and responsibilities.

For the reasons listed above, FAR subpart 22.12 includes the following, using as its source both the text of E.O. 13495 and 29 CFR part 9:

A. The definitions ''service contract'' and ''United States'' at FAR 22.1201 apply to the new subpart. The definition of ''service employee'' has been moved to FAR 22.001 to apply to all of part 22.

B. *Statement of policy:* The sources for the coverage at FAR 22.1202(a) are section 1 of E.O. 13495 and 29 CFR section 9.1. The coverage applies only to service contracts for performance of the same or similar services at the same location.

C. *Exemptions:* The sources for this coverage are section 3 of E.O. 13495 and

29 CFR 9.4. The five exemptions in the E.O. are repeated in FAR 22.1203–2.

D. *Waiver authority and limitations:* The sources of this coverage are section 4 of E.O. 13495 and 29 CFR section 9.4(d), both of which permit waiver, with certain limitations, of the E.O.'s requirements by the head of a contracting department or agency. By longstanding FAR convention, agencies would be able to delegate this authority pursuant to FAR 1.108(b). DoD, GSA, and NASA are evaluating the need for potential restrictions on the level to which the authority may be delegated. When an agency exercises its waiver authority, it must notify DOL of its decision in accordance with 29 CFR 9.4(d)(2) and provide the Department of Labor with a copy of its written analysis no later than 5 business days after the solicitation date which DOL will then post on its Web site. The waiver authority has specific penalties for agencies that do not comply. Contracting officers are impacted because the agency's failure to comply with DOL regulations regarding waivers makes the waiver inoperative and requires the contracting officer to insert the clause in the solicitation.

E. *Certified employee lists:* The sources of this coverage are section 5 of E.O. 13495 and 29 CFR section 9.12(e). The predecessor contractor is required to provide a certified list of its employees who are qualified to work on the successor contract. The contracting officer must provide the list to the successor contractor in a timely manner.

F. *Required notifications to contractors and employees:* The sources for this coverage are 29 CFR 9.11 and 9.12. 29 CFR 9.11(b) states that ''the Contracting Officer will ensure that the predecessor contractor provides written notice to its service employees * * * of their possible right to an offer of employment.'' In addition, 29 CFR 9.12(e) states that ''the contractor shall, not less than 30 days before completion of the contactor's performance of services on a contract, furnish the Contracting Officer with a list of the names of all service employees working under the contract and its subcontracts at the time the list is submitted.'' The likelihood exists that, during the initial implementation of the E.O., service employees of the predecessor contractor may not receive written notice and Contracting Officers (and hence successor contractors) may not receive the list 30 days before the end of the contract. As a general matter, predecessor contractors will be operating under the existing notification clause set forth at FAR 52.222–41(n) (applicable to contracts subject to the Service Contract Act (SCA)). This clause does not address notification to service employees because there was not previously a right of first refusal. In addition, the clause permits submission of the list to the Contracting Officer as few as 10 days prior to completion of the contract. DoD, GSA, and NASA note that under 29 CFR 9.12(a)(2), a successor contractor's obligation to offer a right of first refusal exists even if the information is not provided by the incumbent within the 30-day window (*i.e.,* ''even if the successor contractor was not provided a list of the predecessor contractor's employees or the list did not contain the names of all persons employed during the final month of contract performance.'') The FAR Council is considering possible steps that might be taken, as agencies transition to the new clause, to reduce instances where service employees of the predecessor contractor and successor contractors do not receive notice of their rights and successors receive lists less than 30 days before the end of the contract. One possible step the FAR Council is considering is to encourage agencies to enter into bilateral modifications (starting with the largest SCA-covered contracts) that obligate predecessor contractors to (1) inform their service employees of their right of first refusal and (2) provide the list to the Contracting Officer no less than 30 days before contract completion. DoD, GSA, and NASA invite the public to offer their views and ideas as part of their comments on this rulemaking.

G. *Remedies and sanctions:* The sources of this coverage are section 6 of E.O. 13495 and 29 CFR 9.24. This area is within the purview of the DOL. The FAR, at section 22.1206, addresses the contracting officer's role.

H. *Contract clause:* The sources of this coverage are section 5 of E.O. 13495 and Appendix A of 29 CFR part 9. The paragraphs in the proposed FAR clause have been reordered by importance and in accordance with FAR drafting procedures.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DOD, GSA, and NASA do not believe that this rule will have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act 5 U.S.C. 601, *et seq.* Nonetheless, they are preparing an Initial Regulatory Flexibility Analysis (IRFA), in the interest of soliciting public comments, which is summarized as follows:

DoD, GSA, and NASA are issuing a proposed rule to amend the Federal Acquisition Regulation (FAR) to implement Executive Order (E.O.) 13495, entitled Nondisplacement of Qualified Workers Under Service Contracts (dated January 30, 2009) and the Department of Labor final rule implementing the E.O. (29 CFR part 9, published at 76 FR 53720, dated August 29, 2011).

It is the policy of the Federal Government to require service contractors and their subcontractors under successor contracts to offer employees of the predecessor contractor and its subcontractors a right of first refusal of employment for positions for which they are qualified. The E.O. provides a clause for service contracts that will succeed service contracts for performance of the same or similar work at the same location. The E.O. revoked E.O. 13204 of February 17, 2001, which resulted in the deletion of FAR subpart 22.12 in its entirety. This FAR proposed rule would add subpart 22.12 and a new clause at FAR 52.222–XX.

Executive Order 13495 excludes service contracts and subcontracts in the following categories:

- Under the simplified acquisition threshold.
- Awarded through the AbilityOne Program pursuant to the rules of the Committee for Purchase From People Who Are Blind or Severely Disabled (41 U.S.C. chapter 85).
- Guard, elevator operator, messenger, or custodial services provided to the Federal Government by sheltered workshops employing the severely handicapped as described in 40 U.S.C. 593.
- Vending facility agreements entered into under the Randolph-Sheppard Act.
- Employees who were hired to work under a Federal service contract and one or more nonfederal service contracts as part of a single job, provided that the employees were not deployed in a manner that was designed to avoid the purposes of E.O. 13495.

The FAR proposed rule adds coverage that allows for compliance with (a) the HUBZone Program (see FAR subpart 19.13),(b) Executive Order 11246 (Equal Employment Opportunity), and (c) the Vietnam Era Veterans' Readjustment Assistance Act of 1974.

In addition to the exemptions above, the E.O. provides, at section 4, the authority for the head of a contracting department or agency to waive the application of the E.O. to a contract, subcontract, or purchase order (or a class of contracts, subcontracts, or purchase orders) upon a determination its application would impair the ability of the Government to procure services on an economical and efficient basis or would not serve the purposes of E.O. 13495 (see also 29 CFR 9.4(d)). A decision to exempt a procurement or class of procurements from one or more provisions of the E.O. is a requirements decision, and the associated analysis, documentation, and other requirements necessary for an exemption are subject to 29 CFR part 9. However, the FAR puts contracting officials on notice in this FAR proposed rule that any waiver that is not completed in accordance with 29 CFR part 9 prior to the contract solicitation date automatically makes the agency determination inoperative.

The E.O. tasked the Secretary of Labor with enforcement authority that, among other things, authorizes the Secretary Labor to issue final orders prescribing appropriate sanctions and remedies, including but not limited to, orders requiring employment and payment of wages lost, and required the Secretary to develop implementing regulations. These matters are not addressed in the FAR because they are outside the contracting function.

The estimated impact that follows is based entirely upon the DOL figures reported in the proposed and final rules that it published implementing E.O. 13495. Although DOL prepared an initial regulatory flexibility analysis, the agency, in the final rule, certified that 29 CFR part 9 does not have a significant economic impact on a substantial number of small entities. There is no additional impact due to the implementation of the DOL regulations in the FAR. The requirements in the FAR are taken from the E.O. and 29 CFR part 9 without addition.

DOL estimated that 28,800 small entities will be subject to its regulation and the majority of these small entities will incur compliance costs of less than $100. The analysis offsets the actions that a successor contractor would already be taking, such as determining an individual's suitability for available positions and documentting employment decisions. Further, DOL assumed a time/cost savings on the part of small entities because the entities will not have to engage in recruiting and training an entirely new workforce.

The predecessor contractor is required to provide a certified list of the names of all service employees working under that contract, and its subcontracts, to the contracting agency no later than 30 days before completion of performance of the predecessor contract. DOL notes, however, that there is little or no cost associated with this requirement because the certified list is the same list as the certified seniority list currently required to be provided under the Service Contract Act clause, FAR 52.222–41(n). The minimal new reporting requirements mandated by the DOL implementation of E.O. 13495 are addressed in the information collection justification submitted by DOL in connection with its final rule (see 76 FR 53720 dated August 29, 2011). No additional reporting requirements are imposed by the FAR rule, which merely relocates the contract clause from the E.O. into FAR part 52.

The rule does not duplicate, overlap, or conflict with any other Federal rules. The requirements of E.O. 13495 do not allow for any alternatives.

The FAR Secretariat has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat. DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2011–028), in correspondence.

IV. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does apply; however these changes to the FAR do not imposed additional information collection requirements to the paperwork burden previously approved under the Office of Management and Budget Control Number 1235–0007 and 1235–XXXX, titled: Labor Standards for Federal Service Contracts—Regulations 29 CFR, Part 4 and Nondisplacement of Qualified Workers Under Service Contracts Executive Order 13495, respectively.

List of Subjects in 48 CFR Parts 2, 22, and 52

Government procurement.

Dated: April 30, 2012.

Laura Auletta,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, DoD, GSA, and NASA propose amending 48 CFR parts 2, 22, and 52 as set forth below:

1. The authority citation for 48 CFR parts 2, 22, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 2—DEFINITIONS OF WORDS AND TERMS

2. Amend section 2.101, in paragraph (a), in the definition ''United States'' by redesignating paragraphs 4 through 10 as paragraphs 5 through 11, respectively; and adding a new paragraph 4 to read as follows:

2.101 Definitions.

* * * * *

(a) * * *

Unites States * * *

(4) For use in subpart 22.13, see the definition at 22.1201.

* * * * *

PART 22—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

3. Amend section 22.001 by adding, in alphabetical order, the definition ''Service employee'' to read as follows:

22.001 Definitions.

* * * * *

Service employee means any person engaged in the performance of a service contract other than any person employed in a bona fide executive, administrative, or professional capacity, as those terms are defined in 29 CFR part 541. The term ''service employee'' includes all such persons regardless of any contractual relationship that may be alleged to exist between a contractor or subcontractor and such persons.

* * * * *

22.1001 [Amended]

4. Amend section 22.1001 by removing the definition ''Service employee''.

5. Add subpart 22.12 to read as follows:

Subpart 22.12—Nondisplacement of Qualified Workers Under Service Contracts

22.1200 Scope of subpart.
22.1201 Definitions.
22.1202 Policy.
22.1203 Applicability.
22.1203–1 General.
22.1203–2 Exemptions.
22.1203–3 Waiver.
22.1204 Certified employee lists.
22.1205 Notification to contractors and employees.
22.1206 Remedies and sanctions for violations of this subpart.
22.1207 Contract clause.

Subpart 22.12—Nondisplacement of Qualified Workers Under Service Contracts

22.1200 Scope of subpart.

This subpart prescribes policies and procedures for implementing Executive Order 13495 of January 30, 2009, Nondisplacement of Qualified Workers Under Service Contracts.

22.1201 Definitions.

As used in this subpart—

Service contract means any Government contract, the principal purpose of which is to furnish services in the United States through the use of service employees, except as exempted under the Service Contract Labor Standards (41 U.S.C. chapter 67; see 22.1003–3 and 22.1003–4), or any subcontract at any tier thereunder. See 22.1003–5 and 29 CFR 4.130 for a partial list of services covered by the Act.

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, Johnston Island, Wake Island, and outer Continental Shelf as defined in the outer Continental Shelf Lands Act (43 U.S.C. 1331, *et seq.*), but does not include any other place subject to United States jurisdiction or any United States base or possession in a foreign country (29 CFR 4.112).

22.1202 Policy.

(a) When a service contract succeeds a contract for performance of the same or similar services at the same location, the successor contractor and its subcontractors are required to offer those employees (other than managerial and supervisory employees) that are employed under the predecessor contract, and whose employment will be terminated as a result of the award of the successor contract, a right of first refusal of employment under the contract in positions for which they are qualified. Executive Order 13495 generally prohibits employment openings under the successor contract until such right of first refusal has been provided, when consistent with applicable law.

(b) Nothing in Executive Order 13495 shall be construed to permit a contractor or subcontractor to fail to comply with any provision of any other Executive order or law. For example, the requirements of the HUBZone Program (see subpart 19.13), Executive Order 11246 (Equal Employment Opportunity), and the Vietnam Era Veterans' Readjustment Assistance Act of 1974 may conflict with the requirements of Executive Order 13495. Those laws and Executive orders must be satisfied in tandem with, and if necessary prior to, the requirements of Executive Order 13495 and this subpart.

22.1203 Applicability.

22.1203–1 General.

This subpart applies to service contracts that succeed contracts for the same or similar services at the same location.

22.1203–2 Exemptions.

(a) This subpart does not apply to—

(1) Contracts and subcontracts under the simplified acquisition threshold;

(2) Contracts or subcontracts awarded pursuant to 41 U.S.C. chapter 85, Committee for Purchase from People Who Are Blind or Severely Disabled;

(3) Guard, elevator operator, messenger, or custodial services provided to the Government under contracts or subcontracts with sheltered workshops employing the ''severely handicapped'' as described in 40 U.S.C. 593;

(4) Agreements for vending facilities entered into pursuant to the preference regulations issued under the Randolph Sheppard Act, 20 U.S.C. 107; or

(5) Employees who were hired to work under a Federal service contract and one or more nonfederal service contracts as part of a single job, provided that the employees were not deployed in a manner that was designed to avoid the purposes of this subpart.

(b) The exclusions in paragraphs (a)(2) through (a)(4) of this subsection apply when either the predecessor or successor contract has been awarded for services produced or provided by the ''severely handicapped.''

22.1203–3 Waiver.

(a) If the head of the procuring agency determines in writing that the application of this subpart would not serve the purposes of Executive Order 13495 or would impair the ability of the Federal Government to procure services on an economical and efficient basis, the agency head may waive some or all of the provisions of this subpart. Such waivers may be made for a contract, subcontract, or purchase order, or with respect to a class of contracts, subcontracts, or purchase orders. See 29 CFR 9.4(d)(4) for regulatory provisions addressing circumstances in which a waiver could or would not be appropriate. The waiver must be reflected in a written analysis as described in 29 CFR 9.4(d)(4)(i) and must be completed prior to the contract solicitation date, or the waiver is inoperative.

(b)(1) When an agency exercises its waiver authority with respect to any contract, subcontract, or purchase order, the contracting officer shall direct the contractor to notify affected workers and their collective bargaining representative in writing, no later than five business days after the solicitation issuance date, of the agency's determination. The notice shall include facts supporting the determination. The contracting officer's failure to direct that the contractor provide the notice as provided in this subparagraph shall render the waiver decision inoperative, and the contracting officer shall include the clause at 52.222–XX in the solicitation.

(2) Where a contracting agency waives application to a class of contracts, subcontracts, or purchase orders, the contracting officer shall, with respect to each individual solicitation, direct the contractor to notify incumbent workers and their collective bargaining representatives in writing, no later than five business days after each solicitation issuance date, of the agency's determination. The notice shall include facts supporting the determination. The contracting officer's failure to direct that the contractor provide the notice provided in this subparagraph shall render the waiver decision inoperative, and the contracting officer shall include the clause at 52.222–XX in the solicitation.

(3) In addition, the agency shall notify the Department of Labor of its waiver decision and provide the Department of Labor with a copy of its written analysis no later than five business days after the solicitation issuance date. Failure to comply with this notification requirement shall render the waiver decision inoperative, and the contracting officer shall include the clause at 52.222–XX in the solicitation.

22.1204 Certified employee lists.

(a) The predecessor contractor is required to furnish to the contracting officer, not less than 30 days before completion of the predecessor contract, a certified list of the names of all service employees working under the contract and its subcontracts at the time the list is submitted. The certified list must also contain anniversary dates of employment of each service employee under the contract and subcontracts for services. This list is the same as the seniority list required by paragraph (n) of the clause at 52.222–41, Service Contract Act of 1965. If there are no changes to the workforce before the predecessor contract is completed, then the predecessor contractor is not required to submit a revised list 10 days prior to completion of performance and the requirements of 52.222–41(n) are met. When there are changes to the workforce after submission of the 30-day list, the predecessor contractor shall submit a revised certified list not less than 10 days prior to performance completion.

(b) The contracting officer shall provide the seniority list to the successor contractor and, if requested, to employees of the predecessor

contractor or subcontractors or their authorized representatives.

22.1205 Notification to contractors and employees.

(a) The contracting officer shall ensure that the predecessor contractor provides written notice to service employees of their possible right to an offer of employment with the successor contractor. The written notice shall be—

(1) Posted in a conspicuous place at the worksite; or

(2) Delivered to the employees individually. If such delivery is via email, the notification must result in an electronic delivery receipt or some other reliable confirmation that the intended recipient received the notice.

(b) Contracting officers may advise contractors to provide the notice in Appendix B to 29 CFR chapter 9. Where a significant portion of the predecessor contractor's workforce is not fluent in English, the notice shall be provided in English and language(s) with which employees are more familiar. English and Spanish versions of the notice are available on the Department of Labor Web site at *http://www.dol.gov/whd.*

22.1206 Remedies and sanctions for violations of this subpart.

(a) The Secretary of Labor has the authority to issue orders prescribing appropriate remedies, including, but not limited to, requiring the successor contractor to offer employment, in positions for which the employees are qualified, to employees from the predecessor contract and payment of wages lost.

(b) After an investigation and a determination by the Administrator, Wage and Hour Division, Department of Labor, that lost wages or other monetary relief is due, the Administrator may direct that so much of the accrued payments due on either the contract or any other contract between the contractor and the Government shall be withheld as are necessary to pay the monies due. Upon the final order of the Secretary of Labor that such monies are due, the Administrator may direct that such withheld funds be transferred to the Department of Labor for disbursement.

(c) If the contracting officer or the Administrator, Wage and Hour Division, Department of Labor, finds that the predecessor contractor has failed to provide the list required by 22.1204, the contracting officer may in his or her discretion, or on request by the Administrator, suspend contract payment until such time as the list is provided to the contracting officer.

(d) The Secretary of Labor may also suspend or debar a contractor or subcontractor for a period of up to three years.

22.1207 Contract clause.

The contracting officer shall insert the clause at 52.222–XX, Nondisplacement of Qualified Workers, in solicitations and contracts for services (1) defined at 22.1201, (2) that succeed contracts for performance of the same or similar work at the same location, and (3) that are not exempted by 22.1203–2 or waived in accordance with 22.1203–3.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

6. Amend section 52.212–5 by—

a. Revising the date of the clause;

b. Redesignating paragraphs (c)(7) and (c)(8) as paragraphs (c)(8) and (c)(9), respectively;

c. Adding a new paragraph (c)(7);

d. Redesignating paragraphs (e)(1)(xiii) and (e)(1)(xiv) as paragraphs (e)(1)(xiv) and (e)(1)(xv), respectively; and

e. Adding a new paragraph (e)(1)(xiii) to read as follows.

52.212–5 Contract Terms and Conditions Required To Implement Statutes of Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required To Implement Statutes of Executive Orders—Commercial Items (DATE)

* * * * *

(c) * * *

__(7) 52.222–XX, Nondisplacement of Qualified Workers (DATE) (E.O. 13495).

* * * * *

(e)(1) * * *

(i) * * *

(xiii) 52.222–XX, Nondisplacement of Qualified Workers (DATE) (E.O. 13495).

* * * * *

7. Add section 52.222–XX to read as follows:

52.222–XX Nondisplacement of Qualified Workers.

As prescribed in 22.1207, insert the following clause:

Nondisplacement of Qualified Workers (DATE)

(a) Consistent with the efficient performance of this contract, the Contractor and its subcontractors shall, except as otherwise provided herein, in good faith offer those employees (other than managerial and supervisory employees) employed under the predecessor contract whose employment will be terminated as a result of award of this contract or the expiration of the contract under which the employees were hired, a right of first refusal of employment under this contract in positions for which employees are qualified. The Contractor and its subcontractors shall determine the number of employees necessary for efficient performance of this contract and may elect to employ fewer employees than the predecessor Contractor employed in connection with performance of the work. Except as provided in paragraph (b) of this clause, there shall be no employment opening under this contract, and the Contractor and any subcontractors shall not offer employment under this contract, to any person prior to having complied fully with this obligation. The Contractor and its subcontractors shall make a bona fide express offer of employment to each employee as provided herein and shall state the time within which the employee must accept such offer, but in no case shall the period within which the employee must accept the offer of employment be less than 10 days.

(b)(1) Notwithstanding the obligation under paragraph (a) of this clause, the Contractor and any subcontractors (i) may employ under this contract any employee who has worked for the Contractor or subcontractor for at least three months immediately preceding the commencement of this contract and who would otherwise face lay-off or discharge, (ii) are not required to offer a right of first refusal to any employee(s) of the predecessor Contractor who are not service employees within the meaning of the Service Contract Act of 1965, as amended, 41 U.S.C. 6701(3), and (iii) are not required to offer a right of first refusal to any employee(s) of the predecessor Contractor whom the Contractor or any of its subcontractors reasonably believes, based on the particular employee's past performance, has failed to perform suitably on the job.

(2) In addition, any Contractor or subcontractor that has been certified by the U.S. Small Business Administration as a HUBZone small business concern must ensure that it complies with the statutory and regulatory requirements of the HUBZone Program (*e.g.,* it must ensure that at least 35 percent of all of its employees reside within a HUBZone). The HUBZone small business Contractor or subcontractor must consider whether it can meet the requirements of this clause and Executive Order 13495 while also ensuring it meets the HUBZone Program's requirements.

(3) Nothing in this clause shall be construed to permit a Contractor or subcontractor to fail to comply with any provision of any other Executive order or law. For example, the requirements of the HUBZone Program (see FAR subpart 19.13), Executive Order 11246 (Equal Employment Opportunity), and the Vietnam Era Veterans' Readjustment Assistance Act of 1974 may conflict with the requirements of Executive Order 13495. Those laws and Executive orders must be satisfied in tandem with, and if necessary prior to, the requirements of Executive Order 13495, 29 CFR part 9, and this clause.

(c)(1) The Contractor shall, not less than 30 days before completion of the Contractor's performance of services on a contract, furnish the Contracting Officer with a certified list of the names of all service employees working under this contract and its subcontracts at the

time the list is submitted. The list shall also contain anniversary dates of employment of each service employee under this contract and its predecessor contracts with either the current or predecessor contractors or their subcontractors. Where changes to the workforce are made after the submission of the certified list described in this paragraph, the Contractor shall, in accordance with paragraph (d) of this clause, not less than 10 days before completion of the services on a contract, furnish the Contracting Officer with an updated certified list of the names of all service employees employed within the last month of contract performance. The updated list shall also contain anniversary dates of employment, and, where applicable, dates of separation of each service employee under the contract and its predecessor contracts with either the current or predecessor Contractors or their subcontractors. Only Contractors experiencing a change in their workforce between the 30- and 10-day periods will have to submit a list in accordance with paragraph (d) of this clause.

(2) The Contracting Officer will provide the list to the successor Contractor, and the list shall be provided on request to employees or their representatives.

(3) The Contracting Officer will direct the predecessor Contractor to provide written notice (Appendix B to 29 CFR chapter 9) to service employees of their possible right to an offer of employment with the successor Contractor. Where a significant portion of the predecessor Contractor's workforce is not fluent in English, the notice shall be provided in English and language(s) with which employees are more familiar. The written notice shall be—

(i) Posted in a conspicuous place at the worksite; or

(ii) Delivered to the employees individually. If such delivery is via email, the notification must result in an electronic delivery receipt or some other reliable confirmation that the intended recipient received the notice.

(d)(1) If required in accordance with 52.222–41(n), the Contractor shall, not less than 10 days before completion of this contract, furnish the Contracting Officer a certified list of the names of all service employees working under this contract and its subcontracts during the last month of contract performance. The list shall also contain anniversary dates of employment of each service employee under this contract and its predecessor contracts either with the current or predecessor Contractors or their subcontractors. If there are no changes to the workforce before the predecessor contract is completed, then the predecessor Contractor is not required to submit a revised list 10 days prior to completion of performance and the requirements of 52.222–41(n) are met. When there are changes to the workforce after submission of the 30-day list, the predecessor Contractor shall submit a revised certified list not less than 10 days prior to performance completion.

(2) The Contracting Officer will provide the list to the successor Contractor, and the list shall be provided on request to employees or their authorized representatives.

(e) The Contractor and subcontractor shall maintain the following records (regardless of format, *e.g.,* paper or electronic) of its compliance with this clause for not less than a period of three years from the date the records were created.

(1) Copies of any written offers of employment or a contemporaneous written record of any oral offers of employment, including the date, location, and attendance roster of any employee meeting(s) at which the offers were extended, a summary of each meeting, a copy of any written notice that may have been distributed, and the names of the employees from the predecessor contract to whom an offer was made.

(2) A copy of any record that forms the basis for any exemption claimed under this part.

(3) A copy of the employee list provided to or received from the contracting agency.

(4) An entry on the pay records of the amount of any retroactive payment of wages or compensation under the supervision of the Administrator of the Wage and Hour Division to each employee, the period covered by such payment, and the date of payment, and a copy of any receipt form provided by or authorized by the Wage and Hour Division. The Contractor shall also deliver a copy of the receipt to the employee and file the original, as evidence of payment by the Contractor and receipt by the employee, with the Administrator or an authorized representative within 10 days after payment is made.

(f) Disputes concerning the requirements of this clause shall not be subject to the general disputes clause (52.233–1) of this contract. Such disputes shall be resolved in accordance with the procedures of the Department of Labor set forth in 29 CFR part 9. Disputes within the meaning of this clause include disputes between or among any of the following: The Contractor, the contracting agency, the U.S. Department of Labor, and the employees under the contract or its predecessor contract. The Contracting Officer will refer any employee who wishes to file a complaint, or ask questions concerning this contract clause, to the Branch of Government Contracts Enforcement, Wage and Hour Division, U.S. Department of Labor, Washington, DC 20210. Contact email: *displaced@dol.gov.*

(g) The Contractor shall cooperate in any review or investigation by the Department of Labor into possible violations of the provisions of this clause and shall make such records requested by such official(s) available for inspection, copying, or transcription upon request.

(h) If it is determined, pursuant to regulations issued by the Secretary of Labor (Secretary), that the Contractor or its subcontractors are not in compliance with the requirements of this clause or any regulation or order of the Secretary, appropriate sanctions may be imposed and remedies invoked against the Contractor or its subcontractors, as provided in Executive Order 13495, the regulations, and relevant orders of the Secretary, or as otherwise provided by law.

(i) The Contractor shall take such action with respect to any such subcontract as may be directed by the Secretary as a means of enforcing such provisions, including the imposition of sanctions for noncompliance. However, if the Contractor, as a result of such direction, becomes involved in litigation with a subcontractor, or is threatened with such involvement, the Contractor may request that the United States, through the Secretary of Labor, enter into such litigation to protect the interests of the United States.

(j) The Contracting Officer will withhold, or cause to be withheld, from the prime Contractor under this or any other Government contract with the same prime Contractor, such sums as an authorized official of the Department of Labor requests, upon a determination by the Administrator, the Administrative Law Judge, or the Administrative Review Board, that there has been a failure to comply with the terms of this clause and that wages lost as a result of the violations are due to employees or that other monetary relief is appropriate. If the Contracting Officer or the Administrator, upon final order of the Secretary, finds that the Contractor has failed to provide a list of the names of employees working under the contract, the Contracting Officer may, in his or her discretion, or upon request by the Administrator, take such action as may be necessary to cause the suspension of the payment of contract funds until such time as the list is provided to the Contracting Officer.

(k) *Subcontracts.* In every subcontract over the simplified acquisition threshold entered into in order to perform services under this contract, the Contractor shall include a provision that ensures—

(1) That each subcontractor will honor the requirements of paragraphs (a) through (b) of this clause with respect to the employees of a predecessor subcontractor or subcontractors working under this contract, as well as of a predecessor Contractor and its subcontractors;

(2) That the subcontractor will provide the Contractor with the information about the employees of the subcontractor needed by the Contractor to comply with paragraphs (c) and (d) of this clause; and

(3) The recordkeeping requirements of paragraph (e) of this clause.

(End of clause)

[FR Doc. 2012–10708 Filed 5–2–12; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[Docket No. 120425420–2420–01]

RIN 0648–BB92

Fisheries of the United States; National Standard 1 Guidelines

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

ACTION: Advance notice of proposed rulemaking; request for comments;

consideration of revision to National Standard 1 Guidelines.

SUMMARY: NMFS issues this advance notice of proposed rulemaking (ANPR) to provide background information and request public comment on potential adjustments to the National Standard 1 Guidelines, one of 10 national standards for fishery conservation and management contained in Section 301 of the Magnuson Stevens Fishery Conservation and Management Act. Since the guidelines were last updated in 2009, a number of issues regarding the application of the guidelines were identified by stakeholders and managers that may warrant their revision. This action provides the public with a formal opportunity to comment on the specific ideas mentioned in this ANPR, as well as any additional ideas and solutions that could improve provisions of the National Standard 1 Guidelines.

DATES: Written comments regarding the issues in this ANPR must be received by 5 p.m., local time, on August 1, 2012.

ADDRESSES: You may submit comments on this document, identified by ''NOAA–NMFS–2012–0059'', by any one of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal: *www.regulations.gov.* To submit comments via the e-Rulemaking Portal, first click the ''submit a comment'' icon, then enter ''NOAA–NMFS–2012–0059'' in the keyword search. Locate the document you wish to comment on from the resulting list and click on the ''Submit a Comment'' icon on the right of that line.
- *Fax:* 301–713–1193, Attn: Wesley Patrick.
- *Mail:* Wesley Patrick; National Marine Fisheries Service, NOAA; 1315 East-West Highway, Room 13436; Silver Spring, MD 20910.

Instructions: Comments must be submitted by one of the above methods to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method, to another address or individual, or received after the end of the comment period, may not be considered. All comments received are part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Wesley Patrick, Fisheries Policy Analyst, National Marine Fisheries Service, 301–427–8566.

SUPPLEMENTARY INFORMATION:

Background

Section 301(a) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) contains 10 national standards for fishery conservation and management. Any fishery management plans (FMP) prepared under the MSA, and any regulation promulgated pursuant to the MSA to implement any such plan, must be consistent with these national standards. National Standard 1 (NS1) of the MSA states that conservation and management measures shall prevent overfishing while achieving, on a continuing basis, the optimum yield (OY) from each fishery for the U.S. fishing industry.

Section 301(b) of the MSA requires that the Secretary establish advisory guidelines (which shall not have the force and effect of law), based on the national standards to assist in the development of fishery management plans. Guidelines for NS1 are codified in 50 CFR 600.310. NMFS revised the NS1 Guidelines on January 16, 2009 (74 FR 3178) to reflect the requirements enacted by the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006 for annual catch limits (ACLs) and accountability measures (AMs) to end and prevent overfishing.

From 2007 to 2012, the 46 Federal FMPs have been amended to implement ACLs and AMs to end and prevent overfishing. In the course of this work, a number of issues regarding the application of the NS1 Guidelines were identified that may warrant their revision. NMFS seeks public comments on these and any other issues related to NS1:

1. *Stocks in a fishery.* The MSA requires that Councils develop FMPs for fisheries that require ''conservation and management'' (MSA 302(h)(1)). The MSA provides the Councils with wide latitude in defining the scope of an FMP. Some FMPs include a relatively small number of species, focusing on the primary target species of the fishery. In other FMPs, a much broader range of species are included. The NS1 Guidelines establish and define Ecosystem Component (EC) species and provide that EC species may be included in the FMP but are not considered stocks in the fishery and thus are not required to have biological reference points or ACLs. There has been considerable discussion about the criteria for classifying EC species and the utility of the EC species concept. Thus, revision of the guidance may be warranted to further describe criteria for classifying stocks in a fishery and EC species.

2. *Overfishing and multi-year impacts.* The current NS1 Guidelines provide that overfishing must be determined either by comparing catch to the overfishing limit (OFL) or by comparing fishing mortality to the maximum fishing mortality threshold (§ 600.310 (e)(2)(ii)(A)). Overfishing determinations are made for the most recent year for which there is information. Stakeholders have expressed interest in exploring alternative definitions of overfishing that would take a longer, multi-year view of the impact of fishing on the stock's ability to produce maximum sustainable yield (MSY).

3. *Annual catch limits and optimum yield.* In some fisheries, implementation of the guidance on acceptable biological catch (ABC) control rules, ACLs, and AMs has resulted in real or perceived reductions in catch. Questions have been raised about the relationship between ACLs and the objective of achieving the OY for a fishery. The MSA defines OY as being reduced from MSY to account for relevant economic, social, or ecological factors, and states that OY in an overfished fishery must provide for rebuilding the fishery (MSA 3(33)). There is interest from stakeholders in improving guidance to better address economic, social, and ecological considerations in the establishment of OY and to more clearly describe the relationship between ACL and OY.

4. *Mixed-stock fisheries and optimum yield.* Management of mixed-stock fisheries is challenging, because some stocks are relatively more abundant or are more or less susceptible to overfishing than others. The MSA requires that overfishing be prevented, and that the OY for a fishery provide for rebuilding overfished stocks. Nonetheless, some stakeholders believe that ACL and rebuilding requirements prevent them from achieving OY of healthy stocks. Further guidance on how OY should be specified to balance the multiple considerations in mixed-stock fisheries may be warranted.

5. *Scientific uncertainty and management uncertainty.* The NS1 Guidelines identify two types of uncertainty that should be addressed

when setting catch limits and accountability measures: Scientific uncertainty and management uncertainty (§ 600.310 (f)). Scientific uncertainty is related to the uncertainty of calculating the true OFL, and is addressed by a Council's Scientific and Statistical Committee (SSC) by setting ABC below the OFL. Management uncertainty is the uncertainty of controlling catch so that it does not exceed the ACL, and is addressed when setting AMs and in setting an annual catch target below the ACL. Some stakeholders believe that consideration of both scientific and management uncertainty causes ACLs to be overly precautionary. Further clarification on the consideration of scientific and management uncertainty may be warranted.

6. *Data poor stocks.* Stocks without sufficient data to conduct a formal scientific stock assessment are considered to be data poor stocks. Establishing appropriate ACLs for data poor stocks can be challenging. The experience of the Councils and their SSCs in implementing ABCs and ACLs for data poor stocks may provide valuable information on which to base improvements in the NS1 Guidelines for data poor stocks.

7. *Acceptable biological catch control rules.* The NS1 Guidelines require a Council to establish an ABC control rule for each stock and stock complex, based on scientific advice from its SSC (§ 600.310 (f)). ABC control rules are a specified approach to setting the ABC that addresses scientific uncertainty, and incorporate a policy decision on the acceptable level of risk that overfishing might occur. A variety of ABC control rules have been implemented and a review of those control rules could lead to improvements in the NS1 Guidelines. In addition, for some fisheries there is interest in implementing provisions that carry over unharvested allocations from one year to the next. Guidance may be needed on how to consider carry-over within ABC control rules.

8. *Catch accounting.* Questions have been raised by managers about the types of ''catch'' that must be considered within the ABC and ACL, particularly in regard to catch resulting from exempted fishing permits and scientific research activities. The definition of catch in the NS1 Guidelines includes fish taken in commercial, recreational, subsistence, tribal, and other fisheries. Catch includes fish that are retained for any purpose, as well as mortality of fish that are discarded. In the final rule response to comment number 35 (74 FR 3718; January 16, 2009), NMFS stated that this definition would include allocations for scientific research and mortality from any other fishing activity. Additional guidance may be needed to clarify how to account for all sources of mortality (e.g., bycatch, scientific research catch, etc.) when establishing ABCs and ACLs.

9. *Accountability measures.* AMs are management controls to prevent ACLs from being exceeded, and to correct or mitigate overages of the ACL if they occur. AMs must be tailored to the specific needs of a fishery, and are key to the success of ACL systems in ending and preventing overfishing. NMFS invites comments on the guidance for AMs.

10. *ACL exceptions.* Under the MSA, stocks that have a life cycle of approximately 1 year and stocks subject to international agreements are not required to have ACLs. The NS1 Guidelines describe that the life cycle exception applies to ''a stock for which the average length of time it takes for an individual to produce a reproductively active offspring is approximately 1 year and that the individual has only one breeding season in its lifetime'' (§ 600.310 (h)(2)(i)). The NS1 Guidelines also describe that the international agreement exception applies to stocks that are subject to ''any bilateral or multilateral treaty, convention, or agreement which relates to fishing and to which the United States is party'' (§ 600.310 (h)(2)(ii)). NMFS invites comments on the guidance pertaining to these exceptions from the ACL requirements.

11. *Rebuilding progress and revising rebuilding plans.* The current NS1 Guidelines address how NMFS should respond if a stock reaches the end of its rebuilding plan and is not fully rebuilt, or its rebuilding status is unknown. However, the guidelines do not address the situation that occurs during the course of a rebuilding plan when rebuilding progress is determined to be inadequate. Inadequate progress can result from a number of factors, including:

a. Management measures that do not adequately control the fishery.

b. Environmental factors that limit stock growth.

c. Significant changes in the rebuilding target (Bmsy) resulting from a new stock assessment. NMFS intends to improve guidance on evaluating the progress of stocks in rebuilding plans and on revising the rebuilding plans in these situations.

Public Comments

To help determine the scope of issues to be addressed and to identify significant issues related to this action, NMFS is soliciting written comments on this ANPR. The public is encouraged to submit comments related to the specific ideas mentioned in this ANPR, as well as any additional ideas and solutions that could improve provisions of the NS1 Guidelines. In addition to considering revisions to the NS1 Guidelines, NMFS will consider whether it may be more appropriate to address some topics in technical guidance reports or policy directives than to change the guidelines codified at 50 CFR 600.310. NMFS welcomes comment on the appropriateness and utility of additional technical guidance reports and policy directives.

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

Dated: April 27, 2012.

Alan D. Risenhoover,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2012–10683 Filed 4–30–12; 4:15 pm]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 77, No. 86
Thursday, May 3, 2012

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

Rural Utilities Service

Announcement of Grant Application Deadlines and Funding Levels

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of funds availability and solicitation of applications.

SUMMARY: The United States Department of Agriculture's (USDA) Rural Utilities Service (RUS) announces its Community Connect Grant Program application window for Fiscal Year (FY) 2012. In addition, RUS announces the minimum and maximum amounts for Community Connect grants applicable for the fiscal year. The Community Connect Grant Program regulations can be found at 7 CFR 1739, subpart A.

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

- Paper copies must carry proof of shipping *no later* than June 18, 2012 to be eligible for FY 2012 grant funding. Late applications are not eligible for FY 2012 grant funding.
- Electronic copies must be received by June 18, 2012 to be eligible for FY 2012 grant funding. Late applications are not eligible for FY 2012 grant funding.

ADDRESSES: You may obtain application guides and materials for the Community Connect Grant Program via the Internet at the following Web site: *http://www.rurdev.usda.gov/utp_commconnect.html.* You may also request application guides and materials from RUS by contacting the appropriate individual listed in section VII of the **SUPPLEMENTARY INFORMATION** section of this notice.

Submit completed paper applications for grants to the Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Ave. SW., Room 2868, STOP 1599, Washington, DC 20250–1599. Applications should be marked ''Attention: Director, Broadband Division, Rural Utilities Service.''

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

FOR FURTHER INFORMATION CONTACT: Kenneth Kuchno, Director, Broadband Division, Rural Utilities Service, U.S. Department of Agriculture, telephone: (202) 690–4673, fax: (202) 690–4389.

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency: Rural Utilities Service (RUS).

Funding Opportunity Title: Community Connect Grant Program.

Announcement Type: Initial announcement.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.863.

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

- Paper copies must carry proof of shipping no later than June 18, 2012, to be eligible for FY 2012 grant funding. Late applications are not eligible for FY 2012 grant funding.
- Electronic copies must be received by June 18, 2012, to be eligible for FY 2012 grant funding. Late applications are not eligible for FY 2012 grant funding.

Items in Supplementary Information

I. Funding Opportunity: Brief introduction to the Community Connect Grant Program
II. Award Information: Available funds and minimum and maximum amounts
III. Eligibility Information: Who is eligible, what kinds of projects are eligible, what criteria determine basic eligibility
IV. Application and Submission Information: Where to get application materials, what constitutes a completed application, how and where to submit applications, deadlines, items that are eligible
V. Application Review Information: Considerations and preferences, scoring criteria, review standards, selection information
VI. Award Administration Information: Award notice information, award recipient reporting requirements
VII. Agency Contacts: Web, phone, fax, email, contact name

I. Funding Opportunity

The provision of broadband transmission service is vital to the economic development, education, health, and safety of rural Americans. The purpose of the Community Connect Grant Program is to provide financial assistance in the form of grants to eligible applicants that will provide currently unserved areas, on a ''community-oriented connectivity'' basis, with broadband service that fosters economic growth and delivers enhanced educational, health care, and public safety services. Rural Utilities Service will give priority to rural areas that it believes have the greatest need for broadband services, based on the criteria contained herein.

Grant authority will be used for the deployment of broadband service to extremely rural, lower-income communities on a ''community-oriented connectivity'' basis. The ''community-oriented connectivity'' concept will stimulate practical, everyday uses and applications of broadband facilities by cultivating the deployment of new broadband services that improve economic development and provide enhanced educational and health care opportunities in rural areas. Such an approach will also give rural communities the opportunity to benefit from the advanced technologies that are necessary to achieve these goals. Please see 7 CFR 1739, subpart A for specifics.

This notice has been formatted to conform to a policy directive issued by the Office of Federal Financial Management (OFFM) of the Office of Management and Budget (OMB), published in the **Federal Register** on June 23, 2003. This Notice does not change the Community Connect Grant Program regulation (7 CFR 1739, subpart A).

II. Award Information

A. Available Funds

1. *General.* The Administrator has determined that the following amounts are available for grants in FY 2012 under 7 CFR 1739.2(a).

2. *Grants*

a. $10,372,000 is available for grants. Under 7 CFR 1739.2, the Administrator has established a minimum grant amount of $100,000 and a maximum grant amount of $1,500,000 for FY 2012.

b. Assistance instrument: Rural Utilities Service (RUS) will execute grant documents appropriate to the project prior to any advance of funds with successful applicants.

B. Community Connect Grants Cannot Be Renewed

Award documents specify the term of each award. Applications to supplement existing projects are welcomed (grant applications must be submitted during the application window) and will be evaluated as new applications.

III. Eligibility Information

A. Who is eligible for grants? (See 7 CFR 1739.10.)

1. Only entities legally organized as one of the following are eligible for Community Connect Grant Program financial assistance:

a. An incorporated organization.

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

c. A state or local unit of government.

d. A cooperative, private corporation or limited liability company organized on a for-profit or not-for-profit basis.

2. Individuals are not eligible for Community Connect Grant Program financial assistance directly.

3. Applicants must have the legal capacity and authority to own and operate the broadband facilities as proposed in its application, to enter into contracts and to otherwise comply with applicable federal statutes and regulations.

4. Corporations that have been convicted of a felony (or had an officer or agency acting on behalf of the corporation convicted of a felony) within the past 24 months are not eligible. Any Corporation that has any unpaid federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, is not eligible.

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

1. Required matching contributions. Please see 7 CFR 1739.14 for the requirement. Grant applicants must demonstrate a matching contribution, in cash or in kind (new, non-depreciated items), of at least fifteen (15) percent of the total amount of financial assistance requested. Matching contributions must be used for eligible purposes of the Community Connect grant assistance (see 7 CFR 1739.12).

2. To be eligible for a grant, the Project must (see 7 CFR 1739.11):

a. Serve a Rural Area where Broadband Service does not currently exist, to be verified by RUS prior to the award of the grant;

b. Serve one Community recognized in the latest U.S. Census or in the absence thereof, the most recent edition of the Rand McNally Atlas containing population data;

c. Deploy Basic Broadband Service, free of all charges for at least 2 years, to all Critical Community Facilities located within the proposed Service Area;

d. Offer Basic Broadband Service to residential and business customers within the proposed Service Area; and

e. Provide a Community Center with at least ten (10) Computer Access Points within the proposed Service Area, and make Broadband Transmission Service available therein, free of all charges to users for at least 2 years.

C. See paragraph IV.B of this notice for a discussion of the items that make up a completed application. You may also refer to 7 CFR 1739.15 for completed grant application items.

IV. Application and Submission Information

A. Clarifications to requirements for FY 2011

1. Although 7 CFR 1739.3 defines Broadband Service as 200 kilobits/second both in the downstream and upstream directions, the Agency recognizes that these speeds are not adequate to deliver much needed benefits such as distance learning and telemedicine to communities that are not currently receiving broadband service. Therefore, when the applications are scored for the ''community-oriented connectivity benefits derived from the proposed services,'' emphasis will be placed on the amount of bandwidth that is being delivered to the customer. Although the amount of bandwidth is not the only item that will be evaluated for this criteria, the bandwidth being provided to enhance rural economic development will have a direct impact on the score that is assigned. All applicants are encouraged to construct systems that are capable of delivering the broadband speeds that are identified in the Federal Communications Commission's National Broadband Plan, available on its Web site.

2. When determining the points that will be awarded for the ''community-oriented connectivity'' benefits derived from the proposed service, systems that are proposing to deliver more than the minimum bandwidth requirements have a greater potential of receiving the maximum number of points for this category.

3. When determining if a community has no existing broadband service, applicants are encouraged to refer to the Federal Communication Commission's National Broadband Map, also available on its Web site. Note that wireless services meeting the definition of broadband service will disqualify an area from being eligible to receive funding under this program.

4. RUS clarifies that the definition of ''Critical Community Facilities'' includes the mandatory Community Center.

5. For all funding commitments, including matching funds, evidence must be submitted demonstrating that funding has been obtained and that the entity providing this funding has the resources to fulfill the commitment. If the appropriate funding commitments are not included in the application, the application will be deemed ineligible for consideration. This evidence must:

a. Clearly state the name of the entity that is making the commitment;

b. Include the amount of the commitment and evidence that the entity making the commitment has the necessary resources; and

c. State the purpose of commitment.

6. RUS clarifies that in order to qualify as eligible grant costs or matching fund contributions, operating expenses incurred in providing Broadband Service to Critical Community Facilities for the first 2 years of operation and in providing training and instruction must be for the following purposes subject to the specified maximum amounts:

a. Salary for operations manager, not to exceed $30,000 per year.

b. Salary for technical support staff, not to exceed $30,000 per year.

c. Salary for community center staff, once operational, not to exceed $25,000 per year.

d. Bandwidth expenses, once operational, not to exceed $25,000 per year.

e. Training courses on the use of the Internet, not to exceed $15,000 per year.

The operating costs to be funded by the grant or from matching contributions cannot exceed in the aggregate $250,000. No other operating expenses than those listed above are eligible for grant funding or to be considered as matching funds. The period for expenses to be considered eligible for grant funding or to be used as an in-kind match is three years from the date the Administrator signs the award documents.

7. Community means any incorporated or unincorporated town, village, or borough located in a Rural Area, that is recognized in the latest decennial census as published by the Bureau of the Census or, in the absence thereof, in the most recent edition of a

Rand McNally Atlas containing population data.

8. RUS clarifies that the economic need of the applicant's service territory will be based on the median household income (MHI) for the Community serviced and the state in which the Community is located, as determined by the decennial census for the year 2000 of the U.S. Bureau of the Census. If the community was qualified using the Rand McNally Atlas, the applicant must use the MHI, contained in the 2000 decennial census, of the county in which the Community resides as the Community MHI.

B. Where To Get Application Information

The application guide which contains forms and samples, and the Community Connect Grant Program regulation are available from these sources:

1. The Internet: *http://www.rurdev.usda.gov/utp_commconnect.htm.*

2. The RUS Broadband Division, for paper copies of these materials call (202) 690–4673.

You may file an application in either paper or electronic format. Whether you file a paper or an electronic application, you will need a DUNS number.

1. DUNS Number

As required by the OMB, all applicants for grants must supply a Dun and Bradstreet Data Universal Numbering System (DUNS) number when applying. The Standard Form 424 (SF–424) contains a field for you to use when supplying your DUNS number. Obtaining a DUNS number costs nothing and requires a short telephone call to Dun and Bradstreet. Please see *http://www.grants.gov/applicants/request_duns_number.jsp* for more information on how to obtain a DUNS number or how to verify your organization's number. For electronic applications, you must file an electronic application at the Web site: *http://www.grants.gov.* You must be registered with Grants.gov before you can submit a grant application. If you have not used Grants.gov before, you will need to register with the CCR and the Credential Provider. You will need a DUNS number to access or register at any of the services.

2. Central Contractor Registration (CCR)

(a) In accordance with 2 CFR part 25, applicants, whether applying electronically or by paper, must be registered in the CCR prior to submitting an application. Applicants may register for the CCR at *https://www.uscontractorregistration.com/* or by calling 1–877–252–2700. Completing the CCR registration process takes up to five business days, and applicants are strongly encouraged to begin the process well in advance of the deadline specified in this notice.

(b) The CCR registration must remain active, with current information, at all times during which an entity has an application under consideration by an agency or has an active Federal Award. To remain registered in the CCR database after the initial registration, the applicant is required to review and update, on an annual basis from the date of initial registration or subsequent updates, its information in the CCR database to ensure it is current, accurate and complete.

C. What constitutes a completed application?

1. Detailed information on each item required can be found in the Community Connect Grant Program regulation and the Community Connect Grant Program application guide, available at the internet link above. Applicants are strongly encouraged to read and apply both the regulation and the application guide. This Notice does not change the requirements for a completed application as specified in the Community Connect Grant Program regulation. The Community Connect Grant Program regulation and the application guide provide more specific guidance than contained in this NOFA and the application guide provides all necessary forms and sample worksheets.

2. Applications should be prepared in conformance with the provisions in 7 CFR 1739, subpart A, applicable USDA regulations including 7 CFR parts 3015, 3016, and 3019, and the application guide, which contains instructions and all necessary forms. Completed applications must include the following:

a. *An Application for Federal Assistance.* A completed Standard Form 424 (SF–424).

b. *An executive summary of the Project.* The applicant must provide RUS with a general project overview.

c. *Scoring criteria documentation.* Each grant applicant must address and provide documentation on how it meets each of the scoring criteria detailed 7 CFR 1739.17.

d. *System design.* The applicant must submit a system design, including narrative specifics of the proposal, associated costs, maps, engineering design studies, technical specifications and system capabilities, and any other information necessary to the system design.

e. *Scope of work.* The scope of work must include specific activities and services to be performed under the proposal, who will carry out the activities and services, specific time-frames for completion, and a budget for all capital and administrative expenditures reflecting the line item costs for all grant purposes, the matching contribution, and other sources of funds necessary to complete the project.

f. *Community-Oriented Connectivity Plan.* The applicant must provide a detailed Community-Oriented Connectivity Plan.

g. *Financial information and sustainability.* The applicant must provide financial statements and information, and a narrative description demonstrating the sustainability of the Project.

h. *A statement of experience.* The applicant must provide a written narrative demonstrating its capability and experience, if any, in operating a broadband telecommunications system.

i. *Evidence of legal authority and existence.* The applicant must provide evidence of its legal existence and authority to enter into a grant agreement with RUS and to perform the activities proposed under the grant application.

j. *Funding commitment from other sources.* If the Project requires additional funding from other sources in addition to the RUS grant, the applicant must provide evidence that funding agreements have been obtained to ensure completion of the Project, as outlined in Section IVA.5.

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

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

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

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

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

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

(vi) Certification regarding Architectural Barriers.

(vii) Certification regarding Flood Hazard Precautions.

(viii) An environmental report, in accordance with 7 CFR 1794.

(ix) Certification that grant funds will not be used to duplicate lines, facilities,

or systems providing Broadband Transmission Service.

(x) Federal Obligation Certification on Delinquent Debt.

D. How many copies of an application are required?

1. Applications submitted on paper: Submit an original application and two (2) copies to Rural Development.

2. Electronically submitted applications: The additional paper copies are not necessary if you submit the application electronically through Grants.gov.

E. How and Where To Submit an Application

Grant applications may be submitted on paper or electronically.

1. Submitting Applications on Paper

a. Address paper applications to the Rural Utilities Service, U.S. Department of Agriculture, 1400 Independence Ave. SW., Room 2868, STOP 1599, Washington, DC 20250–1599. Applications should be marked ''Attention: Director, Broadband Division, Rural Utilities Service.''

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

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

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

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

c. Due to screening procedures at the Department of Agriculture, packages arriving via the USPS are irradiated, which can damage the contents. RUS encourages applicants to consider the impact of this procedure in selecting their application delivery method.

2. Electronically Submitted Applications

(a) Applicant may file an electronic application at *http://www.grants.gov*. Applications will not be accepted via facsimile machine transmission or electronic mail. Grants.gov contains full instructions on all required passwords, credentialing, and software. Follow the instructions at Grants.gov for registering and submitting an electronic application. If a system problem or technical difficulty occurs with an electronic application, please use the customer support resources available at the Grants.gov Web site.

(b) First time Grants.gov users should go to the ''Get Started'' tab on the Grants.gov site and carefully read and follow the steps listed. These steps need to be initiated early in the application process to avoid delays in submitting your application online.

(c) Registering with the Central Contractor Registry (CCR), will take some time to complete, so keep that in mind when beginning the application process. In order to register with the CCR, your organization will need a Data Universal Numbering System (DUNS) Number.

F. Deadlines

1. Paper applications must be postmarked and mailed, shipped, or sent overnight no later than June 7, 2012 to be eligible for FY 2012 grant funding. Late applications are not eligible for FY 2012 grant funding.

2. Electronic grant applications must be received by June 18, 2012 to be eligible for FY 2012 funding. Late applications are not eligible for FY 2012 grant funding.

F. Funding Restrictions

1. *Eligible grant purposes.* Grant funds may be used to finance:

a. The construction, acquisition, or leasing of facilities, including spectrum, to deploy Broadband Transmission Service to all participating Critical Community Facilities and all required facilities needed to offer such service to residential and business customers located within the proposed Service Area;

b. The improvement, expansion, construction, or acquisition of a Community Center that furnishes free access to Broadband Transmission Service, provided that the Community Center is open and accessible to all area residents before, during, and after normal working hours and on Saturday or Sunday. Grant funds provided for such costs shall not exceed the lesser of five percent (5%) of the grant amount requested or $100,000;

c. End-User Equipment needed to carry out the Project;

d. Operating expenses incurred in providing Broadband Transmission Service to Critical Community Facilities for the first 2 years of operation and in providing training and instruction, as outlined in Section IV.A.6; and

e. The purchase of land, buildings, or building construction needed to carry out the Project.

2. Ineligible Grant Purposes

a. Grant funds may not be used to finance the duplication of any existing Broadband Transmission Service provided by another entity.

b. Facilities financed with grant funds cannot be utilized, in any way, to provide local exchange telecommunications service to any person or entity already receiving such service.

3. Please see 7 CFR 1739.3 for definitions, 7 CFR 1739.12 for eligible grant purposes, and 7 CFR 1739.13 for ineligible grant purposes.

V. Application Review Information

A. Criteria

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

2. Grant application scoring criteria (total possible points: 100) See 7 CFR 1739.17 for the items that will be reviewed during scoring and for scoring criteria.

a. The rurality of the Project (up to 40 points);

b. The economic need of the Project's Service Area (up to 30 points); and

c. The ''community-oriented connectivity'' benefits derived from the proposed service (up to 30 points).

B. Review Standards

1. All applications for grants must be delivered to RUS at the address and by the date specified in this notice (see also 7 CFR 1739.2) to be eligible for funding. RUS will review each application for conformance with the provisions of this part. RUS may contact the applicant for additional information or clarification.

2. Incomplete applications as of the deadline for submission will not be considered. If an application is determined to be incomplete, the applicant will be notified in writing and the application will be returned with no further action.

3. Applications conforming with this part will then be evaluated competitively by a panel of RUS employees selected by the Administrator of RUS, and will be awarded points as described in the scoring criteria in 7 CFR 1739.17. Applications will be ranked and grants awarded in rank order until all grant funds are expended.

4. Regardless of the score an application receives, if RUS determines that the Project is technically or financially infeasible, RUS will notify the applicant, in writing, and the application will be returned with no further action.

C. Selection Process

Grant applications are ranked by final score. RUS selects applications based on those rankings, subject to the availability of funds.

VI. Award Administration Information

A. Award Notices

RUS recognizes that each funded project is unique, and therefore may attach conditions to a specific project in

the award documents. RUS generally notifies applicants whose projects are selected for awards by faxing an award letter. RUS follows the award letter with a grant agreement that contains all the terms and conditions of the grant. The applicant must execute and return the grant agreement, accompanied by any additional items required by the grant agreement.

B. Administrative and National Policy Requirements

The items listed in paragraph IV.B.2.k of this notice, and the Community Connect Grant Program regulation, application guide, and accompanying materials implement the appropriate administrative and national policy requirements.

C. Reporting

1. *Performance reporting.* All recipients of Community Connect Grant Program financial assistance must provide annual performance activity reports to RUS until the project is complete and the funds are expended. A final performance report is also required; the final report may serve as the last annual report. The final report must include an evaluation of the success of the project. See 7 CFR 1739.19.

2. *Financial reporting.* All recipients of Community Connect Grant Program financial assistance must provide an annual audit, beginning with the first year a portion of the financial assistance is expended. Audits are governed by United States Department of Agriculture audit regulations. Please see 7 CFR 1739.20.

a. Grantees expending $500,000 or more Federal funds per fiscal year will submit an audit conducted in accordance with OMB Circular A–133. The audit will be submitted within 9 months after the grantee's fiscal year. Additional audits may be required if the project period covers more than one fiscal year.

b. Grantees expending less than $500,000 will provide annual financial statements covering the grant period, consisting of the organization's statement of income and expense and balance sheet signed by an appropriate official of the organization. Financial statements will be submitted within 90 days after the grantee's fiscal year.

3. *Recipient and Subrecipient Reporting.* The applicant must have the necessary processes and systems in place to comply with the reporting requirements for first-tier-sub-awards and executive compensation under the Federal Funding Accountability and Transparency Act of 2006 in the event the applicant receives funding unless such applicant is exempt from such reporting requirements pursuant to 2 CFR part 170 Section 170.110(b). The reporting requirements under the Transparency Act pursuant to 2 CFR part 170 are as follows:

a. First Tier SubAwards of $25,000 or more in non-Recovery Act funds (unless they are exempt under 2 CFR part 170) must be reported by the Recipient to *http://www.fsrs.gov* report no later than the end of the month following the month the obligation was made.

b. The Total Compensation of the Recipient's Executives (5 most highly compensated executives) must be reported by the Recipient (if the Recipient meets the criteria under 2 CFR part 170) to *http://www.ccr.gov* by the end of the month following the month in which the award was made.

c. The Total Compensation of Subrecipient Executives (5 most highly compensated executives) must be reported by the Subrecipient (if the Subrecipient meets the criteria under 2 CFR part 170) to the Recipient by the end of the month following the month in which the subaward was made.

VII. Agency Contacts

A. *Web site: http://www.usda.gov/rus/commconnect.htm.* This Web site maintains up-to-date resources and contact information for the Community Connect Grant Program.

B. *Phone:* 202–690–4673.

C. *Fax:* 202–690–4389.

D. *Main point of contact:* Kenneth Kuchno, Director, Broadband Division, Rural Utilities Service, U.S. Department of Agriculture.

Dated: April 13, 2012.

Jonathan Adelstein,

Administrator, Rural Utilities Service.

[FR Doc. 2012–10614 Filed 5–2–12; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Household Water Well System Grant Program Announcement of Application Deadlines and Funding

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of funding availability and solicitation of applications.

SUMMARY: The Rural Utilities Service (RUS) announces the availability of $993,000 in grant funds to be competitively awarded for the Household Water Well System (HWWS) Grant Program for fiscal year 2012 (FY 2012). RUS will make grants to qualified private non-profit organizations to establish lending programs for homeowners to borrow up to $11,000 to construct or repair household water wells for an existing home. The HWWS Grant Program is authorized under 7 U.S.C. 1926e. Regulations are contained in 7 CFR 1776.

DATES: The deadline for completed applications for a HWWS grant is June 4, 2012. Applications in either paper or electronic format must be postmarked or time-stamped electronically on or before the deadline. Late applications will be ineligible for grant consideration.

ADDRESSES: Submit applications to the following addresses:

1. *Electronic applications: http://www.grants.gov* (Grants.gov). Submit electronic applications through Grants.gov, following the instructions on that Web site.

2. *Paper applications:* Water Programs Division, Rural Utilities Service, STOP: 1570, Room 2233–S, 1400 Independence Ave. SW., Washington, DC 20250–1570.

Obtain application guides and materials for the HWWS Grant Program electronically or in paper format from the following addresses:

1. *Electronic copies: http://www.rurdev.usda.gov/UWP-individualwellsystems.htm.*

2. *Paper copies:* Write Water Programs Division, Rural Utilities Service, STOP: 1570, Room 2233–S, 1400 Independence Ave. SW., Washington, DC 20250–1570 or call (202) 720–9589.

FOR FURTHER INFORMATION CONTACT: Joyce M. Taylor, Community Programs Specialist, Water Programs Division, Water and Environmental Programs. Telephone: (202) 720–9589, fax: (202) 690–0649, email: *JoyceM.Taylor@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency: Rural Utilities Service.

Funding Opportunity Title: HWWS Grant Program.

Announcement Type: Grant—Initial.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.862.

Due Date for Applications: June 4, 2012.

Items in Supplementary Information

I. Funding Opportunity: Description of the HWWS Grant Program.
II. Award Information: Available funds.
III. Eligibility Information: Who is eligible, what kinds of projects are eligible, what criteria determine basic eligibility.
IV. Application and Submission Information: Where to get application materials, what constitutes a completed application, how and where to submit applications,

deadlines, items that are eligible.
V. Application Review Information: Considerations and preferences, scoring criteria, review standards, selection information.
VI. Award Administration Information: Award notice information, award recipient reporting requirements.
VII. Agency Contacts: Web, phone, fax, email, contact name.

I. Funding Opportunity

A. Program Description

The HWWS Grant Program has been established to help individuals with low to moderate incomes finance the costs of household water wells that they own or will own. The HWWS Grant Program is authorized under Section 306E of the Consolidated Farm and Rural Development Act (CONACT), 7 U.S.C. 1926e. The CONACT authorizes the RUS to make grants to qualified private non-profit organizations to establish lending programs for household water wells.

As the grant recipients, private non-profit organizations will receive HWWS grants to establish lending programs that will provide water well loans to individuals. The individuals, as loan recipients, may use the loans to construct, refurbish, and service their household well systems. A loan may not exceed $11,000 and will have a term up to 20 years at a one percent annual interest rate.

B. Background

The RUS supports the sound development of rural communities and the growth of our economy without endangering the environment. The RUS provides financial and technical assistance to help communities bring safe drinking water and sanitary, environmentally sound waste disposal facilities to Rural Americans in greatest need.

Central water systems may not be the only or best solution to drinking water problems. Distance or physical barriers make public central water systems costly to deploy in remote areas. A significant number of geographically isolated households without water service might require individual wells rather than connections to new or existing community systems. The goal of the RUS is not only to make funds available to those communities most in need of potable water but also to ensure that facilities used to deliver drinking water are safe and affordable. There is a role for private wells in reaching this goal.

C. Purpose

The purpose of the HWWS Grant Program is to provide funds to private non-profit organizations to assist them in establishing loan programs from which individuals may borrow money for HWWS. Faith-based organizations are eligible and encouraged to apply for this program. Applicants must show that the project will provide technical and financial assistance to eligible individuals to remedy household well problems.

Due to the limited amount of funds available under the HWWS Grant Program, 10 applications may be funded from FY 2012 funds. Applications from existing HWWS grant recipients are acceptable and will be evaluated as new applications.

II. Award Information

Funding Instrument Type: Grant.

Anticipated Total Priority Area Funding: Undetermined at this time.

Anticipated Number of Awards: 10.

Length of Project Periods: 12-month project.

Assistance Instrument: Grant Agreement with successful applicants before any grant funds are disbursed.

III. Eligibility Information

A. Who is eligible for grants?

1. An organization is eligible to receive a HWWS grant if it:

a. Has an active registration with current information in the Central Contractor Registration (CCR) database and has a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number.

b. Is a private, non-profit organization.

c. Is legally established and located within one of the following:

(1) A state within the United States

(2) The District of Columbia

(3) The Commonwealth of Puerto Rico

(4) A United States territory

d. Has the legal capacity and authority to carry out the grant purpose;

e. Has sufficient expertise and experience in lending activities;

f. Has sufficient expertise and experience in promoting the safe and productive use of individually-owned HWWS and ground water;

g. Has no delinquent debt to the Federal Government or no outstanding judgments to repay a Federal debt;

h. Demonstrates that it possesses the financial, technical, and managerial capability to comply with Federal and State laws and requirements;

i. Corporations that have been convicted of a felony (or had an officer or agency acting on behalf of the corporation convicted of a felony) within the past 24 months are not eligible. Any Corporation that has any unpaid federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability is not eligible.

2. An individual is ineligible to receive a Household Water Well grant. An individual may receive a loan from an organization receiving a grant award.

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

1. *Project Eligibility.* To be eligible for a grant, the project must:

a. Be a revolving loan fund created to provide loans to eligible individuals to construct, refurbish, and service individually-owned HWWS (see 7 CFR 1776.11 and 1776.12). Loans may not be provided for home sewer or septic system projects.

b. Be established and maintained by a private, non-profit organization.

c. Be located in a rural area. Rural area is defined as locations other than cities or towns of more than 50,000 people and the contiguous and adjacent urbanized area of such towns and cities.

2. *Required Matching Contributions.* Grant applicants must provide written evidence of a matching contribution of at least 10 percent from sources other than the proceeds of a HWWS grant. In-kind contributions will not be considered for the matching requirement. Please see 7 CFR 1776.9 for the requirement.

3. Other—Requirements

a. DUNS numbers and CCR Registration. Applicants must have Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) numbers and be registered in the Central Contractor Registration (CCR) database prior to submitting an electronic or a paper application. The DUNS numbers and CCR requirements are contained in 2 CFR 25. CCR is the repository for standard information about applicants and recipients.

b. DUNS Number. An organization must have a DUNS number and include the number in its Application for Federal Assistance. A DUNS number will be required whether an applicant is submitting a paper application or an electronic application through Grants.gov. To verify that your organization has a DUNS number or to receive one from D&B at no cost, call the dedicated toll-free request line at 1–866–705–5711 or visit *http://fedgov.dnb.com/webform/on* the Internet.

c. Central Contractor Registry (CCR).

(1) In accordance with 2 CFR part 25, applicants, whether applying

electronically or by paper, must be registered in the CCR prior to submitting an application. Applicants may register for the CCR at *https://www.uscontractorregistration.com/or* by calling 1–877–252–2700. Completing the CCR registration process takes up to five business days, and applicants are strongly encouraged to begin the process well in advance of the deadline specified in this notice.

(2) The CCR registration must remain active, with current information, at all times during which an entity has an application under consideration by an agency or has an active Federal Award. To remain registered in the CCR database after the initial registration, the applicant is required to review and update on an annual basis from the date of initial registration or subsequent updates of its information in the CCR database to ensure it is current, accurate and complete. d. Eligibility for Loans Provided by Grant Recipients. Individuals are not eligible for grants but are eligible for loans from organizations receiving grant awards under the HWWS Program.

d. Eligibility to receive a HWWS loan will be based on the following criteria:

(1) An individual must be a member of a household of which the combined household income of all members does not exceed 100 percent of the median non-metropolitan household income for the State or territory in which the individual resides. Household income is the total income from all sources received by each adult household member for the most recent 12-month period for which the information is available. It does not include income earned or received by dependent children under 18 years old or other benefits that are excluded by Federal law. The non-metropolitan household income must be based on the most recent decennial census of the United States.

RUS publishes a list of income exclusions in 7 CFR 3550.54(b). Also, the Department of Housing and Urban Development published a list of income exclusions in the **Federal Register** on April 20, 2001, at 66 FR 20318 (*See* ''Federally Mandated Exclusions'').

(2) The loan recipient must own and occupy the home being improved with the proceeds of the Household Water Well loan or be purchasing the home to occupy under a legally enforceable land purchase contract which is not in default by either the seller or the purchaser.

(3) The home being improved with the water well system must be located in a rural area.

(4) The loan for a water well system must not be associated with the construction of a new dwelling.

(5) The loan must not be used to substitute a water well system for water service available from collective water systems. (For example, a loan may not be used to restore an old well abandoned when a dwelling was connected to a water district's water line.)

(6) The loan recipient must not be suspended or debarred from participation in Federal programs.

IV. Application and Submission Information

A. Where To Get Application Information

The Household Water Well System Grant Application Guide (Application Guide), copies of necessary forms and samples, and the HWWS Grant Program regulation are available from these sources:

1. Internet for electronic copies: *http://www.grants.gov* or *http://www.rurdev.usda.gov/UWP-individualwellsystems.htm;*

2. Water and Environmental Programs for paper copies: RUS, Water Programs Division, STOP 1570, Room 2233–S, 1400 Independence Ave. SW., Washington, DC 20250–1570, Telephone: (202) 720–9589, Fax: (202) 690–0649.

B. Content and Form of Application Submission

1. Rules and Guidelines

a. Detailed information on each item required can be found in the HWWS Grant Program regulation (7 CFR part 1776) and the Application Guide. Applicants are strongly encouraged to read and apply both the regulation and the application guide. This Notice does not change the requirements for a completed application for any form of HWWS financial assistance specified in the regulation. The regulation and application guide provide specific guidance on each of the items listed.

b. Applications should be prepared in conformance with the provisions in 7 CFR part 1776, subpart B, and applicable regulations including 7 CFR parts 3015 and 3019. Applicants should use the application guide which contains instructions and other important information in preparing their application. Completed applications must include the items found in the checklist in the next paragraph.

2. Checklist of Items in Completed Application Packages

a. The application process—electronic or paper—requires a DUNS number and an active registration in the Central Contractor Registry (CCR).

(1) You will need a DUNS number first to access or register at any of the services. To verify that your organization has a DUNS number or to receive one from D&B at no cost, call the dedicated toll-free request line at 1–866–705–5711 or visit *http://fedgov.dnb.com/webform/* on the Internet.

(2) Your organization must be listed in the CCR. If you have not used Grants.gov before, you will need to register with the CCR and the Credential Provider. You may register for the CCR by calling the CCR Assistance Center at 1–888–227–2423 or you may register online at *http://www.ccr.gov.* New registrations can take 3–5 business days to process in CCR. Updating or renewing an active registration has a shorter turnaround, 24 hours. Setting up a CCR listing is a one-time procedure with annual updates. Registrations in CCR are active for one year. The CCR registers your organization, housing your organizational information and allowing Grants.gov to use the information to verify your identity. The DUNS number, Taxpayer Identification Number (TIN), and name and address of the applicant organization must match CCR data files.

RUS strongly recommends obtaining a DUNS number and listing the applicant organization in the Central Contractor Registry (CCR) well in advance of the deadline specified in this notice.

b. The electronic and paper application process requires forms with the prefixes RD and SF as well as supporting documents and certifications.

Application Items

1. SF–424, ''Application for Federal Assistance''.

2. SF–424A, ''Budget Information—Non-Construction Programs''.

3. SF–424B, ''Assurances—Non-Construction Programs''.

4. SF–LLL, ''Disclosure of Lobbying Activity''.

5. Form RD 400–1, ''Equal Opportunity Agreement''.

6. Form RD 400–4, ''Assurance Agreement (Under Title VI, Civil Rights Act of 1964).

7. Project Proposal, Project Summary, Needs Assessment, Project Goals and Objectives, Project Narrative.

8. Work Plan.

9. Budget and Budget Justification.

10. Evidence of Legal Authority and Existence.

11. Documentation of private non-profit status and Internal Revenue Service (IRS) Tax Exempt Status.

12. List of Directors and Officers.

13. Financial information and sustainability (narrative).

14. Assurances and Certifications of Compliance with Other Federal Statutes.

The forms in items 1 through 6 must be completed and signed where appropriate by an official of your organization who has authority to obligate the organization legally. RD forms are used by programs under the Rural Development mission area. Standard forms (SF) are used Government-wide. In addition to the sources listed in section A, the forms may be accessed electronically through the Rural Development Web site at *http://www.rurdev.usda.gov/FormsAndPublications.html.*

See section V, ''Application Review Information,'' for instructions and guidelines on preparing Items 7 through 13.

3. *Compliance With Other Federal Statutes.* The applicant must provide evidence of compliance with other Federal statutes and regulations, including, but not limited to the following:

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

b. 7 CFR part 3015—Uniform Federal Assistance Regulations.

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

d. 7 CFR part 3018—New Restrictions on Lobbying.

e. 7 CFR part 3019—Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals, and Non-profit Organizations.

f. 7 CFR part 3021—Governmentwide Requirements for Drug-Free Workplace (Financial Assistance).

g. Executive Order 13166, ''Improving Access to Services for Persons with Limited English Proficiency. '' For information on limited English proficiency and agency-specific guidance, go to *http://www.LEP.gov.*

h. Federal Obligation Certification on Delinquent Debt.

C. How many copies of an application are required?

1. *Applications Submitted on Paper.* Submit one signed original and two additional copies. The original and each of the two copies must include all required forms, certifications, assurances, and appendices, be signed by an authorized representative, and have original signatures. Do not include organizational brochures or promotional materials.

2. *Applications Submitted Electronically.* Additional paper copies are unnecessary if the application is submitted electronically through *http://www.grants.gov.*

D. How and where to submit an application?

1. Submitting Paper Applications

a. For paper applications mail or ensure delivery of an original paper application (no stamped, photocopied, or initialed signatures) and two copies by the deadline date to: RUS, Water Programs Division, STOP 1570, Room 2233–S, 1400 Independence Ave. SW., Washington, DC 20250–1570, Telephone: (202) 720–9589.

Submit paper applications marked ''Attention: Water and Environmental Programs.''

b. Applications must show proof of mailing or shipping by one of the following:

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

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

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

c. If a deadline date falls on a weekend, it will be extended to the following Monday. If the date falls on a Federal holiday, it will be extended to the next business day.

d. Due to screening procedures at the Department of Agriculture, packages arriving via the USPS are irradiated, which can damage the contents and delay delivery. RUS encourages applicants to consider the impact of this procedure in selecting an application delivery method.

2. Submitting Electronic Applications

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

b. Electronic applications for grants will be accepted if submitted through Grants.gov at *http://www.grants.gov.*

c. Applicants must preregister successfully with Grants.gov to use the electronic applications option. Application information may be downloaded from Grants.gov without preregistration.

d. Applicants who apply through Grants.gov should submit their electronic applications before the deadline.

e. Grants.gov contains full instructions on all required passwords, credentialing, and software. Follow the instructions at Grants.gov for registering and submitting an electronic application.

f. Grants.gov has two preregistration requirements: A DUNS number and an active registration in the Central Contractor Registry (CCR). See the ''Checklist of Items in Completed Application Packages'' for instructions on obtaining a DUNS number and registering in the CCR.

g. You must be registered with Grants.gov before you can submit an electronic grant application.

(1) You must register at *http://www.grants.gov/applicants/get_registered.jsp.*

(2) Organization registration user guides and checklists are available at *http://www.grants.gov/applicants/get_registered.jsp.*

(3) Grants.gov requires some credentialing and online authentication procedures. When an applicant organization is registered with CCR, the organization designates a point of contract who receives a password authorizing the person to designate staff members who are allowed to submit applications electronically through Grants.gov. These authorized organization representatives must be registered with Grants.gov to receive a username and password to submit applications. These procedures may take several business days to complete.

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

h. To use Grants.gov:

(1) Follow the instructions on the Web site to find grant information.

(2) Download a copy of an application package.

(3) Complete the package off-line.

(4) Upload and submit the application via the Grants.gov Web site.

(5) If a system problem or technical difficulty occurs with an electronic application, please use the customer support resources available at the Grants.gov Web site.

(6) Again, RUS encourages applicants to take early action to complete the sign-up, credentialing and authorization procedures at *http://www.grants.gov* before submitting an application at the Web site.

E. Deadlines

The deadline for paper and electronic submissions is June 4, 2012. Paper applications must be postmarked and mailed, shipped, or sent overnight no later than the closing date to be considered for FY 2012 grant funding. Electronic applications must have an electronic date and time stamp by midnight of June 4, 2012 to be considered on time. RUS will not accept applications by fax or email. Applications that do not meet the criteria above are considered late applications and will not be considered. RUS will notify each late applicant that its application will not be considered.

F. Funding Restrictions

1. Eligible Grant Purposes

a. Grant funds must be used to establish and maintain a revolving loan fund to provide loans to eligible individuals for household water well systems.

b. Individuals may use the loans to construct, refurbish, rehabilitate, or replace household water well systems up to the point of entry of a home. Point of entry for the well system is the junction where water enters into a home water delivery system after being pumped from a well.

c. Grant funds may be used to pay administrative expenses associated with providing Household Water Well loans.

2. Ineligible Grant Purposes

a. Administrative expenses incurred in any calendar year that exceed 10 percent of the household water well loans made during the same period do not qualify for reimbursement.

b. Administrative expenses incurred before RUS executes a grant agreement with the recipient do not qualify for reimbursement.

c. Delinquent debt owed to the Federal Government does not qualify for reimbursement.

d. Grant funds may not be used to provide loans for household sewer or septic systems.

e. Household Water Well loans may not be used to pay the costs of water well systems for the construction of a new house.

f. Household Water Well loans may not be used to pay the costs of a home plumbing system.

V. Application Review Information

A. Criteria

This section contains instructions and guidelines on preparing the project proposal, work plan, and budget sections of the application. Also, guidelines are provided on the additional information required for RUS to determine eligibility and financial feasibility.

1. *Project Proposal.* The project proposal should outline the project in sufficient detail to provide a reader with a complete understanding of the loan program. Explain what will be accomplished by lending funds to individual well owners. Demonstrate the feasibility of the proposed loan program in meeting the objectives of this grant program. The proposal should include the following elements:

a. *Project Summary.* Present a brief project overview. Explain the purpose of the project, how it relates to RUS' purposes, how the project will be executed, what the project will produce, and who will direct it.

b. *Needs Assessment.* To show why the project is necessary, clearly identify the economic, social, financial, or other problems that require solutions. Demonstrate the well owners' need for financial and technical assistance. Quantify the number of prospective borrowers or provide statistical or narrative evidence that a sufficient number of borrowers will exist to justify the grant award. Describe the service area. Provide information on the household income of the area and other demographical information. Address community needs.

c. *Project Goals and Objectives.* Clearly state the project goals. The objectives should clearly describe the goals and be concrete and specific enough to be quantitative or observable. They should also be feasible and relate to the purpose of the grant and loan program.

d. *Project Narrative.* The narrative should cover in more detail the items briefly described in the Project Summary. Demonstrate the grant applicant's experience and expertise in promoting the safe and productive use of individually-owned household water well systems. The narrative should address the following points:

(1) Document the grant applicant's ability to manage and service a revolving fund. The narrative may describe the systems that are in place for the full life cycle of a loan from loan origination through servicing. If a servicing contractor will service the loan portfolio, the arrangement and services provided must be discussed.

(2) Show evidence of the availability of funds from sources other than the HWWS grant. Describe the contributions the project will receive from your organization, state agencies, local government, other federal agencies, non-government organizations, private industry, and individuals. The documentation should describe how the contributions will be used to pay your operational costs and provide financial assistance for projects.

(3) Demonstrate that the organization has secured commitments of significant financial support from other funding sources.

(4) List the fees and charges that borrowers will be assessed.

2. *Work Plan.* The work plan or scope of work must describe the tasks and activities that will be accomplished with available resources during the grant period. It must include who will carry out the activities and services to be performed and specific timeframes for completion. Describe any unusual or unique features of the project such as innovations, reductions in cost or time, or extraordinary community involvement.

3. *Budget and Budget Justification.* Use the Form SF–424A, Budget Information—Non-Construction Programs, to show your budget cost elements. The form summarizes resources as Federal and non-Federal funds and costs. ''Federal'' refers only to the HWWS Grant Program for which you are applying. ''Non-Federal'' refers to resources from your organization, state agencies, local government, other Federal agencies, non-government organizations, private industry, and individuals. Both Federal and non-Federal resources shall be detailed and justified in the budget and narrative justification.

a. Provide a budget with line item detail and detailed calculations for each budget object class identified in section B of the Budget Information form (SF–424A). Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. Also include a breakout by the funding sources identified in Block 15 of the SF–424.

b. Provide a narrative budget justification that describes how the categorical costs are derived for all capital and administrative expenditures, the matching contribution, and other sources of funds necessary to complete the project. Discuss the necessity, reasonableness, and allocability of the proposed costs. Consult OMB Circular A–122: ''Cost Principles for Non-Profit Organizations'' for information about appropriate costs for each budget category.

c. If the grant applicant will use a servicing contractor, the fees may be reimbursed as an administrative expense as provided in 7 CFR 1776.13. These fees must be discussed in the budget narrative. If the grant applicant

will hire a servicing contractor, it must demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open and free competition. Recipients must justify any anticipated procurement action that is expected to be awarded without competition and exceed the simplified acquisition threshold fixed at 41 U.S.C. 403(11) (currently set at $100,000).

d. The indirect cost category should be used only when the grant applicant currently has an indirect cost rate approved by the Department of Agriculture or another cognizant Federal agency. A grant applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. If the grant applicant is in the process of initially developing or renegotiating a rate, the grant applicant shall submit its indirect cost proposal to the cognizant agency immediately after the applicant is advised that an award will be made. In no event, shall the indirect cost proposal be submitted later than three months after the effective date of the award. Consult OMB Circular A–122 for information about indirect costs.

4. *Evidence of Legal Authority and Existence.* The applicant must provide satisfactory documentation that it is legally recognized under state and Federal law as a private non-profit organization. The documentation also must show that it has the authority to enter into a grant agreement with the RUS and to perform the activities proposed under the grant application. Satisfactory documentation includes, but is not limited to, certificates from the Secretary of State, copies of state statutes or laws establishing your organization, and copies of your organization's articles of incorporation and bylaws. Letters from IRS awarding tax-exempt status are not considered adequate evidence.

5. *List of Directors and Officers.* The applicant must submit a certified list of directors and officers with their respective terms.

6. *IRS Tax Exempt Status.* The applicant must submit evidence of tax exempt status from the Internal Revenue Service.

7. *Financial Information and Sustainability.* The applicant must submit pro forma balance sheets, income statements, and cash flow statements for the last three years and projections for three years. Additionally, the most recent audit of the applicant's organization must be submitted.

B. Evaluation Criteria

Grant applications that are complete and eligible will be scored competitively based on the following scoring criteria:

Scoring criteria	Points
Degree of expertise and experience in promoting the safe and productive use of individually-owned household water well systems and ground water.	Up to 30 points.
Degree of expertise and successful experience in making and servicing loans to individuals	Up to 20 points.
Percentage of applicant contributions. Points allowed under this paragraph will be based on written evidence of the availability of funds from sources other than the proceeds of a HWWS grant to pay part of the cost of a loan recipient's project. In-kind contributions will not be considered. Funds from other sources as a percentage of the HWWS grant and points corresponding to such percentages are as follows:	
0 to 9 percent	ineligible.
10 to 25 percent	5 points.
26 to 30 percent	10 points.
31 to 50 percent	15 points.
51 percent or more	20 points.
Extent to which the work plan demonstrates a well thought out, comprehensive approach to accomplishing the objectives of this part, clearly defines who will be served by the project, and appears likely to be sustainable.	Up to 20 points.
Extent to which the goals and objectives are clearly defined, tied to the work plan, and measurable	Up to 10 points.
Lowest ratio of projected administrative expenses to loans advanced	Up to 10 points.
Administrator's discretion, considering such factors as:	
Creative outreach ideas for marketing HWWS loans to rural residents;	Up to 10 points.
The amount of needs demonstrated in the work plan;	
Previous experiences demonstrating excellent utilization of a revolving loan fund grant; and	
Optimizing the use of agency resources	

C. Review Standards

1. Incomplete applications as of the deadline for submission will not be considered. If an application is determined to be incomplete, the applicant will be notified in writing and the application will be returned with no further action.

2. Ineligible applications will be returned to the applicant with an explanation.

3. Complete, eligible applications will be evaluated competitively by a review team, composed of at least two RUS employees selected from the Water Programs Division. They will make overall recommendations based on the program elements found in 7 CFR 1776 and the review criteria presented in this notice. They will award points as described in the scoring criteria in 7 CFR 1776.9 and this notice. Each application will receive a score based on the averages of the reviewers' scores and discretionary points awarded by the RUS Administrator.

4. Applications will be ranked and grants awarded in rank order until all grant funds are expended.

5. Regardless of the score an application receives, if RUS determines that the project is technically infeasible, RUS will notify the applicant, in writing, and the application will be returned with no further action.

VI. Award Administration Information

A. Award Notices

RUS will notify a successful applicant by an award letter accompanied by a grant agreement. The grant agreement will contain the terms and conditions for the grant. The applicant must execute and return the grant agreement, accompanied by any additional items required by the award letter or grant agreement.

B. Administrative and National Policy Requirements

1. This notice, the 7 CFR part 1776, and the application guide implement the appropriate administrative and national policy requirements. Grant recipients are subject to the requirements in 7 CFR part 1776.

2. Direct Federal grants, sub-award funds, or contracts under the HWWS Grant Program shall not be used to fund inherently religious activities, such as

worship, religious instruction, or proselytization. Therefore, organizations that receive direct assistance should take steps to separate, in time or location, their inherently religious activities from the services funded under the HWWS Grant Program. Regulations for the Equal Treatment for Faith-based Organizations are contained in 7 CFR part 16, which includes the prohibition against Federal funding of inherently religious activities.

C. Reporting

1. *Performance Reporting.* All recipients of HWWS Grant Program financial assistance must provide quarterly performance activity reports to RUS until the project is complete and the funds are expended. A final performance report is also required. The final report may serve as the last annual report. The final report must include an evaluation of the success of the project.

2. *Financial Reporting.* All recipients of HWWS Grant Program financial assistance must provide an annual audit, beginning with the first year a portion of the financial assistance is expended. The grantee will provide an audit report or financial statements as follows:

a. Grantees expending $500,000 or more Federal funds per fiscal year will submit an audit conducted in accordance with OMB Circular A–133. The audit will be submitted within 9 months after the grantee's fiscal year. Additional audits may be required if the project period covers more than one fiscal year.

b. Grantees expending less than $500,000 will provide annual financial statements covering the grant period, consisting of the organization's statement of income and expense and balance sheet signed by an appropriate official of the organization. Financial statements will be submitted within 90 days after the grantee's fiscal year.

3. *Recipient and Subrecipient Reporting.* The applicant must have the necessary processes and systems in place to comply with the reporting requirements for first-tier sub-awards and executive compensation under the Federal Funding Accountability and Transparency Act of 2006 in the event the applicant receives funding unless such applicant is exempt from such reporting requirements pursuant to 2 CFR part 170 Section 170.110(b). The reporting requirements under the Transparency Act pursuant to 2 CFR part 170 are as follows:

a. First Tier Sub-Awards of $25,000 or more in non-Recovery Act funds (unless they are exempt under 2 CFR part 170) must be reported by the Recipient to *http://www.fsrs.gov* no later than the end of the month following the month the obligation was made.

b. The Total Compensation of the Recipient's Executives (5 most highly compensated executives) must be reported by the Recipient (if the Recipient meets the criteria under 2 CFR part 170) to *http://www.ccr.gov* by the end of the month following the month in which the award was made.

c. The Total Compensation of the Subrecipient's Executives (5 most highly compensated executives) must be reported by the Subrecipient (if the Subrecipient meets the criteria under 2 CFR part 170) to the Recipient by the end of the month following the month in which the subaward was made.

VII. Agency Contacts

A. *Web site: http://www.rurdev.usda.gov/UWP-individualwellsystems.htm.*

B. *Phone:* 202–720–9589.

C. *Fax:* 202–690–0649.

D. *Email: JoyceM.Taylor@wdc.usda.gov.*

E. *Main point of contact:* Joyce M. Taylor, Community Programs Specialist, Water Programs Division, Water and Environmental Programs, RUS, U.S. Department of Agriculture.

Dated:April 13, 2012.

Jonathan Adelstein,

Administrator, Rural Utilities Service.

[FR Doc. 2012–10615 Filed 5–2–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Proposed Information Collection; Comment Request; Quarterly Survey of Insurance Transactions by U.S. Insurance Companies With Foreign Persons

AGENCY: Bureau of Economic Analysis (BEA), 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 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 July 2, 2012.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230, or via the Internet at *jjessup@doc.gov*.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information or copies of the survey and instructions to Christopher Emond, Chief, Special Surveys Branch, Balance of Payments Division, (BE–50), Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20230; phone: (202) 606–9826; fax: (202) 606–5318; or via the Internet at *christopher.emond@bea.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

Form BE–45, Quarterly Survey of Insurance Transactions by U.S. Insurance Companies with Foreign Persons, obtains quarterly data from U.S. insurance companies that have engaged in reinsurance transactions with foreign persons, that have earned premiums from, or incurred losses to, foreign persons in acting as primary insurers, or that have engaged in international sale or purchase transactions in auxiliary insurance services greater than $8 million (positive or negative) for the prior calendar year or that are expected to be greater than $8 million (positive or negative) in the current calendar year. The data collected are cut-off sample data. In addition, estimates are developed based upon previously reported or estimated data for non-respondents, including those U.S. insurance companies that fall below the reporting threshold for the quarterly survey but reported on a previous benchmark survey.

The data are needed to monitor U.S. international trade in insurance services, analyze its impact on the U.S. and foreign economies, compile and improve the U.S. economic accounts, support U.S. commercial policy on insurance services, conduct trade promotion, and improve the ability of U.S. businesses to identify and evaluate market opportunities.

Responses will be due within 60 days after the close of each calendar quarter, except for the final quarter of the respondents' fiscal year, when reports are due within 90 days after the close of the quarter. The data from the survey are primarily intended as general purpose statistics. They are needed to answer any number of research and policy questions related to cross-border trade in services.

The form is unchanged from the previous version. No changes in the data

collected or in exemption levels are proposed.

II. Method of Collection

The surveys are sent to the respondents by U.S. mail; the surveys are also available from the Bureau of Economic Analysis Web site. Respondents return the surveys one of four ways: U.S. mail, electronically using BEA's electronic collection system (eFile), fax, or email.

III. Data

OMB Control Number: 0608–0066.

Form Number: BE–45.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: U.S. insurance companies that transact with foreign persons in insurance Services; Business or other for-profit organizations.

Estimated Number of Respondents: 535 per quarter; 2,140 annually.

Estimated Time Per Response: 8 hours for mandatory response; and 1 hour for other response.

Estimated Total Annual Burden Hours: 15,440.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Mandatory.

Legal Authority: The International Investment and Trade in Services Survey Act, 22 U.S.C. 3101–3108, as amended.

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 will 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: April 30, 2012.

Gwellnar Banks,

Management Analyst, Office of Chief Information Officer.

[FR Doc. 2012–10678 Filed 5–2–12; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 7–2012]

Foreign-Trade Zone 45—Portland, Oregon, Expansion of Manufacturing Authority, Epson Portland, Inc.; Extension of Comment Period

The comment period for the application to expand the scope of manufacturing authority approved within Subzone 45F on behalf of Epson Portland, Inc., in Hillsboro, Oregon, submitted by the Port of Portland (77 FR 4006–4007, 1/26/2012 and 77 FR 21082, 4/9/2012), is being extended to May 23, 2012, to allow interested parties additional time in which to comment. Rebuttal comments may be submitted during the subsequent 15-day period, until June 7, 2012. Submissions (original and one electronic copy) shall be addressed to the Board's Executive Secretary at: Foreign-Trade Zones Board, U.S. Department of Commerce, Room 2111, 1401 Constitution Ave. NW., Washington, DC 20230 and *ftz@trade.gov*.

FOR FURTHER INFORMATION CONTACT: Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: April 27, 2012.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2012–10685 Filed 5–2–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free Trade Agreement, Article 1904 NAFTA Panel Reviews; First Request for Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of first request for panel review.

SUMMARY: On April 24, 2012, Samsung Electronics Mexico S.A. de C.V. filed a First Request for Panel Review with the United States Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. On April 25, 2012, an additional Request was filed on behalf of LG Electronics Monterrey Mexico, S.A. de C.V. and its affiliate, LG Electronics USA, Inc. (collectively, ''LG). Panel Review was requested of the U.S. Department of Commerce's final determination regarding Bottom Mount Combination Refrigerator-Freezers from Mexico: Final Results of the January 1, 2010—December 31, 2010 Antidumping Duty Administration Review. This determination was published in the **Federal Register** (77 FR 17422), on March 26, 2012. The NAFTA Secretariat has assigned Case Number USA–MEX–2012–1904–02 to this request.

FOR FURTHER INFORMATION CONTACT: Ellen Bohon, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue NW., Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free Trade Agreement (''Agreement'') established a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada, and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* (''Rules''). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

A first Request for Panel Review was filed with the United States Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement, on April 24, 2012, requesting a panel review of the determination and order described above.

The Rules provide that:

(a) a Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 39 within 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is May 24, 2012);

(b) a Party, investigating authority or interested person that does not file a Complaint but that intends to appear in support of any reviewable portion of the final determination may participate in the panel review by filing a Notice of Appearance in accordance with Rule 40 within 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is June 8, 2012); and

(c) the panel review shall be limited to the allegations of error of fact or law,

including the jurisdiction of the investigating authority, that are set out in the Complaints filed in panel review and the procedural and substantive defenses raised in the panel review.

Dated: April 30, 2012.

Ellen Bohon,

United States Secretary, NAFTA Secretariat.

[FR Doc. 2012–10686 Filed 5–2–12; 8:45 am]

BILLING CODE 3510–GT–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2012–0024]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notification Requirements for Coal and Woodburning Appliances

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The information collection requirements in a Consumer Product Safety Commission (''CPSC'' or ''Commission'') coal and woodburning appliance rule have been approved by the Office of Management and Budget (''OMB'') under OMB control number 3041–0040. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Commission now requests comments on a proposed extension of approval of those information collection requirements for a period of three years from the date of approval by the OMB.

The rule, codified at 16 CFR part 1406, requires manufacturers and importers of certain coal and woodburning appliances to provide safety information to consumers on labels and instructions and an explanation of how certain clearance distances in those labels and instructions were determined. The requirements to provide copies of labels and instructions to the Commission have been in effect for stoves manufactured or imported since October 17, 1983, or May 16, 1984, for stoves introduced into United States commerce after May 16, 1984, regardless of the date of manufacture. For this reason, the information burden imposed by this rule is limited to manufacturers and importers introducing new products or models, or making changes to labels, instructions, or information previously provided to the Commission. The purposes of the reporting requirements in part 1406 are to reduce the risk of injuries from fires associated with the installation, operation, and maintenance of the appliances that are subject to the rule, and to assist the Commission in determining the extent to which manufacturers and importers comply with the requirements in part 1406. The Commission will consider all comments received in response to this notice before requesting approval of this collection of information from the OMB.

DATES: Written comments must be received by the Office of the Secretary not later than July 2, 2012.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2012–0024, by any of the following methods:

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (email) except through *www.regulations.gov.*

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For information about the proposed collection of information call or write Mary James, Office of Information Technology and Technology Services, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7213 or by email to *mjames@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Estimated Burden

CPSC staff estimates that existing manufacturers who are subject to the information collection requirements may introduce up to 15 new models in a 3-year period, or approximately five new models per year. No new manufacturers are expected to begin marketing in the United States. CPSC staff estimates that the average number of hours per respondent is three hours per year, for a total of about 15 hours of annual burden for all respondents (5 models x 3 hours). No specific label design is required, but examples of acceptable label formats are provided in the rule. It is assumed that each manufacturer will use the same general label format for all stove models it produces. Therefore, when a manufacturer introduces a new stove model, the only changes that will be required are to insert the specific information that pertains to the new model. Additionally, manufacturers are to provide the Commission with copies of the information required to be disclosed on the label. Because this information should be readily available, it should take a manufacturer 30 minutes or less per model to collect the information and mail it to the Commission. Therefore, an additional 2.5 hours have been added to the total burden (30 minutes × 5 models per year) for a total annual burden of 17.5 hours. The total estimated annualized respondent cost is approximately $1,044, based on an average total hourly employee compensation rate of $59.63 for management, professional, and related occupations (17.5 hours × $59.63) (Bureau of Labor Statistics, September 2011).

B. Request for Comments

The Commission solicits written comments from all interested persons about the proposed collection of information. The Commission specifically solicits information relevant to the following topics:

—Whether the collection of information described above is necessary for the proper performance of the Commission's functions, including whether the information would have practical utility;

—Whether the estimated burden of the proposed collection of information is accurate;

—Whether the quality, utility, and clarity of the information to be collected could be enhanced; and

—Whether the burden imposed by the collection of information could be minimized by use of automated, electronic, or other technological collection techniques, or other forms of information technology.

Dated: April 30, 2012.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2012–10660 Filed 5–2–12; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, May 9, 2012; 10 a.m.–11 a.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Closed to the public.

Matter To Be Considered

Compliance Status Report

The Commission staff will brief the Commission on the status of compliance matters.

For a recorded message containing the latest agenda information, call (301) 504–7948.

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: May 1, 2012.

Todd A. Stevenson,

Secretary.

[FR Doc. 2012–10856 Filed 5–1–12; 4:15 pm]

BILLING CODE 6355–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Sunshine Act Meeting Notice

The Board of Directors of the Corporation for National and Community Service gives notice of the following meeting:

DATE AND TIME: Wednesday, May 9, 2012, 10:00–11:30 a.m.

PLACE: Corporation for National and Community Service, 1201 New York Avenue, NW., Suite 8312, Washington, DC 20525 (Please go to 10th floor reception area for escort).

CALL-IN INFORMATION: This meeting is available to the public through the following toll-free call-in number: 888–391–6586 conference call access code number 8723527. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and CNCS will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Replays are generally available one hour after a call ends. The toll-free phone number for the replay is 800–262–5024. The end replay date is June 9, 2012, 10:29 p.m. (CT). This meeting will also be broadcast live on the web. Members of the public may view proceedings by visiting *http://www.nationalservice.gov/about/newsroom/live.asp*

STATUS: Open.

Matters To Be Considered

I. Chair's Opening Comments and Swearing in of New Members
II. Consideration of Previous Meeting's Minutes
III. CEO Report
IV. Discussion, Deliberation and Official Actions
V. Public Testimony from Senior Corps Participants in Honor of Senior Corps Week
VI. Public Comments

Members of the public who would like to comment on the business of the Board may do so in writing or in person. Individuals may submit written comments to *esamose@cns.gov* subject line: MAY 2012 CNCS BOARD MEETING by 4:00 p.m. ET on Friday May 4th. Individuals attending the meeting in person who would like to comment will be asked to sign-in upon arrival. Comments are requested to be limited to 2 minutes.

REASONABLE ACCOMMODATIONS: The Corporation for National and Community Service provides reasonable accommodations to individuals with disabilities where appropriate. Anyone who needs an interpreter or other accommodation should notify Ida Green at *igreen@cns.gov* or 202–606–6861 by 5 p.m., May 4, 2012.

CONTACT PERSON FOR MORE INFORMATION: Emily Samose, Strategic Advisor for Board Engagement, Corporation for National and Community Service, 1201 New York Avenue NW., Washington, DC 20525. Phone: (202) 606–7564. Fax: (202) 606–3460. TTY: (800) 833–3722. Email: *esamose@cns.gov.*

Dated: May 1, 2012.

Valerie Green,

General Counsel.

[FR Doc. 2012–10816 Filed 5–1–12; 4:15 pm]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notification of an Open Meeting of the National Defense University Board of Visitors (BOV); Cancellation

AGENCY: National Defense University, DoD.

ACTION: Notice of open meeting; cancellation.

SUMMARY: On April 27, 2012 (77 FR 25150), the National Defense University Board of Visitors gave notice of a date correction to an open meeting that was to be held on May 2, 2012, from 10:00 a.m. to 5:00 p.m. Subsequent to the publication of that notice, Department of Defense learned that the May 2 meeting would be cancelled. This notice announcing the cancellation is publishing in the **Federal Register** after the May 2 open meeting was to have been held.

DATES: The meeting was to have been held on May 2, 2012 from 10:00 a.m. to 5:00 p.m. This meeting was cancelled.

ADDRESSES: The Board of Visitors meeting would have been held at Marshall Hall, Building 62, Room 155, the National Defense University, 300 5th Avenue SW., Fort McNair, Washington, DC 20319–5066.

FOR FURTHER INFORMATION CONTACT: The point of contact for this notice is Ms. Dolores Hodge at (202) 685–0082, Fax (202) 685–3748 or *HodgeD@ndu.edu.*

Dated: April 30, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–10667 Filed 5–2–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2012–OS–0031]

Privacy Act of 1974; System of Records

AGENCY: National Security Agency/Central Security Service, DoD.

ACTION: Notice to add a new system of records.

SUMMARY: The National Security Agency/Central Security Service proposes to add a new system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on June 4, 2012 unless

comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Anne Hill, National Security Agency/Central Security Service, Freedom of Information Act and Privacy Act Office, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248, or by phone at (301) 688–6527.

SUPPLEMENTARY INFORMATION: The National Security Agency/Central Security Service notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on March 16, 2012 to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 18, 2012.

Patricia Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

GNSA 29

SYSTEM NAME:

NSA/CSS Office of Inspector General Investigations and Complaints.

SYSTEM LOCATION:

National Security Agency/Central Security Service, 9800 Savage Road, Ft. George G. Meade, MD 20755–6000.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons who are interviewed by or provide information to the Office of the Inspector General; persons who are the subjects of Inspector General reviews, inquiries, or investigations; persons involved with matters under investigation by the Office of the Inspector General, and persons who have filed grievances with the Office of the Inspector General.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, Social Security Number (SSN), employee identification number, date of birth, place of birth, and investigative case number. Investigative files, hotline complaints, inquiries, and/or investigative reports pertaining to complaints, allegations of fraud, waste, abuse, mismanagement, malfeasance, or reprisal as pertaining to NSA/CSS personnel, procedures, policies, or programs. Files may contain Reports of Investigation; testimony; rights waivers; letters; emails; memoranda; and working papers regarding, developed, or obtained as a result of investigation or complaint wherein someone has made allegations involving fraud, waste, abuse, mismanagement, employee misconduct, reprisal, or other matters involving alleged violations of law, rules or regulations pertaining to NSA/CSS personnel, programs, and/or procedures.

Letters/transcriptions of complaints, allegations and queries, letters of appointment, reports of reviews, inquiries and investigations with supporting attachments; exhibits and photographs, record of interviews, witness statements, agent notes, confidential source documents, subpoenas, reports of legal review of case files, congressional responses, memoranda, letters of rebuttal from subjects of investigations, financial documentation, personnel information, administrative information, adverse information, and technical reports.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Law 95–452, The Inspector General Act of 1978, as amended; DoD Directive 5106.04, Combatant Command Inspectors General; NSA/CSS Office of the Inspector General (NSA/CSS Policy 1–60); Whistleblower Protection (NSA/CSS Policy 1–62); and E.O. 9397 (SSN), as amended.

PURPOSE(S):

Records are used to investigate allegations of misconduct or wrongdoing by NSA/CSS personnel related to violations of laws, rules, or regulations or pertaining to mismanagement, waste of funds, fraud or mismanagement on the part of persons assigned or detailed to NSA/CSS and to provide information to NSA/CSS management regarding personnel matters and for evaluating current and proposed programs, policies, and activities, assignments, and requests for awards or promotions.

Records are used to effect corrective personnel or other administrative action; to provide facts and evidence upon which to base prosecution; to provide information to other investigative elements of the Department of Defense, other Federal, State, or local agencies having jurisdiction over the substances of the allegations or a related investigative interest; to provide information upon which determinations may be made for individuals' suitability for various personnel actions including but not limited to retention, promotion, assignment, retirement, or selection for sensitive or critical positions in the Armed Forces or Federal service.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To appropriate officials within the Intelligence Community and other Federal departments, agencies, inspectors general, and elements thereof to the extent that the records concern NSA/CSS funds, personnel, property programs, operations, or contracts or when relevant to the official responsibilities of those organizations and entities, regarding personnel matters, and to evaluate current and proposed programs, policies and activities, selected assignments and requests for awards or promotions.

To Federal, state, local, foreign or international agencies, or to an individual or organization, when necessary to elicit information relevant to an NSA/CSS Inspector General investigation, inquiry, decision, or recommendation.

To the Department of Justice or any other agency responsible for representing NSA/CSS interests in connection with a judicial, administrative, or other proceeding.

To the Department of Justice or other Intelligence Community Inspector General or agency to the extent necessary to obtain information or advice on any matter relevant to an

Office of the Inspector General investigation.

To the President's Foreign Intelligence Advisory Board and the Intelligence Oversight Board, and any successor organizations, when requested by those entities, or when the Inspector General determines that disclosure will assist in the performance of their oversight functions.

Records in the system may be disclosed to members of the President's Council on Integrity and Efficiency or the Executive Council on Integrity and Efficiency for peer review and the preparation of reports to the President and Congress on the activities of the Inspectors General.

The DoD 'Blanket Routine Uses' published at the beginning of the NSA/CSS's compilation of systems of records also apply to this records system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records and electronic storage media.

RETRIEVABILITY:

By name, Social Security Number (SSN), employee identification number, or investigative case number. Information may be retrieved from this system of records by automated or hand searches based on existing indices, and by automated means utilized in the normal course of business.

SAFEGUARDS:

Buildings are secured by a series of guarded pedestrian gates and checkpoints. Access to facilities is limited to security-cleared personnel and escorted visitors only. Inside the offices housing Office of Inspector General records, paper/hard-copy records are stored in locked containers with limited access, and access to electronic records is limited and controlled by password.

RETENTION AND DISPOSAL:

Formal investigations: Temporary, stored at NSA/CSS, and destroyed when 65 years old.

COMPLAINTS ABOUT AN EMPLOYEE (NOT REQUIRING A FORMAL AGENCY INVESTIGATION):

Temporary, maintained at NSA/CSS and destroyed two years after employee separates from NSA/CSS.

Records are destroyed by pulping, burning, shredding, or erasure or destruction of magnetic media.

SYSTEM MANAGER(S) AND ADDRESS:

Inspector General, National Security Agency/Central Security Service, 9800 Savage Road, Fort George G. Meade, Maryland 20755–6000.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the National Security Agency/Central Security Service, Freedom of Information Act/Privacy Act Office, 9800 Savage Road, Suite 6248, Ft. George G. Meade, Maryland 20755–6248.

Written inquiries should contain the individual's full name, Social Security Number (SSN), mailing address, and signature.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the National Security Agency/Central Security Service, Freedom of Information Act/Privacy Act Office, 9800 Savage Road, Suite 6248, Ft. George G. Meade, Maryland 20755–6248.

Written inquiries should contain the individual's full name, Social Security Number (SSN), mailing address, and signature.

CONTESTING RECORD PROCEDURES:

The NSA/CSS rules for contesting contents and appealing initial agency determinations are published at 32 CFR Part 322 or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is supplied by the individual making the complaint; personnel records and documentation; subjects and suspects of NSA/CSS investigations; and interviews of witnesses, victims, and confidential sources. Record sources also include all types of records and information maintained by all levels of government, private industry, and non-profit organizations reviewed during the course of the investigation or furnished the NSA/CSS; and any other type of record deemed necessary to complete the NSA/CSS investigation.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(j)(2), may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if any individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of the information, the individual will be provided access to the information except to the extent that disclosure would reveal the identity of a confidential source. NOTE: When claimed, this exemption allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information may be exempt pursuant to 5 U.S.C. 552a(k)(5), but only to the extent that such material would reveal the identity of a confidential source.

An exemption rule for this records system has been promulgated according to the requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c) and (e) and published in 32 CFR Part 322. For additional information, contact the system manager.

[FR Doc. 2012–10652 Filed 5–2–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2012–OS–0033]

Privacy Act of 1974; System of Records

AGENCY: Defense Intelligence Agency, DoD.

ACTION: Notice to Alter a System of Records.

SUMMARY: The Defense Intelligence Agency is proposing to alter a system to its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on June 4, 2012 unless comments are received that would result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public

is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Theresa Lowery, Defense Intelligence Agency, DAN 1–C, 600 McDill Blvd. Washington, DC 20340–0001; phone number (202) 231–1193.

SUPPLEMENTARY INFORMATION: The Defense Intelligence Agency system of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the **FOR FURTHER INFORMATION CONTACT** address above.

The proposed system report, as required by 5 U.S.C. 552a of the Privacy Act of 1974, as amended, was submitted on January 28, 2011, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals, dated February 8, 1996 (February 20, 1996, 61 FR 6427).''

Dated: April 18, 2012.

Patricia Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

LDIA 0900

SYSTEM NAME:

Accounts Receivable, Indebtedness and Claims (June 5, 2006, 71 FR 32316).

CHANGES:

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Current and former Defense Intelligence Agency civilian and contract employees, military assignees and other individuals regarding payments, indebtedness and claims to the Defense Intelligence Agency.

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Name, Social Security Number (SSN), current address and telephone number, place and date of birth; financial records such as payments, indebtedness, claims, bills, checks, statements of loss or damages, receipts, investigative and court records, financial statements, credit reports, financial statements; time and attendance records and leave and earnings statements.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''5 U.S.C. 5512, Withholding Pay and Indebtedness; 5 U.S.C. 5513, Withholding Pay-Credit disallowed or charge raised for payment; 5 U.S.C. 5514, Installment Deduction For Indebtedness to the U.S; 5 U.S.C. 5584, Claims for Overpayment of Pay, Allowances and of Travel, Transportation and Relocation Expenses and Allowances; 5 U.S.C. 5705, Advancements and Deductions; 10 U.S.C. 2274, Space Surveillance Network; 31 U.S.C. 3322, Disbursing Official; 31 U.S.C. 3527, General Authority to Issue Checks; 31 U.S.C. 3702, Authority to Settle Claims; 31 U.S.C. 3711, Collection and Compromise; 31 U.S.C. 3716, Administrative Offset; 31 U.S.C. 3717, Interest and Penalty on Claims; 31 U.S.C. 3718, Contracts for Collection Services; 40 U.S.C. 705, Handling of Proceeds from Disposal; and E.O. 9397 (SSN), as amended.''

PURPOSE(S):

Delete entry and replace with ''The system will manage records used in cases regarding claims, payments and indebtedness associated with the Defense Intelligence Agency. Information is used to comply with regulatory requirements and to facilitate collections and/or payments.''

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' set forth at the beginning of the DIA's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

* * * * *

STORAGE:

Delete entry and replace with ''Paper records and electronic storage media.''

RETRIEVABILITY:

Delete entry and replace with ''Last name and Social Security Number (SSN).''

SAFEGUARDS:

Delete entry and replace with ''Records are stored in office buildings protected by guards, controlled screenings, use of visitor registers, electronic access, and/or locks. Access to records is limited to individuals who are properly screened and cleared on a need-to-know basis in the performance of their duties. Passwords and User IDs are used to control access to the system data, and procedures are in place to deter and detect browsing and unauthorized access. Physical and electronic access are limited to persons responsible for servicing and authorized to use the system.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Temporary; Cut off each Fiscal Year (FY). Hold 1 year in current files area and transfer to Washington National Records Center, destroy 6 years and 3 months after period covered by account. Electronic Records are deleted from the database, paper records are destroyed by shredding or burning.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Chief, Financial Policy, Financial Operations and Managerial Accounting Branch, Defense Intelligence Agency, 600 MacDill Blvd. Washington, DC 20340–5100.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the DIA Freedom of Information Office (DAN–1A), Defense Intelligence Agency, 200 MacDill Blvd., Washington, DC 20340–5100.

Request should contain the individual's full name, current address, and telephone number.''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''DIA's rules for accessing records, for contesting contents and appealing initial agency determinations are published in DIA Instruction 5400.001 'Defense Intelligence Agency Privacy Program'; or may be obtained from the system manager.''

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Individuals; DoD and other Federal, state and local financial records systems; financial, educational and medical institutions; and open source information, such as property tax records.''

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Delete entry and replace with ''During the course of Accounts Receivable, Indebtedness and Claims actions, exempt materials from other systems of records may in turn become part of the case records in this system. To the extent that copies of exempt records from those 'other' systems of records are entered into this correspondence case record, the Defense Intelligence Agency hereby claims the same exemptions for the records from those 'other' systems that are entered into this system, as claimed for the original primary systems of records which they are a part.

Records are only exempt from pertinent provisions of 5 U.S.C. 552a to the extent such provisions have been identified and an exemption claimed for the original record and the purposes underlying the exemption for the original record still pertain to the record which is now contained in this system of records. In general, the exemptions were claimed in order to protect properly classified information relating to national defense and foreign policy, to avoid interference during the conduct of criminal, civil, or administrative actions or investigations, to ensure protective services provided the President and others are not compromised, to protect the identity of confidential sources incident to Federal employment, military service, contract, and security clearance determinations, to preserve the confidentiality and integrity of Federal testing materials, and to safeguard evaluation materials used for military promotions when furnished by a confidential source. The exemption rule for the original records will identify the specific reasons why the records are exempt from specific provisions of 5 U.S.C. 552a. An exemption rule for this system has been promulgated in accordance with the requirements of 5 U.S.C 553 (b)(1),(2), and (3), (c) and (e) and published in 32 CFR part 319.''

* * * * *

[FR Doc. 2012–10655 Filed 5–2–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2012–OS–0029]

Privacy Act of 1974; System of Records

AGENCY: Defense Intelligence Agency, DoD.

ACTION: Notice to Alter a System of Records.

SUMMARY: The Defense Intelligence Agency is proposing to alter a system to its existing inventory of records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on June 4, 2012 unless comments are received that would result in contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Theresa Lowery, Defense Intelligence Agency, DAN 1–C, 600 McDill Blvd. Washington, DC 20340–0001, or by phone at (202) 231–1193.

SUPPLEMENTARY INFORMATION: The Defense Intelligence Agency system of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**.

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on March 23, 2011, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals, dated February 8, 1996 (February 20, 1996, 61 FR 6427).''

Dated: April 18, 2012.

Patricia Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

LDIA 0010

SYSTEM NAME:

Requests for Freedom of Information Act, Privacy Act, and Mandatory Declassification Review Information (July 19, 2006, 71 FR 41003).

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with ''Information Requests-Freedom of Information Act (FOIA) and Privacy Act.''

SYSTEM LOCATION:

Delete entry and replace with ''Defense Intelligence Agency, 200 MacDill Blvd., Washington, DC 20340–5100.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''All persons who have requested documents under the provisions of the Freedom of Information Act (FOIA) and Privacy Act; individuals whose requests and/or records have been processed under FOIA and Privacy Act along with attorneys representing individuals making such requests.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Name, address and telephone number of the person making the request and/or their representatives, and case number. Records include forms, documents and correspondence providing information created or compiled in response to FOIA and Privacy Act requests, and include responses, all related memorandums, correspondence, notes, and supported documentation along with copies of the requested records.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''5 U.S.C. 552, Freedom of Information Act (FOIA); 5 U.S.C. 552a, The Privacy Act of 1974, as amended; Department of Defense (DoD) Directive 5400.07–R, DoD Freedom of Information Act (FOIA) Program; DoD 5400.11–R, DoD Privacy Program; Defense Intelligence Agency Instruction (DIAI) 5400.002, DIA FOIA Program; DIAI 5400–11R, DIA Privacy Program.''

PURPOSE(S):

Delete entry and replace with ''The system will manage records generated as a result of FOIA and Privacy Act

requests. Information is used to meet regulatory requirements of the FOIA and Privacy Acts and to provide documentation in response to requests from the public sector for information, which is originated by or contained in the files of the Defense Intelligence Agency. To provide information for compiling reports required by public disclosure statutes and to assist the Department of Justice in preparation of the Agency's defense in any law suit arising under these statutes.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete entry and replace with ''In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, these records contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the Department of Justice for litigation purposes.

The DoD 'Blanket Routine Uses' set forth at the beginning of the DIA's compilation of systems of records notices apply to this system.''

* * * * *

STORAGE:

Delete entry and replace with ''Paper and electronic storage media.''

RETRIEVABILITY:

Delete entry and replace with ''By last name and case number.''

SAFEGUARDS:

Delete entry and replace with ''Records are stored in office buildings protected by guards, controlled screenings, use of visitor registers, electronic access, and/or locks. Access to records is limited to individuals who are properly screened, and cleared on a need-to-know basis in the performance of their duties. Passwords and user IDs control access to the system data, and procedures are in place to deter and detect browsing and unauthorized access. Physical and electronic access are limited to persons responsible for servicing and authorized to use the system.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Privacy Act Request Files destroy 2 years after date of reply. Requests not appealed, destroy 5 years after date of reply. Requests appealed, destroy as authorized under Privacy Act Amendment Case Files. Files maintained for control purposes in responding to requests, including registers and similar records listing date, nature, and purpose of request and name and address of requester; destroy 6 years after date of last entry. Other files destroy 6 years after final action by the Agency or after final adjudication by courts, whichever is later.

Electronic files are deleted from the data base, paper files are destroyed by shredding or burning.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Chief, Freedom of Information and Declassification Services Branch, Defense Intelligence Agency 200 McDill Blvd., Washington, DC 20340–5100.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the DIA Freedom of Information Office (DAN–1A), Defense Intelligence Agency, 200 MacDill Blvd., Washington, DC 20340–5100.

Request should contain the individual's full name, current address, and telephone number.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves, contained in this system of records, should address written inquiries to the DIA Freedom of Information Office (DAN–1A), 200 MacDill Blvd., Washington, DC 20340–5100.

Request should contain the individual's full name, current address, and telephone number.''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''DIA's rules for accessing records, for contesting contents and appealing initial agency determinations are published in DIA Instruction 5400.001 ''Defense Intelligence Agency Privacy Program''; 32 CFR part 319—Defense Intelligence Agency Privacy Program; or may be obtained from the system manager.''

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Individual requesters, attorneys representing individuals making such requests, the Defense Intelligence Agency, and other federal government officials.''

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Delete entry and replace with ''During the course of FOIA and or Privacy Act action, exempt materials from other systems of records may in turn become part of the case records in this system. To the extent that copies of exempt records from those 'other' systems of records become part of this correspondence case record, the Defense Intelligence Agency hereby claims the same exemptions for the records from those 'other' systems when they become part of this system, as claimed for the original primary systems of records that they are a part.

Records are only exempt from pertinent provisions of 5 U.S.C. 552a to the extent such provisions have been identified and an exemption claimed for the original record and the purposes underlying the exemption for the original record still pertain to the record which is now contained in this system of records. In general, the exemptions were claimed in order to protect properly classified information relating to national defense and foreign policy, to avoid interference during the conduct of criminal, civil, or administrative actions or investigations, to ensure protective services provided the President and others are not compromised, to protect the identity of confidential sources incident to Federal employment, military service, contract, and security clearance determinations, to preserve the confidentiality and integrity of Federal testing materials, and to safeguard evaluation materials used for military promotions when furnished by a confidential source. The exemption rule for the original records will identify the specific reasons why the records are exempt from specific provisions of 5 U.S.C. 552a.''

[FR Doc. 2012–10654 Filed 5–2–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of Secretary

[Docket ID DoD–2012–OS–0032]

Privacy Act of 1974; System of Records

AGENCY: National Security Agency/ Central Security Service.

ACTION: Notice to Delete a System of Records.

SUMMARY: The National Security Agency/Central Security Service is deleting a system of records notice from its existing inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on June 4, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Anne Hill, National Security Agency/Central Security Service, Freedom of Information Act and Privacy Act Office, 9800 Savage Road, Suite 6248, Ft. George G. Meade, MD 20755–6248 or at (301) 688–6527.

SUPPLEMENTARY INFORMATION: The National Security Agency systems of records notice subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**.

The National Security Agency proposes to delete a system of records notice from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: April 18, 2012.

Patricia Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

Deletion

GNSA 23

NSA/CSS Operations Security Support Program and Training Files (May 19, 2008, 73 FR 28804).

REASON:

The category of records in this system has substantially changed. The Interagency Operations Security Support Staff now collects and maintains only name and business information (work address, work telephone number, work fax number, and agency/organization/affiliate). Social Security Numbers are no longer collected and personal and home information is no longer maintained. As the Interagency Operations Security Support Staff no longer collects and maintains personally identifiable information, this notice can be deleted.

[FR Doc. 2012–10653 Filed 5–2–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2012–OS–0030]

Privacy Act of 1974; System of Records

AGENCY: Defense Intelligence Agency, DoD.

ACTION: Notice to Delete a System of Records.

SUMMARY: The Defense Intelligence Agency proposes to delete a system of records notice in its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective without further notice on June 4, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is of make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Theresa Lowery, DIA Privacy Act Coordinator, Records Management Section, 200 MacDill Blvd., Washington, DC 20340, telephone number (202) 231–1193.

SUPPLEMENTARY INFORMATION: The Defense Intelligence Agency systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the **FOR FURTHER INFORMAITON CONTACT** address above.

The Defense Intelligence Agency proposes to delete a system of records notice from its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: April 18, 2012.

Patricia Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

Deletion

LDIA 0800

SYSTEM NAME: OPERATION RECORD SYSTEM (JUNE 5, 2006, 71 FR 32317).

REASON:

The records contained in this system of records have been incorporated into LDIA 10–0002, Foreign Intelligence and Counterintelligence Operation Records (June 15, 2010, 75 FR 33791).

[FR Doc. 2012–10656 Filed 5–2–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2012–OS–0050]

Privacy Act of 1974; System of Records

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Defense Logistics Agency proposes to alter a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on June 4, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register**

document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Jody Sinkler, DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221, or by phone at (703) 767–5045.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 27, 2012, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 30, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

S500.60

SYSTEM NAME:

Defense Logistics Agency Hotline Program Records (February 3, 2010, 75 FR 5579).

CHANGES:

* * * * *

SYSTEM NAME:

Add ''Enterprise'' after ''Agency''.

SYSTEM LOCATION:

Within entry, replace ''Director, DLA Accountability Office (DA)'' with ''Inspector General, DLA Office of the Inspector General''.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Covered individuals include those who use the DLA Enterprise Hotline Program to report suspected fraud, waste, abuse, or mismanagement. Also included are other individuals identified during the inquiry, such as persons interviewed, complainants, witnesses, subjects, and contractor employees.''

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Add to entry ''DLA Instruction 5104, DLA Enterprise Hotline Program.''

* * * * *

RETRIEVABILITY:

Delete entry and replace with ''Records are retrieved by the name of complainant, witness, contractor employee, and/or subjects; hotline topic; inquiry number; National Stock Number; and/or contract number.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Within entry, replace ''Director, DLA Accountability Office'' with ''Inspector General, DLA Office of the Inspector General''.

NOTIFICATION PROCEDURE:

Delete first paragraph and replace with ''Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, Attn: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.''

RECORD ACCESS PROCEDURES:

Delete first paragraph and replace with ''Individuals seeking access to information about themselves contained in this system should address written inquiries to the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, Attn: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''The DLA rules for accessing records, for contesting contents, and appealing initial Agency determinations are contained in 32 CFR part 323 or may be obtained from the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, Attn: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.''

RECORD SOURCE CATEGORIES:

Add ''the DLA Enterprise Hotline'' to entry.

* * * * *

[FR Doc. 2012–10666 Filed 5–2–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2012–OS–0051]

Privacy Act of 1974; System of Records

AGENCY: Office of the Defense Logistics Agency, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Defense Logistics Agency proposes to alter a system of records in its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This proposed action will be effective on June 4, 2012 unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Jody Sinkler, DLA/FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221, or by phone at (703) 767–5045.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT**. The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on April 27, 2012, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–

130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 30, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

S400.30

SYSTEM NAME:

Mass Transportation Fringe Benefit Program—Outside the National Capital Region (September 22, 2009, 74 FR 48233).

CHANGES:

* * * * *

SYSTEM NAME:

Delete ''Fringe'' from entry.

SYSTEM LOCATION:

Delete entry and replace with ''Headquarters, Defense Logistics Agency, 8725 John J. Kingman Road, Suite 6220, ATTN: DS–B, DLA Installation Support, Fort Belvoir, VA 22060–6221 and the Defense Logistics Agency (DLA) Primary Level Field Activities located outside the National Capital Region. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices. U.S. Department of Transportation, TRANServe, 1200 New Jersey Avenue SE., Room W12–190, Washington, DC 20590–0001.''

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Defense Logistics Agency (DLA) civilian employees; non-appropriated funded employees; interns/students employed and paid directly by DLA (i.e., interns/students hired through contractual agreements are not eligible); eligible interns/students hired for the summer months; and registered and nonregistered vanpool owners/operators.''

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Records include applicant's full name, personalized 4-digit personal identification number (PIN), home address, office symbol and duty location, office telephone number, mode of transportation being used, cost(s) of commuting, reimbursement claim for expenditures, period covered, amount of reimbursement, records of vouchers, receipts or payments distributed, dates of participation and termination in program, and vanpool owner/operator certification.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete ''and E.O. 9397 (SSN) as amended'' from entry.

PURPOSE(S):

Delete ''Fringe'' from first paragraph.

* * * * *

RETRIEVABILITY:

Delete entry and replace with ''Information is retrieved by individual's name and a personalized 4-digit personal identification number (PIN).''

SAFEGUARDS:

Delete entry and replace with ''Paper records are maintained in a controlled facility. Physical entry is restricted by the use of locks, guards, and is accessible only to authorized personnel. Access to records is limited to person(s) responsible for servicing the records in the performance of their official duties and who are properly screened and cleared for need-to-know. Electronic records are maintained by the on Site Point of Contact computer drive. Access is restricted to the Point of Contact who can only access with secured user identification controls such as a common access card (CAC), personalized password, and key encryption. All individuals granted access to this system of records have received Privacy Act training.''

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''ONCR Program Manager, Headquarters, Defense Logistics Agency, 8725 John J. Kingman Road, Suite 2638, ATTN: DS–B, DLA Installation Support, Fort Belvoir, VA 22060–6221, and the ONCR Mass Transportation Benefit Program Points of Contact at the DLA Primary Level Field Activity. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Written inquiries should contain the full name of the record subject, current address, telephone number, and the DLA Primary Level Field Activity which provided the subsidy.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves contained in this system should address written inquiries to the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.

Written inquiries should contain the full name of the record subject, current address, telephone number, and the DLA Primary Level Field Activity which provided the subsidy.''

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''The DLA rules for accessing records, for contesting contents, and appealing initial agency determinations are contained in 32 CFR part 323, or may be obtained from the DLA FOIA/Privacy Act Office, Headquarters, Defense Logistics Agency, ATTN: DGA, 8725 John J. Kingman Road, Suite 1644, Fort Belvoir, VA 22060–6221.''

* * * * *

[FR Doc. 2012–10684 Filed 5–2–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2012–OS–0035]

Privacy Act of 1974; System of Records

AGENCY: Defense Intelligence Agency, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Defense Intelligence Agency is proposing to alter a system to its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on June 4, 2012 unless comments are received that would result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

* *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public

is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Theresa Lowery. Defense Intelligence Agency, DAN 1–C, 600 McDill Blvd., Washington, DC 20340–0001; phone number (202) 231–1193.

SUPPLEMENTARY INFORMATION: The Defense Intelligence Agency system of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the **FOR FURTHER INFORMATION CONTACT** address above.

The proposed system report, as required by 5 U.S.C. 552a of the Privacy Act of 1974, as amended, was submitted on June 8, 2011 to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals, ''dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 18, 2012.

Patricia Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

LDIA 0660

Security Files (July 24, 2006, 71 FR 41784)

* * * * *

CHANGES:

SYSTEM NAME:

Delete entry and replace with ''Security and Counterintelligence Records''.

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with ''Current and former Defense Intelligence Agency (DIA) civilian, military and contractor personnel, nominees for employment with DIA, all persons with access to DIA facilities and infrastructure, all persons under the security cognizance of DIA. Persons about whom other U.S. government agencies have requested investigative assistance from DIA as part of lawful investigations by their agency. Individuals identified as the result of an administrative, security and/or investigative function who could pose a threat to DIA operations, data, personnel, facilities and systems''.

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Personnel: Name, date and place of birth, Social Security Number (SSN), gender, race, home address, family and dependent information, biometric data, medical/psychological information, financial, employment, training records, test results and education history, statements of personal history.

Administrative: Case control number, forms, documents and correspondence relating to security files, personnel security, investigative and employment records, personnel security functions, nomination notices, indoctrination/debriefing memoranda, secrecy and nondisclosure agreements, certificates of clearance.

Adjudication memoranda and supporting documentation, in-house investigations, security violations, security threats and incidents, investigations and inquiries of criminal and counterintelligence matters, investigative referrals, counterintelligence reporting, foreign travel, foreign contacts, identification badge records, retrieval indices, clearance status records, facility and access control records.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''National Security Act of 1947; E.O. 12333, United States Intelligence Activities; DoDD 5105.21, Defense Intelligence Agency; DoDI 5240.06, Counterintelligence Awareness, Briefing, and Reporting Programs; DoDI 5200.08, Security of DoD Installations and Resources; DoD 5200.2.R, Personnel Security Program; DIA Directive 3020.400, DIA Critical Infrastructure Program; Intelligence Community Directive (ICD) 704, Personnel Security Standards and Procedures Governing Eligibility for Access to Special Compartmented Information and other Controlled Access Program Information; DIA Manual 50–8, Personnel Security Program; DIA Manual 50–14, Security Investigations; DIA Regulation 50–17, Reporting Foreign Contact and Foreign Travel; DIA Instruction 5200.002, Credibility Assessment Program and E.O. 9397 (SSN), as amended.''

PURPOSE(S):

Delete entry and replace with ''The system will manage records used to accomplish security and counterintelligence functions. Information is used to comply with regulatory requirements related to initial and continued employment, to determine eligibility for access to classified information, to protect the agency's operations, data, personnel, facilities and systems (by using administrative, security and investigative functions to detect actual or potential threats and risks)and to document training and education''.

* * * * *

STORAGE:

Delete entry and replace with ''Paper and Electronic storage media''.

RETRIEVABILITY:

Delete entry and replace with ''By last name, Social Security Number (SSN), and applicable case control number''.

SAFEGUARDS:

Delete entry and replace with ''Records are stored in office buildings protected by guards, controlled screenings, use of visitor registers, electronic access, and/or locks. Access to records is limited to individuals who are properly screened and cleared on a need-to-know basis in the performance of their duties. Passwords and User IDs are used to control access to the system data, and procedures are in place to deter and detect browsing and unauthorized access. Physical and electronic access are limited to persons responsible for servicing and authorized to use the system''.

RETENTION AND DISPOSAL:

Delete entry and replace with ''Security Files: Personnel Security Records. Case files documenting the processing of investigations on Federal employees or applicants for Federal employment, whether or not a security clearance is granted, and other persons, such as those performing work for a Federal agency under contract, who require an approval before having access to Government facilities or to sensitive data. These files include questionnaires, summaries of reports prepared by the investigating agency, and other records reflecting the processing of the investigation and the status of the clearance, exclusive of copies of investigative reports furnished by the investigating agency. Temporary-Destroy upon notification of death or 5 years after separation or transfer of employee or no later than 5 years after contract relationship expires.

Security Files: Polygraph examinations, favorable examinations; Temporary-Destroy 90 days.

Unfavorable Examinations; examinations considered as part of an investigation action necessary for security adjudicative purposes and includes the Medical/Psychiatric

Condition Statement-Temporary-Destroy when 15 years old.

Medical and Psychiatric Condition Statement (Favorable), Temporary-Destroy when 1 year old; (Unfavorable), Temporary-Destroy when 15 years old.

Examinations considered records of major significance, congressional interest, national security or upon which significant action was taken (trial, courts-martial, employment termination). PERMANENT—Offer to National Archives and Records Administration (NARA) when 25–30 years old. Final disposition determinations of individual cases are made by NARA.

Security Violations: Temporary—Destroy 5 years after close of case. Files referred for prosecution determination; Temporary—Destroy 3 years after close of case.

Orientation and Training: Temporary—Destroy when no longer required for current operations (documents reflecting training, security orientation, and compliance with security regulations).

Non-Disclosure Agreements: Temporary—Destroy when 70 years old.

Logs and Registers: Temporary—Destroy 2 years after final entry.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Counterintelligence and Security Office, Defense Intelligence Agency, 200 MacDill Blvd., Washington, DC 20340–5100''.

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the DIA Freedom of Information Office (DAN–1A), Defense Intelligence Agency, 200 MacDill Blvd., Washington, DC 20340–5100.

Request should contain the individual's full name, current address, and telephone number''.

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to information about themselves, contained in this system of records, should address written inquiries to the DIA Freedom of Information Office (DAN–1A), 200 MacDill Blvd., Washington, DC 20340–5100.

Request should contain the individual's full name, current address, and telephone number''.

CONTESTING RECORD PROCEDURES:

Delete entry and replace with ''DIA's rules for accessing records, for contesting contents and appealing initial agency determinations are published in DIA Instruction 5400.001 ''Defense Intelligence Agency Privacy Program''; or may be obtained from the system manager''.

RECORD SOURCE CATEGORIES:

Delete entry and replace with ''Subject individuals, agency and other government officials as well as open source information''.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Delete entry and replace with ''Investigatory material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(j)(2), may be exempt pursuant to 5 U.S.C. 552(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or which he would otherwise be eligible, as a result of maintenance of the information, the individual will be provided access to the information except to the extent that disclosure would reveal the identity of a confidential source. This exemption provides limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

(k)(5) Investigatory material complied solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information but only to the extent such material would reveal the identity of a confidential source.

(k)(6) Testing or examination material used to determine individual qualifications for appointment or promotion in the Federal or military service, if the disclosure of such material would compromise the objectivity or fairness of the test or examination process.

An exemption rule for this system has been promulgated in accordance with the requirements of 5 U.S.C. 553 (b)(1), (2), and (3), (c), and (e) and published in 32 CFR part 319''.

* * * * *

[FR Doc. 2012–10657 Filed 5–2–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Renewal of Department of Defense Federal Advisory Committees

AGENCY: DoD.

ACTION: Renewal of Federal Advisory Committee.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b), and 41 CFR 102–3.50(d), the Department of Defense gives notice that it is renewing the charter for the Defense Advisory Committee on Military Personnel Testing (hereafter referred to as ''the Committee'').

The Committee shall provide the Secretary of Defense, through the Under Secretary of Defense for Personnel and Readiness (hereafter referred to as the Under Secretary) with assistance and independent advice on matters pertaining to military personnel testing relating to enlisted selection and classification testing.

The Committee shall review the calibration of personnel selection and classification tests to ensure the accuracy of resulting scores, review relevant validations studies to ensure that the tests have utility in predicting success in technical and on-the-job training, review on-going testing research and development in support of the enlistment program, and make recommendations for improvements to make the testing process more responsive to the Department of Defense (DoD), and the Military Services needs.

The Committee shall be composed of not more than seven members who are eminent authorities in the fields of educational and psychological testing. Committee members, with the approval of the Secretary of Defense, shall serve a term of service of three years, with annual renewals of the member's appointment; however, no member shall serve on the Committee for more than two consecutive terms of service.

The Committee members shall elect the Committee's Chairperson for a term not to exceed two years.

Committee members are appointed to provide advice on behalf of the government on the basis of their best judgment without representing any particular point of view and in a manner that is free from conflict of interest.

Committee members appointed by the Secretary of Defense, who are not full-time or permanent part-time federal officers or employees, shall be appointed to serve as experts and consultants under the authority of 5 U.S.C. 3109, and to serve as special government employees. With the exception of travel and per diem for official travel, Committee members shall serve without compensation.

The Under Secretary shall select and appoint the Committee's chairperson from the total membership.

The Department, when necessary, and consistent with the Committee's mission and DoD policies and procedures, may establish task groups, subcommittees, or working groups deemed necessary to support the Committee. Establishment of task groups, subcommittees, or working groups, will be based upon a written determination, to include terms of reference, by the Secretary of Defense, the Deputy Security of Defense, or the advisory committee's sponsor. These subcommittees or working groups shall operate under the provisions of the FACA, the Government in the Sunshine Act, governing Federal statutes and regulations, and governing DoD policies/procedures.

Such subcommittees or task groups shall not work independently of the chartered Committee, and shall report all their recommendations and advice to the Committee for full deliberation and discussion. Subcommittees have no authority to make decisions on behalf of the chartered Committee; nor can any subcommittee or its members update or report directly to the DoD or any Federal officers or employees.

All subcommittee members shall be appointed in the same manner as the Committee members; that is, the Secretary of Defense shall appoint subcommittee members even if the member in question is already a Committee member. Subcommittee members, with the approval of the Secretary of Defense, may serve a term of service on the subcommittee of four years; however, no member shall serve more than two consecutive terms of service on the subcommittee. Subcommittee members, if not full-time or part-time government employees, shall be appointed to serve as experts and consultants under the authority of 5 U.S.C. 3109, and to serve as special government employees, whose appointments must be renewed on an annual basis. With the exception of travel and per diem for official travel, subcommittee members shall serve without compensation.

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Committee shall meet at the call of the Committee's Designated Federal Officer, in consultation with the Committee's Chairperson. The estimated number of Committee meetings is two per year.

In addition, the Designated Federal Officer is required to be in attendance at all Committee and subcommittee meetings for the entire duration of each and every meeting; however, in the absence of the Designated Federal Officer, the Alternate Designated Federal Officer shall attend the entire duration of the Committee or subcommittee meeting.

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written statements to Defense Advisory Committee on Military Personnel Testing membership about the Committee's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of Defense Advisory Committee on Military Personnel Testing.

All written statements shall be submitted to the Designated Federal Officer for the Defense Advisory Committee on Military Personnel Testing, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Defense Advisory Committee on Military Personnel Testing Designated Federal Officer can be obtained from the GSA's FACA Database—*https://www.fido.gov/facadatabase/public.asp.*

The Designated Federal Officer, pursuant to 41 CFR 102–3.150, will announce planned meetings of the Defense Advisory Committee on Military Personnel Testing. The Designated Federal Officer, at that time, may provide additional guidance on the submission of written statements that are in response to the stated agenda for the planned meeting in question.

Dated: April 30, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–10691 Filed 5–2–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Model Demonstration Projects on Reentry of Students With Disabilities From Juvenile Justice Facilities Into Education, Employment, and Community Programs

AGENCY: Office of Special Education and Rehabilitative Services, Office of Special Education Programs, Department of Education.

ACTION: Notice.

Overview Information

Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities—Model Demonstration Projects on Reentry of Students with Disabilities from Juvenile Justice Facilities into Education, Employment, and Community Programs Notice inviting applications for new awards for fiscal year (FY) 2012.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.326M.

DATES:

Applications Available: May 3, 2012.

Deadline for Transmittal of Applications: June 18, 2012.

Deadline for Intergovernmental Review: August 16, 2012.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program is to promote academic achievement and to improve results for children with disabilities by providing technical assistance (TA), supporting model demonstration projects, disseminating useful information, and implementing activities that are supported by scientifically based research.

Priority: In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute or otherwise authorized in the statute (see sections 663 and 681(d) of the Individuals with Disabilities Education Act (IDEA), 20 U.S.C. 1463 and 1481(d)).

Absolute Priority: For FY 2012 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

Model Demonstration Projects on Reentry of Students With Disabilities From Juvenile Justice Facilities Into Education, Employment, and Community Programs

Background

The purpose of this priority is to support the establishment and operation of three model demonstration projects that will develop, adapt, refine, and evaluate models for facilitating the successful reentry of youth with disabilities from juvenile justice facilities into education, employment, and community programs.

In the 2000–2001 school year, ''students ages 6 through 17 [years] with disabilities made up 11.5 percent of the estimated student enrollment for grades prekindergarten through 12th grade'' (U.S. Department of Education, 2002, p. II–19). Based on their December 1, 2000 census, State departments of juvenile justice reported that, on average, one-third of the youth in the juvenile justice system had identified disabilities; the State-reported prevalence ranged from 9.1 percent to 77.5 percent (Quinn, Rutherford, Leone, Osher, & Poirier, 2005). In other words, the average prevalence of disability among youth in State juvenile justice systems was nearly three times the prevalence of disability among all youth. Of the youth with disabilities in the juvenile justice system, 47.7 percent were classified with emotional disturbance; 38.6 percent with specific learning disabilities; and 9.7 percent with intellectual disabilities (Quinn et al., 2005).

Each year, nearly 100,000 youth under the age of 18, with and without disabilities, are released from juvenile facilities,[1] jails, or prisons, and reenter society, returning to families, local schools, and community life (Snyder, 2004). According to Bilchik & Altschuler (2010, Slide 4),

> Reentry [to school and community life] refers to those activities and tasks that: prepare out-of-home placed juveniles for reentry into the specific families and communities to which they will return; establish the necessary arrangements and linkages with the full range of public and private sector departments, organizations, and individuals in the community that can address known risk and protective factors; and ensure the delivery of prescribed services and supervision in the community. As this definition implies, the residential facility and the community have a critical role to play in reentry.

Preparation and supports for successful reentry from juvenile justice facilities are even more crucial for youth with disabilities, since ''barriers encountered by youth from the juvenile justice system during the transition process are exacerbated when these youth have disabilities'' (Clark, 2003, p. 98). At the same time, their outcomes after returning to their communities tend to be worse than their peers without disabilities. For example, a higher percentage of youth with disabilities return to juvenile justice facilities (Bullis, Yovanoff, Meuller, & Havel, 2002), and in a shorter timeframe (Zhang, Barrett, Katsiyannis, & Yoon, 2011), than their peers without disabilities.

Some practices have shown promise in improving outcomes for reentering juveniles. These promising practices frequently include: Intensive educational interventions; multidisciplinary assessments and planning; integrated transition services (i.e., service delivery focused on the youth's reentry to education, employment, and community programs from the beginning of custody); individualized aftercare; interagency collaboration; research-based interventions implemented with fidelity; and evaluation of services, processes, and outcomes (Hogan, Bullock, & Fritsch, 2010; Newell & Salazar, 2010; Wilkins, 2011).

Assessment and planning must be grounded in an understanding of adolescent educational, psychological, cognitive, and emotional development (Scott & Steinberg, 2008). Multiple disciplines and perspectives (i.e., the youth, special educator, parent, juvenile justice case officer, etc.) should identify the juvenile's strengths and needs and develop a plan of interventions to address these needs (Newell & Salazar, 2010; Zhang, Hsu, Katsiyannis, Barrett, & Song, 2011). Studies suggest that focusing on the transition back to school and community from the start of custody increases the likelihood of successful reentry (Newell & Salazar, 2010; Zhang, Barrett, et al., 2011).

Once a youth reenters the community, individualized aftercare continues to provide the planned interventions, which should be identified based on the unique needs of the juvenile (Scott & Steinberg, 2008) and include any court-mandated interventions (Newell & Salazar, 2010). Aftercare services may include, for example, educational and vocational programs, housing assistance, substance abuse and mental health treatment, life skills training, family counseling, and parent education (Baltodano, Platt, & Roberts, 2005; Wilkins, 2011; Zabel & Nigro, 2007).

Interagency collaboration is essential to ensuring that aftercare services are effective. Successful interagency collaboration efforts include case management services and clearly defined expectations and responsibilities among service agencies. Interagency collaboration helps to connect services, such as intensive educational interventions provided in the juvenile facility, with those provided in the community (Bilchik & Altschuler, 2010; Hogan, Bullock, & Fritsch, 2010; Newell & Salazar, 2010).

Implementing research-based interventions with fidelity increases the likelihood of effectiveness (Fixsen, Naoom, Blasé, Friedman, & Wallace, 2005). The evaluation of services, processes, and outcomes provides formative and summative information needed to demonstrate and improve the quality and effectiveness of interventions. Unfortunately, there is limited research on the quality and effectiveness of reentry models to improve the post-release outcomes of youth in juvenile justice facilities who are identified as having disabilities, most of whom have learning disabilities or emotional disturbance. The Office of Special Education Programs (OSEP) intends to support the development and evaluation of model demonstration projects that serve youth with disabilities reentering education, employment, and community programs from juvenile justice facilities.

Priority: The purpose of this priority is to support the establishment and operation of three model demonstration projects that will develop, adapt, refine, and evaluate models for facilitating the successful reentry of youth with disabilities from juvenile justice facilities into education, employment, and community programs. Each model demonstration project must include the following elements: Intensive educational interventions, multidisciplinary assessments and planning, integrated transition services, individualized aftercare, interagency collaboration, research-based interventions implemented with fidelity, and evaluation of services, processes, and outcomes. The projects must be designed to reduce recidivism and to support the successful transition of these youth with disabilities back into their communities. Successful transition must be measured, in part, using data on high school completion, postsecondary education, and employment. For purposes of this priority, the term ''youth with disabilities'' refers to individuals who are in 7th to 12th grades and are under 18 years of age unless the State where the project is located provides services to students ages 18, 19, 20 or 21 consistent with State law or practice or the order of any court, in which case, the term refers to individuals who are in 7th to 12th grades and are under the maximum age consistent with State law or practice of court order.

To be considered for funding under this absolute priority, applicants must meet the application requirements contained in this priority. Each project

[1] The types of juvenile facilities include detention centers, shelters, reception/diagnostic centers, group homes, ranches, wilderness camps, training schools, and residential treatment centers. The facilities are run by State governments, local governments, and private organizations. Some are secure, while others are not equipped to confine youth.

funded under this absolute priority also must meet the programmatic and administrative requirements specified in the priority.

Application Requirements. An applicant must include in its application—

(a) A description of a proposed model demonstration project that provides services for youth reentering their schools and communities from juvenile justice facilities. The services must be coordinated among a juvenile justice facility, a student's home school district, and any cooperating community programs (see also the section on *Required Activities*). The description must include:

(1) Intervention components, including:

(i) Special education and related services, including therapeutic (e.g., mental health, drug treatment, etc.) and transition services, to be provided to the youth with disabilities, and the responsibilities of the proposed project, local educational agency (LEA), school, juvenile justice facility, and any cooperating agencies to provide such services;

(ii) Processes that support the successful transition of youth with disabilities from the juvenile justice facility to education, employment, and community programs, including: Placement in appropriate education programs that provide special education and related services, as described in students' individualized education programs; support, as appropriate, in locating employment, transportation, and housing; and determination of the type, duration, and intensity of needed aftercare services;

(iii) A data plan that outlines the process for assessing, collecting, and sharing [2] academic, vocational, behavioral, and developmental data for participating youth with disabilities among the collaborating agencies to support the implementation of the model; and

(iv) Description of systems or tools that will be used for storing, managing, analyzing, and reporting data and for communicating among the collaborating agencies and that are necessary to implement the model's services, processes, and data plan.

(2) Implementation components, including the:

(i) Methods and criteria to be used for selecting [3] and recruiting [4] at least three schools from at least one LEA, and at least one juvenile justice facility whose students with disabilities are approaching release to these schools, including descriptions of the juvenile facilities, the schools and LEAs, their populations, and whether the LEAs are considered high-poverty, high-need,[5] rural,[6] urban, or suburban;

Note: Applicants are encouraged to identify, to the extent possible, the juvenile facilities, LEAs, and schools willing to participate in the applicant's model demonstration. Final site selection will be determined in consultation with the OSEP Project Officer following the kick-off meeting (see paragraph (e)(1) in the *Application Requirements* section).

(ii) Strategies to identify and to allocate human resources among the collaborating agencies needed to implement the model;

(iii) Approach to initial and ongoing personnel development or training, including coaching, for personnel involved in implementing the model;

(iv) Approach to measuring fidelity of implementation of the model; and

(v) Approach to measuring the social validity of the model—in other words, measuring the stakeholders' (i.e., service providers', teachers', parents', and students') satisfaction with the model components, processes and outcomes.

(3) Sustainability components, including a plan for:

(i) Transferring the responsibility for project maintenance and support to the collaborating agency personnel at the participating sites by the end of the project period; and

(ii) Continuing the opportunities for training personnel in the collaborating agencies to implement the model, if successful, after the project ends;

(b) A detailed review of the research evidence that supports the effectiveness of the proposed model, its components, and processes with the targeted population(s) and age(s) of youth with disabilities;

(c) A plan and timeline to implement the model described in paragraph (a) of this section that includes details on the elements in the *Required Activities* section of this priority;

(d) A logic model that depicts, at a minimum, the goals, activities, outputs, and outcomes of the proposed model demonstration project. The logic model must make distinct the contributions of each collaborating agency to the activities, outputs, and outcomes of the proposed project. A logic model communicates how a project will achieve its outcomes and provides a framework for both the formative and summative evaluations of the project; and

Note: The following Web sites provide more information on logic models: *www.researchutilization.org/matrix/logicmodel_resource3c.html* and *www.tadnet.org/model_and_performance.*

(e) A budget for attendance at the following:

(1) A one and one half-day kick-off meeting to be held in Washington, DC, after receipt of the award. At the kick-off meeting, OSEP personnel and the grantees, in consultation with the Model Demonstration Coordination Center (MDCC), will develop a project data coordination plan that includes common cross-project data collection instruments, a timeline for collecting these data, and evaluation questions. As part of the cross-project data coordination plan, projects funded under this priority must collect data using common measures that may or may not be the same as those initially proposed by the applicant. These may include student measures; implementation measures such as qualitative descriptions of activities; or site contextual data. The project timeline required under paragraph (c) of this section must be adjusted according to decisions made during kick-off;

[2] Applicants must ensure the confidentiality of individual data, consistent with the requirements of the Family Education Rights and Privacy Act (FERPA) and State laws or regulations concerning the confidentiality of individual records. Final FERPA regulatory changes became effective January 3, 2012, and include requirements for data sharing. Applicants are encouraged to review the final FERPA regulations published on December 2, 2011 (76 FR 75604). Questions can be forwarded to the Family Policy Compliance Office (www.ed.gov/fpco) at (202) 260–3887 or FERPA@ed.gov.

[3] For factors to consider when selecting model demonstration sites, the applicant should refer to *Assessing Sites for Model Demonstration: Lessons Learned for OSEP Grantees* at *http://mdcc.sri.com/documents/reports/MDCC_Site_Assessment_Brief_09-30-11.pdf.* The document also contains a site assessment tool.

[4] The applicant must describe who is going to be contacted within the district(s) and how ''buy-in'' from these and other leaders will be solicited.

[5] Section 2102(3) of the Elementary and Secondary Education Act of 1965, as amended (ESEA) defines a ''high-need LEA'' as an LEA—(A)(i) That serves not fewer than 10,000 children from families with incomes below the poverty line (as that term is defined in section 9101(33) of the ESEA);, or (ii) for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line; and (B)(i) for which there is a high percentage of teachers not teaching in the academic subjects or grade levels that the teachers were trained to teach; or (ii) for which there is a high percentage of teachers with emergency, provisional, or temporary certification or licensing.

[6] For purposes of this priority, ''rural LEA'' means an LEA that is eligible under the Small Rural School Achievement (SRSA) program or the Rural and Low-Income School (RLIS) program authorized under Title VI, Part B of the ESEA. Applicants may determine whether a particular LEA is eligible for these programs by referring to the information on the following Department Web sites. For SRSA: *http://www2.ed.gov/programs/reapsrsa/index.html* For RLIS: *http://www.ed.gov/programs/reaprlisp/eligibility.html.*

(2) A one-day annual planning meeting held in Washington, DC, with the OSEP Project Officer during years 2–4 of the project period;

(3) The three-day Project Directors' Conference in Washington, DC, during each year of the project period; and

(4) Two two-day trips annually to attend Department briefings, Department-sponsored conferences, and other meetings, as requested by OSEP.

Required Activities. To meet the requirements of this priority, each project, at a minimum, must conduct the following activities consistent with the plan proposed in paragraph (c) of the *Application Requirements* section:

(a) Implement a model demonstration project in the participating schools, LEAs, and juvenile justice facilities that—

(1) Address the individual educational, psychological, cognitive, and emotional needs of youth with disabilities in juvenile justice facilities using culturally responsive principles;[7]

(2) Identify a mentor, coach, educational advocate, or case manager to coordinate the transition of youth with disabilities from custody to community life; and

(3) Establish collaborative processes for service provision among the juvenile justice facility, the LEA, and schools, and appropriate community service providers such as mental health and substance abuse treatment providers, to facilitate the outcomes outlined in paragraphs (b) and (c) in this section.

(b) Include, at a minimum in the project's logic model and data plan, the timeline and plan to collect summative evaluation data on the following outcome measures:

(1) Progress toward and rates of high school completion;

(2) Exploration, application, acceptance, and enrollment in postsecondary education, as age appropriate;

(3) Employment, if age appropriate, or progress to obtain the knowledge and skills that will reasonably enable the youth to meet the goal of employment (e.g., enrollment in courses of study leading to employment);

(4) Number and time lag of referrals to juvenile justice following release from the juvenile justice facility; and

(5) Progress in positive, healthy, and pro-social behaviors (voluntary behaviors intended to benefit another), as reflected by reductions in school disciplinary actions and participation in mental health or substance abuse treatment.

(c) Include, at a minimum, in the project's logic model and data plan, the timeline and plan to collect summative evaluation data on the following system outcomes:

(1) Changes to policies, procedures, or data collection systems in the LEAs, schools, and juvenile facilities, including changes related to information or record sharing,[8] referrals for services, instruction, assessment, and transition planning;

(2) Changes to resource allocations in the LEAs, schools, and juvenile facilities, including personnel assignments and transportation costs; and

(3) Estimates of the cost of implementing the model, including costs of the various components of the model.

(d) Implement a formative evaluation plan, consistent with the project's logic model and the data collection plan, to include, as appropriate, periodic collection of student and system data in addition to other largely formative data relating to fidelity of implementation, stakeholder acceptability, and descriptions of the site context. The plan must outline how these data will be reviewed by the project, when they will be reviewed (consistent with the timeline in paragraph (c) under *Application Requirements*), and how they will be used during the course of the project to adjust the model or its implementation to increase the model's usefulness, generalizability, and potential for sustainability.

Other Project Activities. To meet the requirements of this priority, each project, at a minimum, must conduct the following activities:

(a) Participate in ongoing discussions, facilitated by the MDCC, with the other funded projects concerning the development of a data coordination plan that is common to all funded projects and includes evaluation questions; site data collection instruments; synthesis and analysis of the data; acceptable variations across projects for the measurement of implementation fidelity, model acceptability, and data reliability; and collaborative efforts to disseminate information about the models. Projects must be prepared to share some data with the MDCC in the process of implementing the data coordination plan;

Note: In addition to common data and instrumentation, applicants may propose in the application to collect and analyze data that are not commonly collected by all projects, but that support their particular model demonstration project.

(b) Initiate a detailed documentation process sufficient for model replication purposes, should the model be successful;

(c) Communicate and collaborate on an ongoing basis with Department-funded projects such as the National Dropout Prevention Center for Students with Disabilities (*http://www.ndpc-sd.org/*), National Secondary Transition Technical Assistance Center (*http://www.nsttac.org/*), and National Post-School Outcomes Center (*http://www.psocenter.org/*), to share information on successful strategies and implementation challenges regarding school reentry, dropout prevention, job training, and post-secondary transition for youth with disabilities in the juvenile justice system;

(d) Prior to developing any new product, submit a proposal for the product to the Technical Assistance Coordination Center (TACC) database for approval from the OSEP Project Officer. The development of new products should be consistent with the product definition and guidelines posted on the TACC Web site (*www.tadnet.org*);

(e) Maintain ongoing telephone and email communication with the OSEP Project Officer and other projects funded under this priority; and

Note: The MDCC will provide support for monthly teleconferences with all projects to discuss cross-project activities.

(f) If the project maintains a Web site, include relevant information about the model demonstration and documents in a form that meets government or industry recognized standards for accessibility.

References:

Baltodano, H. M., Platt, D., & Roberts, C. W. (2005). Transition from secure care to the community: Significant issues for youth

[7] Culturally responsive principles promote redesigning the learning environments to support the development and success of all students. Some examples of incorporating culturally responsive principles into learning environments include communicating high expectations to all students, incorporating students' cultural and home experiences into lessons by reshaping the curriculum to reflect students' experiences, and engaging students in activities where they can converse with one another on topics that tap into their background knowledge and experiences (Gay, 2000; King, Artiles, & Kozleski, 2010).

[8] As noted elsewhere in this priority, applicants must ensure the confidentiality of individual data, consistent with the requirements of the Family Education Rights and Privacy Act (FERPA) and State laws or regulations concerning the confidentiality of individual records. Final FERPA regulatory changes became effective January 3, 2012, and include requirements for data sharing. Applicants are encouraged to review the final FERPA regulations published December 2, 2011 (76 FR 75604). Questions can be forwarded to the Family Policy Compliance Office (*www.ed.gov/fpco*) at (202) 260–3887 or *FERPA@ed.gov.*

in detention. *Journal of Correctional Education, 56*(4), 372–388.
Bilchik, S., & Altschuler, D. (2010, January 26). *Juvenile reentry in concept and practice.* Webinar by National Reentry Resource Center and the U.S. Department of Justice, Bureau of Justice Assistance and Office for Juvenile Justice and Delinquency Prevention. Available from *http://www.nationalreentryresourcecenter.org/topics/juveniles.*
Bullis, M., Yovanoff, P., Mueller, G., & Havel, E. (2002). Life on the ''outs''—Examination of the facility-to-community transition of incarcerated youth. *Exceptional Children, 69,* 7.
Clark, H. G. (2003). *Resilience: Gender, disability, and justice status in youth transitioning to school* (Doctoral dissertation). Arizona State University. ProQuest Dissertations and Theses. Retrieved from *http://search.proquest.com/docview/305339804?accountid=27030.*
Fixsen, D. L., Naoom, S. F., Blasé, K. A., Friedman, R. M., & Wallace, F. (2005). *Implementation research: A synthesis of the literature.* Tampa, FL: University of South Florida, Louis de la Parte Florida Mental Health Institute, The National Implementation Research Network (FMHI Publication #231).
Gay, G. (2000). *Culturally responsive teaching: Theory, research, and practice.* New York: Teachers College Press.
Hogan, K. A., Bullock, L. M., & Fritsch, E. J. (2010). Meeting the transition needs of incarcerated youth with disabilities. *Journal of Correctional Education, 61*(2), 133–147.
King, A., Artiles, A. J., & Kozleski, E. (2010). *Professional learning for culturally responsive teaching.* Retrieved from *http://www.equityallianceasu.org/sites/default/files/Website-files/exemplarFINAL.pdf.*
Newell, M., & Salazar, A. (2010). *Juvenile reentry in Los Angeles County: An exploration of strengths, barriers, and policy options: A report to the 2nd District of Los Angeles.* Retrieved from *http://www.childrensdefense.org/child-research-data-publications/data/la-county-juvenile-justice.pdf.*
Quinn, M. M., Rutherford, R. B., Leone, P. E., Osher, D. M. & Poirier, J. M. (2005). Youth with disabilities in juvenile corrections: A national survey. *Exceptional Children, 71,* 339–345.
Scott, E. S., & Steinberg, L. (2008). *Rethinking juvenile justice.* Cambridge, MA: Harvard University Press.
Snyder, H. (2004). An empirical portrait of the youth reentry population. *Youth Violence and Juvenile Justice, 2*(1), 39–55. doi: 10.1177/1541204003260046.
U.S. Department of Education. (2002). *Twenty-fourth annual report to Congress on the implementation of the Individuals with Disabilities Education Act.* Washington, DC: Author. Available from *http://www2.ed.gov/about/reports/annual/osep/2002/index.html.*
Wilkins, J. (2011). *Reentry programs for out-of-school youth with disabilities: Part III Characteristics of reentry programs.* Clemson, SC: National Dropout Prevention Center for Students with Disabilities, Clemson University. Available from *http://www.ndpc-sd.org/knowledge/reentry_programs.php.*
Zabel, R., & Nigro, F. (2007). Occupational interests and aptitudes of juvenile offenders: Influence of special education experience and gender. *Journal of Correctional Education, 58*(4), 337–355.
Zhang, D., Barrett, D. E., Katsiyannis, A., & Yoon, M. (2011). Juvenile offenders with and without disabilities: Risks and patterns of recidivism. *Learning & Individual Differences, 21*(1), 12–18. doi: 10.1016/j.lindif.2010.09.006.
Zhang, D., Hsu, H.-Y., Katsiyannis, A., Barrett, D. E., & Song, J. (2011). Adolescents with disabilities in the juvenile justice system: Patterns of recidivism. *Exceptional Children, 77,* 283–296.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1463 and 1481.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 86, 97, 98, and 99.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Cooperative agreements.

Estimated Available Funds: $1,200,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2013 from the list of unfunded applicants from this competition.

Estimated Average Size of Award: $400,000.

Estimated Range of Awards: $375,000 to $400,000.

Maximum Awards: We will reject any application that proposes a budget exceeding $400,000 for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

Estimated Number of Awards: 3.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 48 months.

III. Eligibility Information

1. *Eligible Applicants:* State educational agencies (SEAs); LEAs, including public charter schools that are considered LEAs under State law; IHEs; other public agencies; private nonprofit organizations; outlying areas; freely associated States; Indian tribes or tribal organizations; and for-profit organizations.

2. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

3. *Other: General Requirements*—(a) The projects funded under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants and the grant recipients funded under this competition must involve individuals with disabilities or parents of individuals with disabilities ages birth through 26 in planning, implementing, and evaluating the projects (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet, from the Education Publications Center (ED Pubs), or from the program office.

To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.*

To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application package from ED Pubs, be sure to identify this competition as follows: CFDA number 84.326M.

To obtain a copy from the program office, contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit the application narrative to the equivalent of no more than 70 pages, using the following standards:

• A ''page'' is 8.5″ x 11″, on one side only, with 1'' margins at the top, bottom, and both sides.

• Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions.

• Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

• Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, the references, or the letters of support. However, the page limit does apply to all of the application narrative section (Part III).

We will reject your application if you exceed the page limit or if you apply other standards and exceed the equivalent of the page limit.

3. *Submission Dates and Times:*

Applications Available: May 3, 2012.

Deadline for Transmittal of Applications: June 18, 2012.

Applications for grants under this competition may be submitted electronically using the Grants.gov Apply site (Grants.gov), or in paper format by mail or hand delivery. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: August 16, 2012.

4. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Number System Number, Taxpayer Identification Number, and Central Contractor Registry:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: *www.grants.gov/applicants/get_registered.jsp.*

7. *Other Submission Requirements:* Applications for grants under this competition may be submitted electronically or in paper format by mail or hand delivery.

a. *Electronic Submission of Applications*

We are participating as a partner in the Governmentwide Grants.gov Apply site. The Model Demonstration Projects on Reentry of Students with Disabilities from Juvenile Justice Facilities into Education, Employment, and Community Programs competition, CFDA number 84.326M, is included in this project. We request your participation in *Grants.gov.*

If you choose to submit your application electronically, you must use the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

You may access the electronic grant application for the Model Demonstration Projects on Reentry of Students with Disabilities from Juvenile Justice Facilities into Education, Employment, and Community Programs competition at *www.Grants.gov.* You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.326, not 84.326M).

Please note the following:

• Your participation in Grants.gov is voluntary.

• When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

• Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will

notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *http://www.G5.gov.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you submit your application in paper format.
- If you submit your application electronically, you must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- If you submit your application electronically, you must upload any narrative sections and all other attachments to your application as files in a PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).
- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

b. *Submission of Paper Applications by Mail*

If you submit your application in paper format by mail (through the U.S. Postal Service or a commercial carrier), you must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.326M), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

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

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery*

If you submit your application in paper format by hand delivery, you (or a courier service) must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.326M), 550 12th Street SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34

CFR 75.210 and are listed in the application package.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The Standing Panel requirements under IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within the specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications. However, if the Department decides to select an equal number of applications in each group for funding, this may result in different cut-off points for fundable applications in each group.

4. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program. These measures focus on the extent to which projects provide high-quality products and services, the relevance of project products and services to educational and early intervention policy and practice, and the use of products and services to improve educational and early intervention policy and practice.

Grantees will be required to report information on their project's performance in annual reports to the Department (34 CFR 75.590).

5. *Continuation Awards:* In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made ''substantial progress toward meeting the objectives in its approved application.'' This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: David Emenheiser, U.S. Department of Education, 400 Maryland Avenue SW., Room 4116, Potomac Center Plaza (PCP), Washington, DC 20202–2600. Telephone: (202) 245–7556.

If you use a TDD or a TTY, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: 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 via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must

have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: April 27, 2012.

Alexa Posny,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2012–10692 Filed 5–2–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Department of Energy, DoE.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, May 30, 2012; 1:00 p.m.–7:00 p.m.

ADDRESSES: The Lodge at Santa Fe, 750 North St. Francis Drive, Santa Fe, NM 87501.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board (NNMCAB), 94 Cities of Gold Road, Santa Fe, NM 87506. Phone (505) 995–0393; Fax (505) 989–1752 or Email: *msantistevan@doeal.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

1:00 p.m. Call to Order by Deputy Designated Federal Officer (DDFO), Ed Worth.
- Establishment of a Quorum: Roll Call and Excused Absences, Karen Erickson.
- Welcome and Introductions, Ralph Phelps, Chair.
- Approval of Agenda and March 28, 2012, Meeting Minutes.

1:15 p.m. Public Comment Period.

1:30 p.m. Old Business.
- Written Reports.
- Report on Spring EM SSAB Chairs' Meeting, Ralph Phelps and Carlos Valdez.
- Other Items.

2:00 p.m. New Business.
- Letter from EM SSAB Chairs to Dave Huizenga, Senior Advisor for EM.
- Appointment of Nominating Committee for September Elections.
- Other Items.

2:15 p.m. Items from the DDFO, Ed Worth.
- Update from DOE.
- Definition of One Contaminant.
- Other Items.

2:30 p.m. New Mexico Environment Department (NMED—State Regulator), John Kieling.
- Status of Consent Order.
- Overview of RCRA Permit.
- NMED Top Three Issues.

3:15 p.m. Break.

3:30 p.m. ''State of the Laboratory,'' Pete Maggiore and Michael Graham.
- Organizational Charts (Los Alamos Site Office, Los Alamos National Security and DOE–EM).
- EM Baseline.
- Progress in Clean-up.
- Framework Agreement.
- Top Three Issues.
- Future Activities.

4:30 p.m. Environmental Protection Agency (Federal Regulator), Rich Mayer.
- Federal Facilities Compliance Act.
- National Pollutant Discharge Elimination System (NPDES) Permit Program.
- Waste Isolation Pilot Plant (WIPP).
- Other EPA Regulatory Activities at Los Alamos National Laboratory.

5:15 p.m. Dinner Break.

6:00 p.m. Public Comment Period.

6:15 p.m. Update on ''3706 TRU Waste Campaign,'' Lee Bishop.

6:45 p.m. Wrap-up and Comments from Board Members, Ralph Phelps.

7:00 p.m. Adjourn, Ed Worth, DDFO.

Public Participation: The EM SSAB, Northern New Mexico, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Menice Santistevan at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Menice Santistevan at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Menice Santistevan at the address or phone number listed above. Minutes and other Board documents are on the Internet at: *http://www.nnmcab.energy.gov/.*

Issued at Washington, DC, on April 30, 2012.

LaTanya R. Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2012–10672 Filed 5–2–12; 8:45 am]

BILLING CODE 6405–01–P

DEPARTMENT OF ENERGY

President's Council of Advisors on Science and Technology (PCAST)

AGENCY: Department of Energy.

ACTION: Notice of partially closed meeting.

SUMMARY: This notice sets forth the schedule and summary agenda for a partially closed meeting of the President's Council of Advisors on Science and Technology (PCAST), and describes the functions of the Council. Notice of this meeting is required under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2.

DATES: Friday, May 25, 2012; 9:00 a.m.–5:00 p.m. (EST).

ADDRESSES: The meeting will be held at the Marriott Metro Center (in Ballroom Salon A), 775 12th Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Information regarding the meeting agenda, time, location, and how to register for the meeting is available on the PCAST Web site at: *http://whitehouse.gov/ostp/pcast.* A live video webcast and an archive of the webcast after the event are expected to be available at *http://whitehouse.gov/ostp/pcast.* The archived video will be available within one week of the meeting. Questions about the meeting should be directed to Dr. Deborah D. Stine, PCAST Executive Director, by email at: *dstine@ostp.eop.gov,* or by

telephone at: (202) 456–6006. Please note that public seating for this meeting is limited and is available on a first-come, first-served basis.

SUPPLEMENTARY INFORMATION: The President's Council of Advisors on Science and Technology (PCAST) is an advisory group of the nation's leading scientists and engineers, appointed by the President to augment the science and technology advice available to him from inside the White House and from cabinet departments and other Federal agencies. See the Executive Order at *http://www.whitehouse.gov/ostp/pcast.* PCAST is consulted about and provides analyses and recommendations concerning a wide range of issues where understandings from the domains of science, technology, and innovation may bear on the policy choices before the President. PCAST is co-chaired by Dr. John P. Holdren, Assistant to the President for Science and Technology, and Director, Office of Science and Technology Policy, Executive Office of the President, The White House; and Dr. Eric S. Lander, President, Broad Institute of the Massachusetts Institute of Technology and Harvard.

Type of Meeting: Open and Closed.

Proposed Schedule and Agenda: The President's Council of Advisors on Science and Technology (PCAST) is scheduled to meet in open session on Friday, May 25, 2012, from 9:00 a.m.–5:00 p.m.

Open Portion of Meeting: During this open meeting, PCAST is tentatively scheduled to hear from speakers who will provide information on the National Institute of Food and Agriculture, the U.S. Chief Technology Officer Team Agenda 2012, and two information technology applications—IBM's Watson Project and Google's Self-Driving Car. PCAST will also receive an update on the status of several of its studies including those on the Future of the U.S. Science and Technology Research Enterprise and Realizing the Full Potential of Government-Held Spectrum to Spur Economic Growth. Additional information and the agenda, including any changes that arise, will be posted at the PCAST Web site at: *http://whitehouse.gov/ostp/pcast.*

Closed Portion of the Meeting: PCAST may hold a closed meeting of approximately one hour with the President on May 25, 2012, which must take place in the White House for the President's scheduling convenience and to maintain Secret Service protection. This meeting will be closed to the public because such portion of the meeting is likely to disclose matters that are to be kept secret in the interest of national defense or foreign policy under 5 U.S.C. 552b(c)(1).

Public Comments: It is the policy of the PCAST to accept written public comments of any length, and to accommodate oral public comments whenever possible. The PCAST expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements.

The public comment period for this meeting will take place on May 25, 2012, at a time specified in the meeting agenda posted on the PCAST Web site at *http://whitehouse.gov/ostp/pcast.* This public comment period is designed only for substantive commentary on PCAST's work, not for business marketing purposes.

Oral Comments: To be considered for the public speaker list at the meeting, interested parties should register to speak at *http://whitehouse.gov/ostp/pcast,* no later than 12:00 p.m. (EST) on Thursday, May 17, 2012. Phone or email reservations will not be accepted. To accommodate as many speakers as possible, the time for public comments will be limited to two minutes per person, with a total public comment period of 30 minutes. If more speakers register than there is space available on the agenda, PCAST will randomly select speakers from among those who applied. Those not selected to present oral comments may always file written comments with the committee. Speakers are requested to bring at least 25 copies of their oral comments for distribution to the PCAST members.

Written Comments: Although written comments are accepted continuously, written comments should be submitted to PCAST no later than 12:00 p.m. (EST) on Thursday, May 17, 2012, so that the comments may be made available to the PCAST members prior to this meeting for their consideration. Information regarding how to submit comments and documents to PCAST is available at *http://whitehouse.gov/ostp/pcast* in the section entitled ''Connect with PCAST.''

Please note that because PCAST operates under the provisions of FACA, all public comments and/or presentations will be treated as public documents and will be made available for public inspection, including being posted on the PCAST Web site.

Meeting Accommodations: Individuals requiring special accommodation to access this public meeting should contact Dr. Stine at the telephone or email address listed above, at least ten business days prior to the meeting, so that appropriate arrangements can be made.

Issued in Washington, DC on April 27, 2012.

LaTanya R. Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2012–10723 Filed 5–2–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Nuclear Energy Advisory Committee

AGENCY: Department of Energy, Office of Nuclear Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Nuclear Energy Advisory Committee (NEAC). The Federal Advisory Committee Act (Pub. Law 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Tuesday, June 12, 2012; 8:30 a.m.–4:00 p.m.

ADDRESSES: L'Enfant Plaza Hotel, 480 L'Enfant Plaza SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Kenneth Chuck Wade, Designated Federal Officer, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; Telephone: (301) 903–6509; Email: *Kenneth.wade@nuclear.energy.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Nuclear Energy Advisory Committee (NEAC), formerly the Nuclear Energy Research Advisory Committee (NERAC), was established in 1998 by the U.S. Department of Energy (DOE) to provide advice on complex scientific, technical, and policy issues that arise in the planning, managing, and implementation of DOE's civilian nuclear energy research programs. The committee is composed of 23 individuals of diverse backgrounds selected for their technical expertise and experience, established records of distinguished professional service, and their knowledge of issues that pertain to nuclear energy.

Purpose of the Meeting: Briefing the committee on recent developments and current status of research programs and projects pursued by the Department of Energy's Office of Nuclear Energy; and receiving advice and comments in return from the committee.

Tentative Agenda: The meeting is expected to include presentations that cover such topics as the Office of Nuclear Energy's (NE) 2013 Budget, the status of NE's Small Modular Reactor Program, and the status of NE's Used Fuel Disposition Program. In addition,

there will be presentations by three Nuclear Energy Advisory Committee subcommittees and a presentation on Accident Tolerant Fuels. Finally, a presentation will be given on the status of NE's University Program. The agenda may change to accommodate committee business. For updates, one is directed to the NEAC Web site: *http://www.ne.doe.gov/neac/neNeacMeetings.html.*

Public Participation: Individuals and representatives of organizations who would like to offer comments and suggestions may do so on the day of the meeting, Tuesday June 12, 2012. Approximately thirty minutes will be reserved for public comments. Time allotted per speaker will depend on the number who wish to speak but is not expected to exceed 5 minutes. Anyone who is not able to make the meeting or has had insufficient time to address the committee is invited to send a written statement to Kenneth Chuck Wade at the address or email listed above.

Minutes: The minutes of the meeting will be available by contacting Mr. Wade at the address above or on the Department of Energy, Office of Nuclear Energy Web site at: *http://www.ne.doe.gov/neac/neNeacMeetings.html.*

Issued at Washington, DC on April 27, 2012.

LaTanya R. Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2012–10724 Filed 5–2–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Advisory Board Meeting

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Advisory Board (EMAB). The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, May 31, 2012; 9 a.m.–5 p.m.

ADDRESSES: Hotel on The Falls, 475 River Parkway, Idaho Falls, Idaho 83402.

FOR FURTHER INFORMATION CONTACT: Kristen G. Ellis, Designated Federal Officer, EMAB (EM–42), U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585. Phone (202) 586–5810; fax (202) 586–0293 or email: *kristen.ellis@em.doe.gov*.

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of EMAB is to provide the Assistant Secretary for Environmental Management (EM) with advice and recommendations on corporate issues confronting the EM program. EMAB contributes to the effective operation of the program by providing individual citizens and representatives of interested groups an opportunity to present their views on issues facing EM and by helping to secure consensus recommendations on those issues.

Tentative Agenda Topics

- EM Update
- Updates on EMAB Fiscal Year 2012 Work Plan Assignments
- Tank Waste Strategy Update
- Citizens' Advisory Board Update
- Subcommittee Updates

Public Participation: EMAB welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristen G. Ellis at least seven days in advance of the meeting at the phone number or email address listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to the agenda should contact Kristen G. Ellis at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Kristen G. Ellis at the address or phone number listed above. Minutes will also be available at the following Web site *http://www.em.doe.gov/stakepages/emabmeetings.aspx.*

Issued at Washington, DC on April 27, 2012.

LaTanya R. Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2012–10681 Filed 5–2–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Bonneville Power Administration; Montana-to-Washington Transmission System Upgrade Project EIS

AGENCY: Bonneville Power Administration (BPA), Department of Energy (DOE).

ACTION: Notice of intent to prepare an Environmental Impact Statement (EIS) and notice of floodplain and wetlands involvement.

SUMMARY: BPA intends to prepare an EIS in accordance with the National Environmental Policy Act (NEPA) on several proposed upgrades to its existing transmission system. The proposed upgrades would consist of a combination of reinforcements of five existing BPA substations, placement of new conductor on sections of an existing BPA transmission line, and the addition of a new series compensation substation along an existing BPA transmission line corridor. The substation reinforcements would occur at Garrison and Hot Springs substations in Montana, Dworshak and Hatwai substations in Idaho, and Bell Substation in Washington. The line reconductoring would occur on four sections, totaling 12 miles, of the Dworshak-Taft No. 1 500-kilovolt (kV) line in Montana and Idaho. The series compensation substation would be added along the Garrison-Taft 500-kV line corridor in Montana.

The proposed upgrades are needed to respond to requests for long-term firm transmission service that BPA has received for the West of Garrison and West of Hatwai transmission paths. These upgrades would increase the firm east-to-west transfer capability from BPA's Garrison Substation in Western Montana to load centers west of the Cascades and to market hubs serving the entire Northwest power market.

With this Notice of Intent, BPA is initiating the public scoping process for the EIS. BPA is requesting comments about potential environmental impacts that it should consider as it prepares the EIS for the proposed project.

In accordance with DOE regulations for compliance with floodplain and wetlands environmental review requirements, BPA will prepare a floodplain and wetlands assessment to avoid or minimize potential harm to or within any affected floodplains and wetlands. The assessment will be included in the EIS.

DATES: Written scoping comments are due no later than June 18, 2012, and can be submitted at the addresses below. Verbal and written comments may also

be made at the EIS scoping meetings that will be held at the locations listed below.

ADDRESSES: Send letters with comments and suggestions on the proposed scope of the Draft EIS, and requests to be placed on the project mailing list, to Bonneville Power Administration, Public Affairs Office—DKE–7, P.O. Box 14428, Portland, OR 97293–4428, or by fax to (503) 230–4019. You also may call BPA's toll free comment line at (800) 622–4519 and leave a message (please include the name of this project); or submit comments online at *www.bpa.gov/comment.* BPA will also post all comment letters received in their entirety on BPA's Web site at *www.bpa.gov/comment.*

On May 22, 2012, a scoping meeting will be held from 5:00 p.m. to 7:00 p.m. at the Lewiston Community Center, 1424 Main Street, Lewiston, Idaho 83501. On May 23, 2012, a scoping meeting will be held from 5:00 p.m. to 7:00 p.m. at the Linwood Elementary School, 906 West Weile Avenue, Spokane, Washington 99208. On June 12, 2012, a scoping meeting will be held from 5:00 p.m. to 7:00 p.m. at the Missoula Fire Department (Station 4), 3011 Latimor Street, Missoula, Montana 59808. And lastly, on June 13, 2012, a scoping meeting will be held from 5:00 p.m. to 7:00 p.m. at the St. Regis School, 6 Tiger Street, St. Regis, Montana 59866.

At these informal open-house style meetings, BPA will provide maps and other information about the project and have members of the project team available to answer questions and accept oral and written comments. You may stop by anytime during the open house.

FOR FURTHER INFORMATION CONTACT: Andrew M. Montaño, Environmental Protection Specialist, Bonneville Power Administration—KEC–4, P.O. Box 3621, Portland, Oregon 97208–3621; toll-free telephone 1–800–282–3713; direct telephone 503–230–4145; or email *ammontano@bpa.gov.* You may also contact Amit Sinha, Project Manager, Bonneville Power Administration—TEP–3, P.O. Box 3621, Portland, Oregon 97208–3621; toll-free telephone 1–800–282–3713; direct telephone 360–619–6178; or email *axsinha@bpa.gov.* Additional information can be found at BPA's project Web site at *www.bpa.gov/go/M2W.*

SUPPLEMENTARY INFORMATION: In 2010, BPA conducted a Network Open Season (NOS) process to help manage its list of reque‘‘’’sts for long-term transmission service. During the NOS process, utilities and power generators (including wind generators and power marketers) requested the use of BPA's transmission system to transmit their power. To determine if BPA could offer the service requested, BPA studied the transmission system and identified where existing capacity was available and where the system needed upgrades. The studies found that there was not enough available transmission capacity to accommodate all requests for long-term service from the west side of its Garrison Substation in Western Montana to load centers west of the Cascades. Wind generation facilities built and proposed in the region have greatly increased the amount of power being produced in Montana seeking load and markets in the Northwest. Further studies revealed that reinforcing the BPA Network at strategic locations on the Garrison-Taft, Taft-Dworshak and Taft-Bell, Hatwai-Lower Granite, and Grand Coulee-Bell sections would allow BPA to accommodate the requests for transmission service in this area.

BPA must respond to these requests for transmission service under its Open Access Transmission Tariff. This tariff, which is generally consistent with the Federal Energy Regulatory Commission's *pro forma* open access tariff, has procedures that provide access to BPA's transmission system for all eligible customers, consistent with all BPA requirements (including the availability or development of sufficient transmission capacity) and subject to an environmental review under NEPA. The proposed Montana-to-Washington Transmission System Upgrade Project, formerly known as the Colstrip Upgrade Project or ''CUP West,'' would respond to these requests for transmission service.

BPA will prepare an EIS under NEPA to assist the agency as it decides whether to perform these proposed transmission system upgrades. The EIS will study two alternatives: The proposed system upgrades and a No Action Alternative in which BPA would not upgrade its system and not be able to provide the requested transmission service. BPA will be the lead agency for preparation of the EIS. Cooperating agencies for the EIS may be identified as the proposed project proceeds through the NEPA process.

Public Participation and Identification of Environmental Issues. The potential environmental issues identified for most transmission line projects include land use, socioeconomics, cultural resources, visual resources, electric and magnetic fields, sensitive plants and animals, soil erosion, wetlands, floodplains, and fish and water resources. BPA has established a 45-day scoping period during which tribes, affected landowners, concerned citizens, special interest groups, local and federal governments, and any other interested parties are invited to comment on the scope of the proposed EIS, including the environmental impacts to be evaluated. Scoping will help BPA ensure that a full range of issues related to this proposal is addressed in the EIS, and also will identify significant or potentially significant impacts that may result from the proposed project. When completed, the Draft EIS will be circulated for review and comment, and BPA will hold public meetings to hear comments. The Draft EIS is expected to be published in the fall of 2013. BPA will consider and respond to comments received on the Draft EIS in the Final EIS. The Final EIS is expected to be published in fall of 2014. BPA's decision will be documented in a Record of Decision that will follow the Final EIS.

Issued in Portland, Oregon, on April 23, 2012.

Stephen J. Wright,

Administrator and Chief Executive Officer.

[FR Doc. 2012–10673 Filed 5–2–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Efficiency and Renewable Energy

Biomass Research and Development Technical Advisory Committee

AGENCY: Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an open meeting of the Biomass Research and Development Technical Advisory Committee. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Tuesday, May 22, 2012; 8:30 a.m.–1:30 p.m. and Wednesday, May 23, 2012; 8:30 a.m.–12:00 p.m.

ADDRESSES: Pacific Northwest National Laboratory, Biological Sciences Facility & Computational Sciences Facility, 3300 Stevens Drive, Richland, Washington 99354.

FOR FURTHER INFORMATION CONTACT: Elliott Levine, Designated Federal Officer, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy, 1000 Independence Avenue

SW., Washington, DC 20585; (202) 586–1476; Email: *Elliott.Levine@ee.doe.gov*.

SUPPLEMENTARY INFORMATION: *Purpose of Meeting:* To provide advice and guidance that promotes research and development leading to the production of biobased fuels and biobased products.

Tentative Agenda: Agenda will include the following:

- Update on USDA Biomass R&D Activities
- Update on DOE Biomass R&D Activities
- Presentations on Biomass related research in the Northwest
- Update on the Biomass Research and Development Initiative

Public Participation: In keeping with procedures, members of the public are welcome to observe the business of the Biomass Research and Development Technical Advisory Committee. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, you must contact Elliott Levine at 202–586–1476; Email: *Elliott.Levine@ee.doe.gov* or Roy Tiley at (410) 997–7778 ext. 220; Email: *rtiley@bcs-hq.com* at least 5 business days prior to the meeting. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Co-chairs of the Committee will make every effort to hear the views of all interested parties. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. The Co-chairs will conduct the meeting to facilitate the orderly conduct of business.

Minutes: The minutes of the meeting will be available for public review and copying at the following Web site: *http://biomassboard.gov/committee/meetings.html*.

Issued at Washington, DC, on April 27, 2012.

LaTanya R. Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2012–10670 Filed 5–2–12; 8:45 am]

BILLING CODE 6450–01–P

EXPORT-IMPORT BANK OF THE U.S.

[Public Notice 2012–0088]

Agency Information Collection Activities: Final Collection; Comment Request

AGENCY: Export-Import Bank of the U.S.

ACTION: Submission for OMB Review and Comments Request.

Form Title: EIB 99–14 Export Import Bank Trade Reference form.

SUMMARY: The Export-Import Bank of the United States (Ex-Im Bank), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

Ex-Im Bank is requesting an emergency approval of Ex-Im Bank form EIB 99–14 Export Import Bank Trade Reference form. Export-Import (Ex-Im) Bank is requesting an emergency approval of form EIB 99–14, Trade Reference Form. This form provides essential credit information used by Ex-Im Bank credit officers when analyzing requests for export credit insurance/financing support, both short-term (360 days & less) & medium-term (longer than 360 days), for the export of their US goods and services. Additionally, this form is an integral part of the short-term Multi-Buyer export credit insurance policy for those policyholders granted foreign buyer discretionary credit limit authority (DCL). Multi-Buyer policy holders given DCL authority may use this form as the sole source or one piece among several sources of credit information for their internal foreign buyer credit decision in which, in turn, commits Ex-Im's guarantee.

Lack of an emergency approval of this form would greatly restrict our ability to support many of the export sales made by U.S. businesses. Ex-Im Bank and its Multi-Buyer policyholders use the Trade Reference Form approximately 6,500 times annually. Thus the Trade Reference Form is critical to Ex-Im Bank and in particular to over 2,300 Multi-Buyer policyholders during their foreign buyer credit review process. This would adversely impact Ex-Im Bank's ability to finance small business exporters and its overall mission to support U.S. exports and maintain U.S. jobs. Accordingly, Ex-Im Bank requests emergency approval of EIB 99–14 in order to continue operation of this important export program.

The form can be viewed at *www.exim.gov/pub/pending/eib99-14.pdf.*

DATES: Comments should be received on or before July 2, 2012 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* or by mail to Jean Fitzgibbon, Export Import Bank of the United States, 811 Vermont Ave. NW., Washington, DC 20571.

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 99–14 Export Import Bank Trade Reference form.

OMB Number: 3048–xxx.

Type of Review: Emergency Clearance.

Need and Use: This form provides essential credit information used by Ex-Im Bank credit officers when analyzing requests for export credit insurance/financing support, both short-term (360 days & less) & medium-term (longer than 360 days), for the export of their US goods and services. Additionally, this form is an integral part of the short-term Multi-Buyer export credit insurance policy for those policyholders granted foreign buyer discretionary credit limit authority (DCL). Multi-Buyer policy holders given DCL authority may use this form as the sole source or one piece among several sources of credit information for their internal foreign buyer credit decision in which, in turn, commits Ex-Im's guarantee.

Affected Public: This form affects entities involved in the export of U.S goods and services.

Annual Number of Respondents: 6,500.

Estimated Time per Respondent: 15 minutes.

Government Annual Burden Hours: 1,625 hours.

Frequency of Reporting or Use: As needed.

Sharon A. Whitt,

Agency Clearance Officer.

[FR Doc. 2012–10662 Filed 5–2–12; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK OF THE UNITED STATES

Economic Impact Policy

This notice is to inform the public that the Export-Import Bank of the United States has received an application for a $35 million transaction specific working capital guarantee to support the export of approximately $63.5 million worth of sulphur purification equipment and services to Iraq. The repayment term of the working capital guarantee is 24 months. The U.S. exports will enable the Iraqi mining company to establish a maximum production capacity of 500,000 metric tons of sulphur per year. Available information indicates that all of the Iraqi sulphur production will be sold domestically in Iraq. Interested parties may submit comments on this transaction by email to *economic.impact@exim.gov* or by mail to 811 Vermont Avenue NW., Room

947, Washington, DC 20571, within 14 days of the date this notice appears in the **Federal Register**.

Angela Mariana Freyre,

Senior Vice President and General Counsel.

[FR Doc. 2012–10664 Filed 5–2–12; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Issuance of Statement of Federal Financial Accounting Standard 42

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Board Action: Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and the FASAB Rules of Procedure, as amended in October, 2010, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has issued Statement of Federal Financial Accounting Standard 42, *Deferred Maintenance and Repairs, Amending Statements of Federal Financial Accounting Standards 6, 14, 29 and 32.*

The Standard is available on the FASAB home page *http://www.fasab.gov/standards.html.*

Copies can be obtained by contacting FASAB at (202) 512–7350.

FOR FURTHER INFORMATION CONTACT: Wendy Payne, Executive Director, at (202) 512–7350.

Authority: Federal Advisory Committee Act, Pub. L. 92–463.

Dated: April 27, 2012.

Charles Jackson,

Federal Register Liaison Officer.

[FR Doc. 2012–10610 Filed 5–2–12; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before July 2, 2012. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Judith B. Herman, Federal Communications Commission, via the Internet at *Judith-b.herman@fcc.gov.* To submit your PRA comments by email send them to: *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0484.

Title: Sections 4.1 and 4.2, Part 4 of the Commission's Rules Concerning Disruptions to Communications (NORS).

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities and Not-for-profit Institutions.

Number of Respondents: 118 respondents; 15,444 responses.

Estimated Time per Response: .25 hours to 2 hours.

Frequency of Response: On occasion and annual reporting requirements.

Obligation to Respond: Mandatory. Statutory authority for this collection of information is contained in 47 U.S.C. sections 151, 152, 154(i)–(k), 154(o), 218, 219, 230, 256, 301, 302(a), 303(f), 303(g), 303(j), 303(r), 403, 615a–l, 621(b)(3), 621(d), 1302(a) and 1302(b) of the Communications Act of 1934, as amended; and Section 1704 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1998, 44 U.S.C. section 3504.

Total Annual Burden: 29,647 hours.

Total Annual Cost: N/A.

Privacy Impact Assessment: N/A.

Nature and Extent of Confidentiality: Outage reports filed pursuant to Part 4 of the Commission's rules are presumed confidential. The information in the filings may be shared with the Department of Homeland Security only under appropriate confidential disclosure provisions. Other persons seeking disclosure must follow the procedures delineated in 47 CFR sections 0.457 and 0.459 of the Commission's rules for requests for and disclosure of information.

Needs and Uses: The Commission is seeking OMB approval for a revision of this information collection in order to obtain the full three year approval from OMB. The Commission is reporting a 9,909 hours program change increase in the Commission's previous burden estimates. The increase in the burden estimates is due to adoption of FCC 12–22, Report and Order, extending the Part 4 outage reporting requirements to interconnected Voice over Internet Providers (VoIP) which are new respondents subject to the requirements of this information collection.

Specifically, the Commission extended mandatory outage reporting rules to facilities-based and non-facilities-based interconnected VoIP service providers and applied the current Part 4 definition of ''outage'' to outages of interconnected VoIP service, covering the complete loss of service and/or connectivity to customers at least 30 minutes duration that potentially affects at least 900,000 user minutes of interconnected VoIP services and results in complete loss of service; or potentially affects any special offices and facilities such as a 911 facility.

Collecting data on significant outages of interconnected VoIP services will help the Commission to monitor compliance with the statutory 911 obligations of interconnected VoIP service providers, as well as help ensure the Nation's current and future 911 systems are as reliable and resilient as possible both on a day-to-day basis and in times of a major emergency. The Commission recognizes that consumers are increasingly relying on Internet Protocol (IP)-based technologies as

substitutes for communications services provided by older communications technologies, and increasingly use interconnected VoIP services in lieu of traditional telephone service. As of December 31, 2010, 31 percent of the more than 87 million residential telephone subscriptions in the United States were users of interconnected VoIP providers—an increase of 21 percent (from 22.4 million to 27.1 million) from the end of 2009. Additionally, the Commission estimates that approximately 31 percent of residential wireline 911 calls are made using VoIP service.

The information collected is administered by the FCC's Public Safety and Homeland Security Bureau (PSHSB) which maintains an Internet Web site portal for the electronic submission of the required outage reports. In addition, provision is made for the submission of required data by other than electronic means in cases where electronic submission is not feasible. In cases where specified offices and facilities (other than 911 offices and facilities) are submitted within 120 minutes of an outage to the Commission's duty officer (a post staffed 24 hours a day) in the FCC's Communications and Crisis Management Center in Washington, DC.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2012–10634 Filed 5–2–12; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Scheduled Change and Deletion of Agenda Item From April 27, 2012, Open Meeting

Date: April 25, 2012.

The following item has been deleted from the list of Agenda items scheduled for consideration at the Friday, April 27, 2012, Open Meeting and previously listed in the Commission's Notice of April 20, 2012. Also, please note that the time for the Open Meeting is rescheduled from 10:30 a.m. to 10 a.m.

Item No.	Bureau	Subject
2	MEDIA	**TITLE:** Noncommercial Educational Station Fundraising for Third-Party Non-Profit Organizations **SUMMARY:** The Commission will consider a Notice of Proposed Rulemaking inviting comment on whether to allow noncommercial educational broadcast stations to conduct on-air fundraising activities that interrupt regular programming for the benefit of third-party non-profit organizations.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2012–10639 Filed 5–2–12; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting Notice

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday May 8, 2012 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

Investigatory records compiled for law enforcement purposes, or information which if written would be contained in such records.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

* * * * *

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Signed:

Shelley E. Garr,

Deputy Secretary of the Commission.

[FR Doc. 2012–10798 Filed 5–1–12; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS12–08]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of Meeting.

Description: In accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for its regular meeting:

Location: OCC—250 E Street SW., Room 2C, Washington, DC 20219.

Date: May 9, 2012.

Time: 10:30 a.m.

Status: Open,

Matters to be Considered:

Summary Agenda: April 11, 2012 minutes—Open Session.

(No substantive discussion of the above items is anticipated. These matters will be resolved with a single vote unless a member of the ASC requests that an item be moved to the discussion agenda.)

Discussion Agenda:

Appraisal Foundation January–February 2012 Grant Reimbursement Requests,

Appraisal Foundation 2011 Grant Reprogramming Request,

Illinois Compliance Review,

ASC Draft Revised Policy Statements,

Selection of ASC Vice Chairperson.

How to Attend and Observe an ASC meeting:

Email your name, organization and contact information to *meetings@asc.gov.* You may also send a written request via U.S. Mail, fax or commercial carrier to the Executive Director of the ASC, 1401 H Street NW., Ste 760, Washington, DC 20005. The fax number is 202–289–4101. Your request must be received no later than 4:30 p.m., ET, on the Monday prior to the meeting. Attendees must have a valid government-issued photo ID and must agree to submit to reasonable security measures. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC meetings.

Dated: April 27, 2012.

James R. Park,

Executive Director.

[FR Doc. 2012–10612 Filed 5–2–12; 8:45 am]

BILLING CODE P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS12–09]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of meeting.

Description: In accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in closed session:

Location: OCC—250 E Street SW., Room 2C, Washington, DC 20219.

Date: May 9, 2012.

Time: Immediately following the ASC open session.

Status: Closed.

Matters to be Considered:

April 11, 2012 minutes—Closed Session.

Preliminary discussion of State Compliance Reviews.

Dated: April 27, 2012.

James R. Park,

Executive Director.

[FR Doc. 2012–10613 Filed 5–2–12; 8:45 am]

BILLING CODE 6700–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

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 shares of 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 offices 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 May 18, 2012.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *Bixby Bridge Financial Trust, and David D. Colburn, as Trustee,* both of Northbrook, Illinois; to collectively acquire voting shares of PCNB Bancshares, Inc., and thereby indirectly acquire voting shares of Peoples Community Bank, both in Bremen, Georgia.

Board of Governors of the Federal Reserve System, April 30, 2012.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2012–10675 Filed 5–2–12; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also 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.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 30, 2012.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001:

1. *RSB Bancorp, MHC and RSB Bancorp, Inc.,* both of Roselle, New Jersey; to become bank holding companies by acquiring 100 percent of the voting shares of Roselle Savings Bank, Roselle, New Jersey.

B. Federal Reserve Bank of San Francisco (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *Franklin Resources, Inc., San Mateo, California,* to acquire up to 5.57 percent of Oriental Financial Group, Inc., and indirectly acquire, Oriental Bank & Trust, both of San Juan, Puerto Rico.

Board of Governors of the Federal Reserve System, April 30, 2012.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2012–10674 Filed 5–2–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From CareRise LLC

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Delisting.

SUMMARY: AHRQ has accepted a notification of voluntary relinquishment from CareRise LLC of its status as a Patient Safety Organization (PSO). The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity is to conduct activities to improve patient safety and the quality of health care delivery. HHS issued the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on March 30, 2012.

ADDRESSES: Both directories can be accessed electronically at the following HHS Web site: *http://www.pso.AHRQ.gov/index.html.*

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality

Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act, Public Law 109–41, 42 U.S.C. 299b–21—b–26, provides for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Rule, 42 CFR Part 3, authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs, including when a PSO chooses to voluntarily relinquish its status as a PSO for any reason. Accordingly, CareRise LLC, PSO number P0058, was delisted effective at 12:00 Midnight ET (2400) on March 30, 2012.

More information on PSOs can be obtained through AHRQ's PSO Web site at *http://www.pso.AHRQ.gov/index.html.*

Dated: April 24, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–10596 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

National Advisory Council for Healthcare Research and Quality: Request for Nominations for Public Members

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of request for nominations for public members.

SUMMARY: 42 U.S.C. 299c establishes a National Advisory Council for Healthcare Research and Quality (the Council). The Council is to advise the Secretary of HHS (Secretary) and the Director of the Agency for Healthcare Research and Quality (AHRQ) on matters related to activities of the Agency to improve the quality, safety, efficiency, and effectiveness of health care for all Americans.

Seven current members' terms will expire in November 2012. To fill these positions, we are seeking individuals who are distinguished: (1) In the conduct of research, demonstration projects, and evaluations with respect to health care; (2) in the fields of health care quality research or health care improvement; (3) in the practice of medicine; (4) in other health professions; (5) in representing the private health care sector (including health plans, providers, and purchasers) or administrators of health care delivery systems; (6) in the fields of health care economics, information systems, law, ethics, business, or public policy; and, (7) in representing the interests of patients and consumers of health care. 42 U.S.C. 299c(c)(2). Individuals are particularly sought with experience and success in activities specified in the summary above.

DATES: Nominations should be received on or before 60 days after date of publication.

ADDRESSES: Nominations should be sent to Ms. Karen Brooks, AHRQ, 540 Gaither Road, Room 3006, Rockville, Maryland 20850. Nominations may also be emailed to *Karen.Brooks@ahrq.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Karen Brooks, AHRQ, at (301) 427–1801.

SUPPLEMENTARY INFORMATION: 42 U.S.C. 299c provides that the Secretary shall appoint to the National Advisory Council for Healthcare Research and Quality twenty one appropriately qualified individuals. At least seventeen members shall be representatives of the public and at least one member shall be a specialist in the rural aspects of one or more of the professions or fields listed in the above summary. In addition, the Secretary designates, as ex officio members, representatives from other Federal agencies, principally agencies that conduct or support health care research, as well as Federal officials the Secretary may consider appropriate. 42 U.S.C. 299c(c)(3). The Council meets in the Washington, DC, metropolitan area, generally in Rockville, Maryland, approximately three times a year to provide broad guidance to the Secretary and AHRQ's Director on the direction of and programs undertaken by AHRQ.

Seven individuals will be selected presently by the Secretary to serve on the Council beginning with the meeting in the spring of 2012. Members generally serve 3-year terms. Appointments are staggered to permit an orderly rotation of membership.

Interested persons may nominate one or more qualified persons for membership on the Council. Self-nominations are accepted. Nominations shall include: (1) A copy of the nominee's resume or curriculum vitae; and (2) a statement that the nominee is willing to serve as a member of the Council. Selected candidates will be asked to provide detailed information concerning their financial interests, consultant positions and research grants and contracts, to permit evaluation of possible sources of conflict of interest. Please note that once you are nominated, AHRQ may consider your nomination for future positions on the Council. Federally registered lobbyists are not permitted to serve on this advisory board pursuant to the Presidential Memorandum entitled ''Lobbyists on Agency Boards and Commissions'' dated June 10, 2010, and the Office of Management and Budget's ''Final Guidance on Appointment of Lobbyists to Federal Boards and Commissions,'' 76 FR 61756 (October 5, 2011).

The Department seeks a broad geographic representation. In addition, AHRQ conducts and supports research concerning priority populations, which include: Low-income groups; minority groups; women; children; the elderly; and individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care. See 42 U.S.C. 299(c). Nominations of persons with expertise in health care for these priority populations are encouraged.

Dated: April 24, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–10595 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA–2012–N–0386]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 proposed extension of an existing collection of information pertaining to registration and product listing for owners and operators of domestic tobacco product establishments and to listing of ingredients in tobacco products under the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

DATES: Submit either electronic or written comments on the collection of information by July 2, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.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 requests 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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.

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products (OMB Control Number 0910–0650)—Extension

On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*) by, among other things, adding a new chapter granting the FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 905(b) of the FD&C Act (21 U.S.C. 395(b)), as amended by the Tobacco Control Act, requires that ''every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products * * *'' register with the FDA the name, places of business, and all establishments owned operated by that person. Every person must register by December 31 of each year. Section 905(c) of the FD&C Act requires that first-time persons ''engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person.'' Section 905(d) states that persons required to register under sections 905(b) or 905(c) shall register any additional establishment that they own or operate in any state which begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products. Section 905(h) addresses foreign establishment registration requirements, which will go into effect when regulations are promulgated by the Secretary. Section 905(i)(1) of the FD&C Act, as amended by the Tobacco Control Act, requires that all registrants ''shall, at the time of registration under any such subsection, file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution,'' along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements. Section 904(a)(1) of the FD&C Act, as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit ''a listing of all ingredients, including tobacco, substances, compounds, and additives that are * * * added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand or by quantity in each brand and subbrand.'' Since the Tobacco Control Act was enacted on June 22, 2009, the information required under section 904(a)(1) must be submitted to FDA by December 22, 2009, and include the ingredients added as of the date of submission. Section 904(c) of the FD&C Act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both: (1) Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (November 12, 2009, 74 FR 58298) and (2) Listing of Ingredients in Tobacco Products (December 1, 2009, 74 FR 62795) to assist persons making such submissions to FDA under the Tobacco Control Act. While electronic submission of registration and product listing information and ingredient listing information are not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application to streamline the data entry process for registration and product listing and for ingredient listing. This tool allows for importation of large quantities of structured data, attachment of files (e.g., in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA's receipt of submissions. FDA also developed paper forms (Form FDA 3742—Registration and Listing for Owners and Operators of

Domestic Tobacco Product Establishments and Form FDA 3743—Listing of Ingredients in Tobacco Products) as an alternative submission tool. Both the eSubmitter application and the paper forms can be accessed at *http://www.fda.gov/tobacco.*

FDA estimates the burden of this collection of information as follows:

FDA form/ activity/TCA section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Form FDA 3742 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submission) Sections 905(b), 905(c), 905(d) 905(h), or 905(i)	125	1.6	200	3.75	750
Form FDA 3743 Listing of Ingredients (Electronic and Paper Submissions) Sections 904(a)(1) or 904(c)	125	1.6	200	3.00	600
Obtaining a DUNS Number (10% of total respondents)	8	1	8	0.50	4
Total					1,354

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Since this collection of information was last approved by OMB on December 2, 2010, its burden has decreased by 407,421 hours, from 408,775 to 1,354 reporting hours. This adjustment is a result of FDA experience over the past 2 years in the regulation of tobacco products and is based on the actual number of establishment registration and product ingredient submissions received during this time period. In 2010, when this collection was first published for public comment in the **Federal Register**, FDA attempted to determine the actual number of tobacco manufacturers by using the Security and Exchange Commission's Standard Industrial Classification (SIC) codes, which are identifying codes that appear in a company's EDGAR filings to show the company's type of business. When preparing the collection of information package for publication in 2010, the tobacco industry codes indicated that over 10,000 tobacco manufacturers existed under the SIC codes for tobacco products and cigarettes. However, upon further examination of these codes, it appears that the number of tobacco manufacturers was greatly inflated, as the SIC codes included tobacco retail in addition to tobacco manufacturers. In addition, no comments were received from the 2010 initial 60-Day **Federal Register** Notice regarding either the number of respondents or the number of reporting burden hours listed in the notice, so FDA used the collection's SIC-researched manufacturer numbers for this collection of information. Actual FDA registration and product listing report submissions and FDA experience indicate in the past 2 years, the number of tobacco manufacturers required to register and list their products and ingredient listings is approximately 125, a substantial decrease from the number of potential respondents listed in 2010. By applying the revised number of manufacturers to the burden chart, the total burden for registration and listing now is currently estimated to be 1,354 reporting burden hours, much less than the 408,775 OMB-approved reporting burden hours stated in 2010.

Based on the actual number of registration and product ingredient listing reports received by FDA over the past 2 years, the number of expected annual responses is projected to decrease from 100,000 registration responses to 200 annual responses, and from 11,000 annual product ingredient listing responses to 200 annual product ingredient responses. The Agency bases its estimate on the actual number of registration and listing and product ingredient listing reports received, its experience with the submission of registration and listing requirements applicable to other FDA regulated products, and ongoing interactions with industry. FDA estimates that the submission of registration information as required by section 905 of the FD&C Act will remain at 3.75 hours per establishment. Based on the actual number of registration information submitted over the past 2 years and its experience, the Agency estimates that approximately 200 registrations will be submitted from 125 tobacco product establishments annually, for a total 750 hour burden (125 respondents × 1.6 responses per respondent × 3.75 hours per response).

FDA estimates that the submission of ingredient listing information as required by section 904 of the FD&C Act will remain at 3.0 hours per tobacco product. Based on the actual number of product ingredient listings submitted over the past 2 years and its experience, the Agency estimates that approximately 200 ingredient listings will be submitted from 125 tobacco establishments, for a total 600 burden hours (125 respondents × 1.6 responses per respondent × 3.0 hours per response).

FDA estimates that obtaining a Dun and Bradstreet (DUNS) number will take 0.5 hours, and that 8 respondents (1 percent (1.25) of establishments required to register under section 905 and 5 percent (6.25) of submitters required to list ingredients under section 904) will not already have a DUNS number. The total burden, therefore, will be 4 hours (8 respondents × 1 response per respondent × 0.5 hours per response).

Total burden hours for this collection, therefore is 1,354 hours (750 + 600 + 4 hours).

Dated: April 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10645 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0781]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 4, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0428. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, 301–796–5733, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim—21 CFR 101.82(c)(2)(ii)(B) (OMB Control Number 0910–0428)—Extension

Section 403(r)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)(A)) provides for the use of food label statements characterizing a relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health-related condition only where that statement meets the requirements of the regulations promulgated by the Secretary of Health and Human Services to authorize the use of such a health claim. Section 101.82 (21 CFR 101.82) of FDA's regulations authorizes a health claim for food labels about soy protein and the risk of coronary heart disease (CHD). To bear the soy protein and CHD health claim, foods must contain at least 6.25 grams of soy protein per reference amount customarily consumed. Analytical methods for measuring total protein can be used to quantify the amount of soy protein in foods that contain soy as the sole source of protein. However, at the present time there is no validated analytical methodology available to quantify the amount of soy protein in foods that contain other sources of protein. For these latter foods, FDA must rely on information known only to the manufacturer to assess compliance with the requirement that the food contain the qualifying amount of soy protein. Thus, FDA requires manufacturers to have and keep records to substantiate the amount of soy protein in a food that bears the health claim and contains sources of protein other than soy, and to make such records available to appropriate regulatory officials upon written request. The information collected includes nutrient databases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein.

In the **Federal Register** of November 16, 2011 (76 FR 71040), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the Agency's experience with the use of health claims, FDA estimates that only about 25 firms would be likely to market products bearing a soy protein/coronary heart disease health claim and that only, perhaps, one of each firm's products might contain non-soy sources of protein along with soy protein. The records required to be retained by § 101.82(c)(2)(ii)(B) are the records, e.g., the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is limited to assembling and retaining the records, which FDA estimates will take 1 hour annually.

Dated: April 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10647 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0867]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Review; Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by June 7, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA

has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents—(OMB Control Number 0910–NEW)

The Tobacco Control Act (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Section 904(d)(1) of the FD&C Act (21 U.S.C. 387d(d)(1)) states, ''Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list [of harmful or potentially harmful constituents] established under [section 904(e)]'' of the FD&C Act. Section 904(e) of the FD&C Act (21 U.S.C. 387d(e)) directs FDA to establish ''a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand, and by quantity in each brand and subbrand.'' On January 31, 2011, FDA announced the availability of a final guidance representing the Agency's current thinking on the meaning of the term ''harmful and potentially harmful constituent'' (see 76 FR 5387, January 31, 2011). On April 3, 2012, FDA published a notice in the **Federal Register** establishing a list of the harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke (see 77 FR 20034) as required by section 904(e) of the FD&C Act.

FDA intends to conduct research with consumers to help inform decisions about how to implement section 904(d)(1) of the FD&C Act and to provide information about how consumers understand information about HPHCs. The primary research goal is to evaluate the impact of different list formats on the public's ability to understand HPHC information. The impact of different list formats will be measured by evaluating respondents' understanding of certain communication objectives addressed in this document. Secondary outcomes of interest include measuring effects of different list formats upon respondents' susceptibility to initiation of tobacco use, motivation and confidence to quit tobacco use, and risk perceptions about tobacco use.

FDA proposes to conduct an experimental study with current smokers aged 13 years and older, smokeless tobacco users aged 18 years and older, and nonsmokers aged between 13 and 17 years who may be susceptible to initiation of smoking. Data will be collected from members of an Internet panel. Participation in the experimental study is voluntary. The information collected from the study is necessary to inform the Agency's efforts to implement the requirement of the FD&C Act to place on public display a list of HPHCs in tobacco products and tobacco smoke in a format that is understandable and not misleading to a lay person, and is expected to provide information that may inform Agency communications about HPHCs. The data obtained from this study is one factor that will be used to inform FDA's decisionmaking regarding the public display of the list of HPHCs required under section 904(d)(1). By evaluating respondents' understanding of the concepts listed in this document we do not intend to imply that consumer understanding of all concepts is needed to comply with these requirements.

In the **Federal Register** of December 14, 2011 (76 FR 77837), FDA published a 60-day notice requesting public comment on its proposed collection of information. FDA received eight comments that were PRA related, which required a total of 10 responses.

(Comment 1) One comment recommended that the study examine the effects of HPHC lists for smokeless tobacco products as well as for cigarettes.

(Response) FDA agrees. The proposed study will assess the impact of different HPHC list formats for three classes of tobacco products (cigarettes, smokeless tobacco products, and roll-your-own tobacco) on consumer comprehension, beliefs, perceptions, and other precursors to behavior.

(Comment 2) One comment encouraged FDA to recruit participants from multiple demographic groups.

(Response) FDA agrees that it is important to include a diverse group of individuals in the study and plans to include a demographically diverse sample of respondents drawn from four primary groups: Adult smoker, young adult smoker, youth smoker, and youth at risk for tobacco initiation.

(Comment 3) One comment recommended that FDA compare consumer responses to the HPHC lists against those that do not view an HPHC list. This would facilitate an evaluation of what consumers may understand, believe, perceive, or do in the absence of the HPHC list.

(Response) FDA agrees. Within each sample group, respondents will be randomly assigned to one of the treatment groups that view an HPHC list format or to a control group that does not view a list. Some of the formats will include additional information to provide context for the HPHC lists to the consumer. The effects of each list will be determined during analysis through a comparison of responses between treatment and control groups.

(Comment 4) One comment cautioned FDA to consider the utility of including underage nonsmokers in the experimental study.

(Response) FDA has considered the utility of including under age nonsmokers in the study. FDA believes it is important to consider the risks and benefits of the HPHC lists to the population as a whole, including users and nonusers of the tobacco product, and taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using such products. Although FDA does not believe that there is any information on the HPHC list that would encourage nonusers to initiate tobacco use, one of the secondary outcomes it is to assess the effects of the provision of HPHC lists on youth that do not currently use tobacco products but who may be at risk of initiating the use of tobacco products.

(Comment 5) One comment recommended that the data collected from the users of smokeless tobacco products be analyzed separately from cigarette smokers.

(Response) FDA agrees. FDA will collect data on the use of tobacco products. The study now includes a sample of adult smokeless tobacco users aged 18 years and older. The data from those who use smokeless products will be analyzed separately.

(Comment 6) Three comments provided recommendations on pretesting the information provided in the lists with target audiences prior to implementation. One of these comments suggested that FDA use open-ended questions to allow respondents to say/type what they understand each statement to mean.

(Response) FDA agrees. FDA intends to conduct cognitive interviews with individuals to assess comprehension of the test instrument and certain aspects of the list formats prior to conducting the study. Individuals will be asked open-ended questions during the

cognitive testing of the list formats and the survey questions.

(Comment 7) Two comments encouraged FDA to provide additional information for public comment during the development of the study including the list formats, study design, and measurement plans for the listed unintended consequences.

(Response) The study protocol, list formats, and the survey questionnaire are available for review and public comment upon request. To request this information see the **FOR FURTHER INFORMATION CONTACT** section of this document.

(Comment 8) One commenter stated that the HPHC list could not fully inform consumers because the list is not complete, and the consumer would not understand that the listed quantity of the chemicals were based on machine testing and therefore are not necessarily a reflection of human use. Other comments argued there was a high likelihood that consumers will conclude that lower numbers or fewer constituents means a product is less risky. They also suggested the need to have disclaimers that provide information to counter potential misunderstandings.

(Response) FDA agrees that the list format may have the potential to mislead consumers, which is why FDA plans to conduct an experiment with consumers to assess the impact of various formats of the HPHC lists on consumer comprehension and precursors to behavior, such as beliefs, attitudes, and intentions. Some of the list formats to be included in the study will contain additional text and graphics to convey other information to consumers that may not be evident from a list of chemicals and numerical values. The study will assess various formats for conveying the communication goals enumerated in this document, such as uncertainty about the information contained in the list; that other relationships between the constituents in tobacco products and health problems may be discovered in the future; that the values are the results of machine testing; and that exposure to the chemicals also depends on other factors, such as the variability of human use.

FDA's proposed study will also assess each list's potential for increasing the likelihood that consumers will conclude that lower numbers or fewer constituents imply that a tobacco product is less risky. To evaluate whether the lists encourage consumers to compare the relative risks of products, the study will include measures, such as whether consumers comprehend that the amount of a chemical listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem, and the number of chemicals listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem.

(Comment 9) Two comments stressed the importance of using clear language with one suggesting that information be written at a fifth grade reading level. They also recommended FDA consider the impact of color, font type, and font size on consumer comprehension.

(Response) FDA intends to use plain language, where additional information is provided, and to select colors, font type, and font size that are likely to improve consumer comprehension.

(Comment 10) One commenter suggested FDA prioritize the communication objectives to facilitate evaluation of study results.

(Response) FDA agrees that a prioritization of the communication objectives may facilitate the evaluation of the results. At this time, FDA proposes a study to test the impact of various HPHC list formats on consumer comprehension of the communication objectives, although it is unlikely that a single format will be completely successful at meeting all of those objectives.

Based on comments received and preliminary qualitative research,[1] FDA has refined the communication objectives listed in the **Federal Register** of December 14, 2011 (76 FR 77837) to the following: (1) The chemicals come from the tobacco leaf itself and different parts of a tobacco product, such as the tobacco smoke, glues, inks, paper, and additives; (2) for smokeless products, many of the chemicals come from the tobacco leaf itself; for smoked products, many of the chemicals come from burning the tobacco leaf; (3) tobacco companies are required to test their tobacco products and smoke for the chemicals on the list and report the amounts to FDA; (4) science has linked the chemicals on these lists to health problems or potential health problems; (5) these lists do not necessarily identify all of the health problems that may be caused by the tobacco product; (6) these lists do not necessarily include all of the chemicals in the tobacco product that may be harmful; (7) the amount of a chemical listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem; (8) the number of chemicals listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem; and (9) when a chemical is listed without a quantity it may mean that the chemical was not detected or the information is not currently available.

The remaining comments were unresponsive to the 60-day **Federal Register** notice. These comments were related to the development of an accompanying education campaign; the development of a Web site for consumers to get additional information; the provision of HPHC information on the packages of tobacco products; the use of claims by tobacco manufacturers, such as ''all natural'' or ''no additives''; and the conformance of tobacco manufacturers and retailers to section 911 of the FD&C Act (21 U.S.C. 387k) regarding modified risk claims.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	60	1	60	0.5	30
Screener	10,000	1	10,000	0.0167	167
Experimental Survey	3,150	1	3,150	0.5	1,575
Total					1,772

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[1] OMB control number 0910–0674.

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here. Sixty panel members will take part in a pretest of the study, estimated to last 30 minutes (0.5 hours), for a total of 30 hours. Approximately 10,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take 1 minute (0.0167 hours), for a total of 167 hours. Three thousand one hundred and fifty respondents will complete the full study, estimated to last 30 minutes (0.5 hours), for a total of 1,575 hours. The total estimated burden is 1,772 hours.

Dated: April 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10659 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0009]

Cooperative Agreement To Support the Joint Institute for Food Safety and Applied Nutrition, JIFSAN (U01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). FDA believes that University of Maryland, College Park (UMCP)–JIFSAN is a sound investment to protect and promote public health. FDA faces an increasing number of critical and complex food safety and public health issues associated with the products that FDA regulates. These complex issues can be addressed most efficiently by expanding the scientific base through the development of collaborative partnerships. FDA believes that partnering with UMCP–JIFSAN will enhance FDA's ability to address safety and other public health issues related to foods, cosmetics, and animal health and continue to stimulate the integration of applied research, education, and outreach programs.

DATES: Important dates are as follows:

1. The application due date is June 1, 2012.

2. The anticipated start date is August 1, 2012.

3. The opening date is May 3, 2012.

4. The expiration date is June 2, 2012.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Elizabeth M. Calvey, Center for Food Safety and Applied Nutrition (HFS–560), Food and Drug Administration, CPK1, Rm. 4A007 (HFS–006), 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1981, *elizabeth.calvey@fda.hhs.gov.*

Gladys Melendez, Office of Acquisition & Grants Services (HFA–500), Food and Drug Administration, 5630 Fishers Lane, Rm. 1078, Rockville, MD 20857, 301–827–7175, *gladys.bohler@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.fda.gov/food/newsevents/default.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Funding Opportunity Number: RFA–12–016.

Catalog of Federal Domestic Assistance Number: 93.103.

A. Background

FDA is announcing its intention to receive and consider a single source application for the award of a cooperative agreement in fiscal year 2012 (FY12) to UMCP to support JIFSAN.

FDA believes that the UMCP–JIFSAN collaboration is a sound investment. The last 15 years of FDA's partnership with UMCP–JIFSAN have been successful in developing multiple programs to support public health policy. The goal of JIFSAN is to advance sound strategies that improve public health, nutrition, and food/feed safety through three broad program areas: research, education, and outreach.

With an increasingly diverse domestic and global food supply, FDA continues to face complex food safety issues associated with products that it regulates (i.e., conventional foods; food ingredients; dietary supplements; cosmetics; animal feed, feed additives, and animal drugs). FDA believes that some of these complex issues can be effectively addressed by further strengthening the available science-based programs established through JIFSAN. FDA also believes that innovative capacity-building partnerships with various sectors of stakeholders in conjunction with JIFSAN's research and training programs can further support the development of proactive approaches to the prevention of problems before they occur. A proposal is being solicited for meeting this need as well as FDA's strategic goals to protect and promote public health.

B. Research Objectives

This cooperative agreement will provide continued support so that UMCP–JIFSAN can meet the following objectives:

- Establish multi-institutional, multidisciplinary applied research projects to address complex food/feed safety and public health issues associated with products that FDA regulates. Applied research includes not only traditional laboratory and field research, but also epidemiological, educational, social and behavioral science.
- Continue the development of mechanisms for the exchange of technical information and scientific concepts between FDA and other sectors of the international and domestic community, through workshops, short courses and symposia, and online resources that focus on existing and emerging complex food/feed safety and public health issues.
- Continue the development and refinement of programs based on the application of the principles of risk analysis to address food/feed defense and safety issues.
- Continue the design and improvement of domestic and international collaborations, which foster greater implementation of effective food safety practices.
- Continue developing innovative education and outreach programs that will provide opportunities to leverage resources among various sectors of stakeholders to address complex safety issues associated with an increasingly diverse global food supply.

C. Eligibility Information

Competition is limited to UMCP–JIFSAN because UMCP–JIFSAN is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. The administrative structure and policies of UMCP–JIFSAN offer the flexibility needed to create and operate strategic alliances involving multiple partners. They also allow effective utilization of resources to plan and run multidisciplinary and multi-institutional research programs and internationally-recognized food safety training and risk analysis programs.

UMCP and FDA, through their collaboration in JIFSAN, developed FoodRisk.org, which is an extensive Web-based information resource addressing many aspects of food safety risk analysis, as well as providing tools

and resources for food-borne infectious disease epidemiology and surveillance; developed a risk analysis professional development training program taught through several different modalities (*e.g.,* face-to-face and online); developed international food safety education and outreach programs that foster implementation of effective food safety practices (i.e., Good Agricultural Practices, Good Aquaculture Practices, and Commercially Sterile Packaged Foods); and, recently, established the first-of-its-kind full-time international food safety laboratory training facility at College Park, MD, to train domestic and foreign government officials, third party laboratory scientists, and food producers on fit-for-purpose analytical procedures that would meet global food safety standards.

Since its inception, JIFSAN has funded over 60 research projects as well as provided over 250 internships to undergraduate students to work with FDA scientists. JIFSAN food safety research topics are diverse and include the development of methods for detecting food pathogens; risk assessment studies on nutrients; food packaging materials; dietary supplements; microbial dose-responses; and risk communication. JIFSAN's unique structure permits it to reach beyond the UMCP campus and support research at other universities.

Moreover, UMCP–JIFSAN provides an environment in which scientific and regulatory experts from various sectors can pool their resources and ideas and promote more efficient development and dissemination of science-based information that can support public policy.

II. Award Information/Funds Available

A. Award Amount

The Center for Food Safety and Applied Nutrition (CFSAN) at FDA intends to fund one award up to $2.2 million for FY 2012, with the possibility of 4 additional years of support, subject to the availability of funds. Future year amounts will depend on annual appropriations and successful performance.

B. Length of Support

The award will provide 1 year of support, with the possibility of 4 additional years of support, contingent upon satisfactory performance in the achievement of project and program reporting objectives during the preceding year and the availability of Federal fiscal year appropriations.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at *www.fda.gov/food/newsevents/default.htm.* (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**) Persons interested in applying for a grant may obtain an application at *http://grants2.nih.gov/GRANTS/FORMS.HTM.* For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With Central Contractor Registration
- Step 3: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 3, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit paper applications to:

Applications must be prepared using the PHS 398 research grant application forms and instructions for preparing a research grant application. Submit one signed, typewritten original of the application, including the checklist, and five signed photocopies as follows:

Submit one original to: Gladys Melendez, Division of Acquisition and Grant Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 1078, Rockville, MD 20857, 240–731–3905, *gladys.bohler@fda.hhs.gov.*

Submit the five signed photocopies to: Kevin W. Robinson, Center for Food Safety and Applied Nutrition (HFS–650), Food and Drug Administration, CPK1, Rm. 4C035, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2118, *kevin.robinson@fda.hhs.gov.*

Dated: April 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10648 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–E–0156]

Determination of Regulatory Review Period for Purposes of Patent Extension; HALAVEN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for HALAVEN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6284, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product.

Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product HALAVEN (eribulin mesylate). HALAVEN is indicated for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for HALAVEN (U.S. Patent No. 6,214,865) from Eisai R&D Management Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 26, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of HALAVEN represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for HALAVEN is 2,758 days. Of this time, 2,527 days occurred during the testing phase of the regulatory review period, while 231 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* April 30, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 30, 2003.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 30, 2010. FDA has verified the applicant's claim that the new drug application (NDA) for HALAVEN (NDA 201–532) was submitted on March 30, 2010.

3. *The date the application was approved:* November 15, 2010. FDA has verified the applicant's claim that NDA 201–532 was approved on November 15, 2010.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,495 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 2, 2012. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 30, 2012. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 16, 2012.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2012–10716 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–E–0117]

Determination of Regulatory Review Period for Purposes of Patent Extension; PRADAXA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PRADAXA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6284, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product PRADAXA (dabigatran etexilate mesylate). PRADAXA is indicated to reduce the risk of stroke and systemic embolism in

patients with non-valvular atrial fibrillation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PRADAXA (U.S. Patent No. 6,087,380) from Boehringer Ingelheim Pharma GmbH & Co. KG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 25, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PRADAXA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PRADAXA is 2,633 days. Of this time, 2,449 days occurred during the testing phase of the regulatory review period, while 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* August 6, 2003. The applicant claims August 7, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 6, 2003, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 19, 2010. The applicant claims December 15, 2009, as the date the new drug application (NDA) for PRADAXA (NDA 22–512) was initially submitted. However, FDA records indicate that NDA 22–512, received December 15, 2009, was incomplete. FDA refused to file this application and notified the applicant of this fact by letter dated February 12, 2010. The completed NDA was then submitted on April 19, 2010, which is considered to be the NDA initially submitted date.

3. *The date the application was approved:* October 19, 2010. FDA has verified the applicant's claim that NDA 22–512 was approved on October 19, 2010.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,469 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 2, 2012. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 30, 2012. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 16, 2012.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2012–10712 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–E–0168]

Determination of Regulatory Review Period for Purposes of Patent Extension; KRYSTEXXA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for KRYSTEXXA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6284, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product KRYSTEXXA (pegloticase). KRYSTEXXA is indicated for treatment of chronic gout in adult patients refractory to conventional therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for KRYSTEXXA (U.S. Patent No.

6,783,965) from Mountain View Pharmaceuticals, Inc., and Duke University, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 8, 2011, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of KRYSTEXXA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for KRYSTEXXA is 3,193 days. Of this time, 2,509 days occurred during the testing phase of the regulatory review period, while 684 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* December 19, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 19, 2001.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262*): October 31, 2008. FDA has verified the applicant's claim that the biologics license application (BLA) for KRYSTEXXA (BLA 125293) was initially submitted on October 31, 2008.

3. *The date the application was approved:* September 14, 2010. FDA has verified the applicant's claim that BLA 125293 was approved on September 14, 2010.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,445 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 2, 2012. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 30, 2012. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 16, 2012.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2012–10697 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–E–0141]

Determination of Regulatory Review Period for Purposes of Patent Extension; LASTACAFT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LASTACAFT and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6284, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product LASTACAFT (alcaftadine ophthalmic solution). LASTACAFT is indicated for prevention of itching associated with allergic conjunctivitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LASTACAFT (U.S. Patent No. 5,468,743) from Janssen Pharmaceutica N.V., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 3, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LASTACAFT represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LASTACAFT is 2,189 days. Of this time, 1,886 days occurred during the testing phase of the regulatory review period, while 303 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* August 1, 2004. The applicant claims July 31, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 1, 2004, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 29, 2009. The applicant claims September 28, 2009, as the date the new drug application (NDA) for LASTACAFT (NDA 22–134) was initially submitted. However, FDA records indicate that NDA 22–134 was submitted on September 29, 2009.

3. *The date the application was approved:* July 28, 2010. FDA has verified the applicant's claim that NDA 22–134 was approved on July 28, 2010.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,246 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 2, 2012. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 30, 2012. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 16, 2012.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2012–10694 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0408]

Risk Evaluation and Mitigation Strategy Assessments: Social Science Methodologies to Assess Goals Related to Knowledge; Public Workshop; Issue Paper

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Risk Evaluation and Mitigation Strategy Assessments: Social Science Methodologies to Assess Goals Related to Knowledge.'' The purpose of the public workshop is to initiate constructive dialogue and information-sharing among regulators, researchers, the pharmaceutical industry, health care organizations, health care providers, and others from the general public about survey methodologies and instruments that can be used to evaluate patients' and health care providers' knowledge about the risks of drugs marketed with an approved Risk Evaluation and Mitigation Strategy (REMS). The input from this workshop will be used to develop guidance for industry describing the best practices for conducting an assessment of a REMS goal regarding patient and/or health care provider knowledge about a drug's risk(s). To assist in the workshop discussion and the ultimate development of the guidance, FDA is making available an issue paper that discusses our experience with knowledge assessments for REMS and contains specific questions we hope to receive input on. FDA is also opening a public docket to receive written comments.

Date and Time: The public workshop will be held on June 7, 2012, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* Participants are encouraged to arrive early to ensure time for parking and security screening before the workshop.

Contact Person: Colleen O'Malley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4305, Silver Spring, MD 20993–0002, 301–796–1786, FAX: 301–796–9832, email: *colleen.omalley@fda.hhs.gov.*

Registration and Requests for Oral Presentations: There is no fee to attend the workshop, and attendees who do not wish to make a formal presentation do not need to register. Seating will be on a first-come, first-served basis. Individuals who wish to make a presentation at the public workshop must register and provide an abstract of your presentation by 5 p.m. on May 21, 2012.

Submit electronic registration requests to make a presentation to *KnowledgeAssessmentWorkshop@fda.hhs.gov.* Submit written registration requests to make a presentation to Colleen O'Malley (see *Contact Person*). Please provide your name, title, business affiliation (if applicable), address, telephone, FAX number, and email address. Identify the Panel number(s) for the question(s) you will discuss in your presentation (see section IV of this document).

FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Persons registered to make a formal presentation should check in before the workshop. Time will be allowed during the scheduled agenda for attendees to ask questions of the panelists. In addition, we strongly

encourage electronic or written comments to the docket.

FDA has developed an issue paper entitled ''Risk Evaluation and Mitigation Strategy Assessments: Social Science Methodologies to Assess Goals Related to Knowledge'' that discusses our experience with knowledge assessments for REMS. The issue paper also contains a number of specific questions that we hope to receive input on. The issue paper can be found on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm292337.htm.*

Background information on the public workshop, registration information, the agenda, and other relevant information will be posted on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm* as it becomes available.

If you need special accommodations due to a disability, please contact Colleen O'Malley (see *Contact Person*) at least 7 days before the workshop.

Comments: FDA is opening a docket to allow for public comments to be submitted to the Agency on the issues and questions presented in the issue paper or at the workshop. Regardless of attendance at the public workshop, interested persons may submit to the Division of Dockets Management either electronic or written comments by July 7, 2012, to receive consideration. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

Title IX, Subtitle A, section 901 of the Food and Drug Administration Amendments Act (FDAAA) (Pub. L. 110–85) [1] created new section 505–1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355–1), which authorizes FDA to require persons submitting new drug applications (NDAs) or abbreviated new drug applications (ANDAs) for prescription products, or biologics license applications (BLAs), to submit and implement a REMS if FDA determines that a REMS is necessary to ensure the benefits of a drug outweigh the risks of the drug. To require a REMS for an already approved drug, FDA must have become aware of new safety information as defined in the statute. Elements for REMS approved for NDAs and BLAs may include a Medication Guide, a communication plan, and/or elements to assure safe use (ETASU), and an implementation system, if specific statutory criteria are met. All approved REMS for products approved under an NDA or BLA must include a timetable for submission of assessments of the REMS. FDAAA contains provisions that are specifically directed to REMS for ANDAs, and these REMS may include only a Medication Guide and/or ETASU and an implementation system.

Because most REMS include a goal related to knowledge, such as to inform or educate patients and/or health care providers about the serious risks associated with and safe use of a drug, assessments for a drug subject to a REMS frequently include assessments of patients' and providers' knowledge. To conduct this assessment, most applicants have undertaken cross-sectional surveys of patients who have taken the drug and health care providers who have prescribed or dispensed the drug.

As a result of FDA's review of the surveys that are included as components of a REMS assessment, the Agency has identified certain challenges to conducting these types of studies. FDA has specific questions about the methodology for obtaining survey data and presenting the results, including about appropriate sample size; methods to ensure representativeness; how to determine endpoints; questionnaire design and analyses; and presentation of survey results.

To date, FDA has worked with individual applicants to attempt to introduce and sustain some measure of consistency in methods and expectations. Although absolute uniformity is not possible, the Agency seeks to solicit information and feedback about valid survey methods that can improve the quality and consistency of REMS assessment surveys. In addition, FDA seeks feedback on whether methodologies other than surveys could be used to obtain this information. Finally, FDA seeks to solicit information about using surveys other than knowledge assessment surveys as a tool to assess whether the elements of a REMS are meeting its goals including: (1) Changes in behavior for both patients and prescribers such as whether a drug is used to a large degree in patients at higher risk of an adverse reaction; (2) burden on the health care system, which could include the time required to accomplish REMS-related activities; and (3) adverse effects on patient access to the drug, such as substantial delays between the time of presentation of a prescription and the time of drug dispensing or prescribers choosing not to prescribe the drug anymore.

II. Why are we holding this public workshop?

FDA is soliciting information and feedback to optimize the assessment of REMS goals related to knowledge. Because we have received only surveys that assess knowledge, the workshop will invest considerable time in identifying best methodological practices for conducting REMS assessment surveys. However, FDA is also encouraging discussion of alternatives to surveys, given the issues we have observed, as discussed in the issue paper. Feedback received in the docket and resulting from this workshop will assist the Agency in developing guidance for industry.

The workshop objectives are as follows: (1) Initiate constructive dialogue and information-sharing about survey methodologies and instruments used to evaluate patients' and healthcare providers' knowledge about drugs' risks; (2) share current FDA experience regarding social science assessments of surveys as a component of REMS Assessment Plans; (3) obtain information that will be used to develop standardized survey methodologies for evaluating patient and health care provider knowledge under a REMS; (4) discuss alternative methodologies to surveys to assess knowledge; and (5) discuss the use of surveys as a tool to assess patient and prescriber behavior changes, burden on the health care system, and patient access to the drug under a REMS.

III. Who is the target audience and who should attend this public workshop?

Although the workshop is open to all interested parties, the target audience includes social science professionals; statisticians; regulators; researchers; and representatives from academia, the pharmaceutical industry, and the scientific community who may be interested in improving the quality and consistency of methodology for evaluating REMS goals related to knowledge.

IV. What are the topics we intend to discuss at the public workshop?

The workshop will include panel discussions and individual and/or joint presentations. The key issues to be addressed are: (1) How should

[1] See *http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf.*

assessments of knowledge be structured to achieve valid, reliable, and informative results; (2) how can surveys be used to assess changes in patient and prescriber behavior, burden to the health care system, and patient access to the drug; and (3) what are appropriate alternatives to surveys to assess educational components of REMS? Two panel discussions will focus on areas in which the Agency requests specific input.

- *Panel 1* will focus on using surveys to assess knowledge. Topics will include, but are not limited to, recruiting a representative sample, sample size, question design, process, and endpoints.
- *Panel 2* will focus on alternatives to surveys and the use of surveys to assess patient and prescriber behavior changes, burden on the health care system, and patient access to the drug. Topics will include, but are not limited to, recruiting a representative sample, question design, interpretation of results, and specific pros and cons of the alternatives.

V. Transcripts

Please be advised that as soon as a transcript of the workshop is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: April 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10646 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Mouse Monoclonal Antibody Targeting Human NOX1, a Target for Cancer and Inflammation

Description of Technology: Available for licensing is a mouse monoclonal antibodies targeting human nicotinamide adenine dinucleotide phosphate-oxidase (NAPH) oxidase 1 (NOX1) enzyme. NOX mediates the homeostasis of reactive oxygen species, which play a critical regulatory role in cancer cell signal transduction and tumor cell differentiation. NOX1-generated hydrogen peroxide can trigger an ''angiogenic switch'' that includes the induction of angiogenic factors that promote tumor cell vascularization. Additionally, NOX1 may play a role in inflammation.

Investigators at the National Cancer Institute found NOX1 is significantly expressed more in colon and gastric cancers compared with adjacent normal bowel and gastric mucosa respectively. To the best of NIH's knowledge, this is the only monoclonal antibody that can be used to detect human NOX1. This antibody detects endogenous levels of the NOX1 protein and could potentially be used in biochemical laboratory studies as well as diagnostic tests that involve the functional significance of NOX1 in human physiology and pathophysiology, particularly its role in cancer and inflammation.

Potential Commercial Applications:

- Research tool to study cancer and inflammation
- Method to diagnose colon and gastric cancer
- Treatment for cancer and inflammation

Competitive Advantages: To the best of NIH's knowledge, this is the only available monoclonal antibody to detect human NOX1.

Development Stage:

- Early-stage
- In vitro data available

Inventors: James Doroshaw, Krishnendu Roy, Guojian Jiang, Jiamo Lu, and Smitha Antony (all of NCI).

Intellectual Property: HHS Reference No. E–097–2012/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Sabarni K. Chatterjee, Ph.D.; 301–435–5587; *chatterjeesa@mail.nih.gov.*

A Non-Invasive Post-Treatment Strategy for Stroke by Intranasal Delivery of Cocaine- and Amphetamine-Regulated Transcript (CART)

Description of Technology: Cocaine and amphetamine-regulated transcript (CART) is a neuropeptide known to protect against ischemic brain injury when administered before the onset of stroke in mice, both in vivo and in vitro. Utilizing a classic stroke model in rodents, middle cerebral artery occlusion (MCAo), inventors at NIDA discovered a novel post-stroke therapeutic approach involving the intranasal administration of CART. This new non-invasive treatment strategy for stroke patients is effective when initiated three days after stroke, providing a longer treatment window. Nasal delivery of CART improved behavioral recovery and reduced neurological scores in stroke animals. CART, given after stroke, modifies endogenous neural repair in stroke brain by facilitating neuroprogenitor cell proliferation and migration, enhancing reinnervation, and improving the functional recovery.

Potential Commercial Applications: Method of treating stroke

Competitive Advantages:

- New treatment strategy for stroke patients
- Non-invasive (nasal spray)
- Longer treatment window (3 days post-stroke)
- Current strategies aim to protect lesion site from damage, whereas this method helps brain repair

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Yun Wang, Hui Shen, Seong Jin Yu, Yihong Yang (all of NIDA).

Publications: Manuscript in preparation.

Intellectual Property: HHS Reference No. E–058–2012/0—U.S. Provisional Application No. 61/592,761 filed 31 Jan 2012.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov.*

Chimeric Antigen Receptors That Recognize BCMA/CD269 for Treating Multiple Myeloma

Description of Technology: Available for licensing are chimeric antigen receptors (CARs) that specifically target B-cell maturation antigen (BCMA, CD269), a protein that is highly expressed on the surface of multiple myeloma cells. Multiple myeloma is a malignancy of plasma cells. It is almost always incurable.

A CAR is a fusion protein that can recognize a specific protein on a tumor cell and activate an adaptive immune response to attack the tumor cell. When cultured with multiple myeloma cells in vitro, T-cells engineered to express the CARs were able to induce cell death in the myeloma cells. CARs currently are being evaluated in clinical trials as a promising new area of cancer therapy. The technology available for licensing includes vectors incorporating the CARs, as well as methods of destroying multiple myeloma cells using T-cells engineered to express a CAR.

Potential Commercial Applications:

- Development of a tumor-specific T-cell treatment for multiple myeloma
- Development of a tumor-specific T-cell treatment for Hodgkin's lymphoma
- Treatment of diseases associated with increased or preferential expression of BCMA/CD269

Competitive Advantages:

- Specifically targets an antigen that is highly expressed in tumor cells of multiple myeloma and Hodgkin's lymphoma
- Amenable for adoptive transfer approaches
- No other anti-BCMA immunotherapies are in clinical trials
- Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer non-specific side-effects and healthier patients

Development Stage:

- Pre-clinical
- Clinical.
- In vitro data available.

Inventor: James N. Kochenderfer (NCI).

Intellectual Property: HHS Reference No. E–040–2012/0—U.S. Provisional Application 61/622,600 filed 11 April 2012.

Related Technologies:

- HHS Reference No. E–205–2009/0—Treating Cancer with Anti-angiogenic Chimeric Antigen Receptors.
- HHS Reference No. E–148–2011/0—Breakthrough Immunotherapy for Brain Cancer: Epidermal Growth Factor Receptor Variant III Chimeric Antigen Receptors.
- HHS Reference No. E–086–2006/0—Hybrid T–Cell Receptors for the Development of Improved Vaccines.
- HHS Reference No. E–265–2011/0—Chimeric Antigen Receptors to CD22 for Treating Hematological Cancers.

Licensing Contact: Patrick McCue, Ph.D.; 301–435–5560; *mccuepat@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Experimental Transplantation and Immunology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize chimeric antigen receptors to genetically-modify T cells to recognize BCMA/CD269. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

ROCK Inhibitors for the Prevention of Breast Cancer Metastasis and Tumor Relapse

Description of Technology: The recent success of therapeutic approaches has significantly reduced breast cancer mortality, however, breast cancers that are diagnosed as ''triple-negative'' (lacking the estrogen receptors, HER2/Neu, and progesterone receptors) don't respond to these available therapies and some hormone receptor or NER2/Neu-positive breast cancers have shown a resistance to these treatments. These breast cancers account for nearly 90% of all breast cancer deaths. Therefore, examining the mechanisms by which the breast cancer cells spread from their primary sites to distant organs is an active area of research. The NIH inventors have discovered that by blocking a key biochemical route necessary for the egress of breast cancer cells into circulation, the CXCR4-Galpha13-Rho signaling pathway, they can prevent the dissemination of breast cancer cells and thereby prevent breast cancer metastasis. In particular, they have discovered that ROCK inhibitors, such as Fasudil, can be used to treat of breast cancer patients after the initial clinical intervention (i.e., surgery, radiation, chemo-radiation, or their combination) to delay or prevent patient relapse due to the metastasis of any residual or prior undetected breast cancer cells.

Potential Commercial Applications:

- Treatment of ''triple-negative'' breast cancers.
- Treatment of hormone receptor or NER2/Neu-positive breast cancers that are resistant to currently available therapies.

Competitive Advantages: ROCK inhibitors can delay or prevent breast cancer metastasis in patients where there are no effective therapies currently available.

Development Stage:

- Pre-clinical.
- In vitro data available.
- In vivo data available (animal)

Inventors: Silvio Gutkind and Alfredo Molinolo (NIDCR).

Intellectual Property: HHS Reference No. E–280–2011/0—U.S. Application No. 61/536,434 filed 19 Sep 2011.

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov.*

Cell Line for Producing Furin That Can Cleave Papillomavirus L2, Toxins and Other Substrates

Description of Technology: Human papillomavirus (HPV) is an infectious agent that is responsible for several different diseases. Although HPV often manifests as warts, it can also result in certain types of cancer. Since HPV can remain latent for long periods of time, the disease can be transmitted by someone who is not aware they are contagious. This partially explains why HPV is the most common sexually transmitted disease. The HPV genome consists of several genes, including the two late-expressed genes known as L1 and L2. The HPV L1 and HPV L2 genes encapsulate amplified HPV genomes prior to their release in virions, which infect other cells. Since HPV L2 is present on the HPV virion when it is released from a cell, people infected with HPV will generate an immune response against HPV L2 to help contain the infection. This includes the generation of neutralizing antibodies against HPV L2. By examining a sample for the presence of these neutralizing antibodies, it can be determined whether a patient has HPV and is capable of spreading the disease.

This technology describes a Chinese Hamster Ovary (CHO) cell line which expresses a truncated version of mouse furin which retains activity. Furin is an enzyme that cleaves proteins at a specific, defined amino acid sequence. The cleavage of HPV L2 makes it more susceptible to detection by neutralizing antibodies. As a result, the cell line can increase the sensitivity of an assay for detecting neutralizing antibodies to HPV L2.

Potential Commercial Applications:

- The cell line secretes a truncated mouse furin for use in any assays which benefit from furin activity.
- A specific use for the cell line is testing samples for neutralizing antibodies to HPV L2.
- The cells can be developed into a validated assay for detecting

neutralizing antibodies to HPV L2 as a means of diagnosing HPV infection.

Competitive Advantages:

• Neutralizing antibodies to HPV L2 are more readily detected when the protein is first cleaved by furin.

• The cell lines represent an established and efficient research tool for cleaving HPV L2 for more efficient detection of neutralizing antibodies to the protein.

• An assay for detecting HPV infection can be useful for detecting those who are asymptomatic, which is common with HPV infections.

Development Stage: In vitro data available.

Inventors: David FitzGerald et al. (NCI)

Publications:

1. Chiron MF, et al. Furin-mediated cleavage of Pseudomonas exotoxin-derived chimeric toxins. J Biol Chem. 1997 Dec 12;272(50):31707–11. [PMID 9395513]

2. Richards RM, et al. Cleavage of the papillomavirus minor capsid protein, L2, at a furin consensus site is necessary for infection. Proc Natl Acad Sci U.S.A. 2006 Jan 31;103(5):1522–7. [PMID 16432208]

3. Day PM, Schiller JT. The role of furin in papillomavirus infection. Future Microbiol. 2009 Dec;4(10):1255–62. Review. [PMID 19995186]

Intellectual Property: HHS Reference No. E–233–2011/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: David A. Lambertson, Ph.D.; 301–435–4632; *lambertsond@mail.nih.gov*

Novel Reduced Toxicity Tropolone Derivative Compounds That Have Anti-Viral Activity Through Inhibiting RNase H Activity

Description of Technology: Several novel tropolone derivatives have been identified that inhibit HIV–1 RNase H function and have potential for anti-viral activity due to reduced cellular toxicity. Inhibiting RNase H function is a potential treatment for many viral infections, since RNase H function is essential for viral replication for many pathogenic retroviruses such as HIV–1 and HIV–2. Although many hydroxytropolone compounds are potent RNase H inhibitors biding at the enzymatic active site, they are limited as therapeutic candidates by their toxicity in mammalian cells. The toxicity thought to be a result of inhibition of multiple essential mammalian metalloenzymes. We reasoned that the potential beneficial application of tropolone RNase H inhibition might be of therapeutic use if the toxic effects in mammalian cell were eliminated. By selectively adding steric bulk to add new drug-enzyme contacts for the RNase H active site, a number of novel compounds, that have initially demonstrated reduced cytotoxicity, have been produced. Importantly, these novel compounds appear to retain antiviral activity essential for use as therapeutics.

Potential Commercial Applications: Anti-viral therapeutic: HIV–1 and other RNase H-dependent viral infections

Competitive Advantages:

• Potentially reduced toxicity

• Availability of x ray crystallographic information to guide analog design

Development Stage:

• Pre-clinical

• In vitro data available

Inventors: John Beutler, Suhman Chung, Stuart F. LeGrice, Jennifer A. Wilson (NCI); Craig J. Thomas and Jiankang Jiang (NCATS)

Publications:

1. Chung S, et al. Synthesis, activity and structural analysis of novel alpha-hydroxytropolone inhibitors of human immunodeficiency virus reverse transcriptase-associated ribonuclease H. J Med Chem 2011 Jul 14;54(13):4462–4473. [PMID 21568335]

2. Budihas SR, et al. Selective inhibition of HIV–1 reverse transcriptase-associated ribonuclease H activity by hydroxylated tropolones. Nucl Acids Res 2005 33 (4):1249–1256. [PMID 15741178]

Intellectual Property: HHS Reference No. E–081–2011/0 — U.S. Provisional Application No. 61/484,779 filed 11 May 2011

Licensing Contact: Edward ''Tedd'' Fenn, J.D.; 301–435–5031; *fenned@mail.nih.gov*

Collaborative Research Opportunity: The Molecular Targets Laboratory, National Cancer Institute, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize antiviral tropolone derivatives developed by systematic medicinal chemistry on the lead series. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov*.

Hspa2 Knockout Mice for Study of Spermatogenesis and Male Infertility

Description of Technology: HSPA2 is a member of the HSP70 family of heat-shock proteins that serve as molecular chaperones. Researchers discovered that HSPA2 protein is expressed in spermatogenesis during the meiotic phase. Spermatogenic cells lacking the HSPA2 protein arrest in mid-meiosis and undergo apoptosis. HSPA2 is present in the synaptonemal complex of wild-type mice and the chromosomes fail to separate in HSPA2-deficient mice (previously known as Hsp70–2-/-mice), suggesting that HSPA2 is required for the chromosomal events of meiosis such as synapsis, crossing over, or recombination.

Researchers at NIEHS developed a knockout strain of mice in which the heat shock protein gene (Hspa2) is disrupted. This mouse model is useful in studying the process of spermatogenesis and the influence of various environmental toxins or drugs on sperm production and male infertility.

Potential Commercial Applications:

• Mouse model to study spermatogenesis and male infertility

• Mouse model to study meiosis or the roles of heat-shock proteins in general

• Mouse model to evaluate effects of meiosis-disrupting agents on meiotic recombination and generation of mutations transmitted to offspring

Development Stage:

• In vitro data available

• In vivo data available (animal)

Inventor: Edward M. Eddy (NIEHS)

Publication: Dix DJ, et al. Targeted gene disruption of Hsp70–2 results in failed meiosis, germ cell apoptosis, and male infertility. Proc Natl Acad Sci USA. 1996 Apr 93(8):3264–3268. [PMID 8622925]

Intellectual Property: HHS Reference No. E–052–2011/0—Research Tool. Patent protection is not being pursued for this technology.

Related Technology: HHS Reference No. E–290–2011/0—Research Tool (Transgenic Hspa2-Cre Mice for Studying Spermatogenesis and Male Infertility). Patent protection is not being pursued for this technology.

Licensing Contact: Lauren Nguyen-Antczak, Ph.D., J.D.; 301–435–4074; *Lauren.Nguyen-Antczak@nih.gov*

Collaborative Research Opportunity: The NIEHS is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this mouse strain. For collaboration opportunities, please contact Elizabeth Denholm, Ph.D. at *denholme@niehs.nih.gov*.

Transgenic Hspa2-Cre Mice for Studying Spermatogenesis and Male Infertility

Description of Technology: HSPA2 is a member of the HSP70 family of heat-shock proteins that serve as molecular chaperones. Hspa2-cre expression mimics the spermatogenic cell-specific

expression of endogenous HSPA2 within the testis, being first observed in leptotene/zygotene spermatocytes. Expression of the transgene is also detected at restricted sites in the brain, as occurs for endogenous HSPA2.

Researchers at NIEHS developed the first transgenic mouse line that expresses Cre-recombinase under the control of the promoter of the heat shock protein A2 (Hspa2) gene. Expression of the Hspa2-Cre transgene during meiosis in male germ cells makes these mice a useful tool for defining the roles of genes expressed at different times during spermatogenesis or expressed in spermatogenic cells.

Potential Commercial Applications:

• New mouse model to study spermatogenesis and male infertility

• New mouse model to study meiosis or the roles of heat-shock proteins in general

Competitive Advantages: Researchers generated an Hspa2-cre line that expresses cre in spermatocytes to overcome the limitations of other transgenic lines.

Development Stage:

• In vitro data available

• In vivo data available (animal)

Inventor: Edward M. Eddy (NIEHS)

Publication: Inselman AL, et al. Heat shock protein 2 promoter drives cre expression in spermatocytes of transgenic mice. Genesis. 2010 Feb 48(2):114–120. [PMID 20027617]

Intellectual Property: HHS Reference No. E–290–2011/0—Research Tool. Patent protection is not being pursued for this technology.

Related Technology: HHS Reference No. E–052–2011/0—Research Tool (Hspa2 Knockout Mice for Study of Spermatogenesis and Male Infertility). Patent protection is not being pursued for this technology.

Licensing Contact: Lauren Nguyen-Antczak, Ph.D., J.D.; 301–435–4074; *Lauren.Nguyen-Antczak@nih.gov*

Collaborative Research Opportunity: The NIEHS is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this mouse strain. For collaboration opportunities, please contact Elizabeth Denholm, Ph.D. at *denholme@niehs.nih.gov*.

Diagnostic H5N1 Avian Influenza Virus Peptides

Description of Technology: The recent spread of highly pathogenic H5N1 avian influenza viruses among poultry and transmission of these viruses to humans raises concerns of a potential influenza pandemic. There is a need to track the spread of these viruses both in the animal and human populations to avert or reduce the impact of any potential influenza pandemic as well as to know the actual number (accurate surveillance) of people infected with H5N1, including individuals with subclinical H5N1 infection.

The subject technology is a specific combination of H5N1 peptides useful for assays to detect antibodies generated against a wide range of different H5N1 strains. The combination of peptides was able to specifically detect anti-H5N1 antibodies from serum samples of H5N1 survivors at early and later times post infection while excluding antibodies generated in individuals infected with other strains of influenza virus. Also, the peptides did not react with sera from individuals vaccinated with H5N1 vaccine, in contrast to the strain-specific detection of anti-H5N1 antibodies in sera from infected individuals. Immunoassays using the H5N1 peptide combination provide highly specific, sensitive and reproducible methods for diagnosing H5N1 infection in humans and animals.

Potential Commercial Applications: Diagnostics for influenza virus specific antibodies in humans and animals.

Competitive Advantages: High specificity, sensitivity, and reproducibility

Development Stage:

• Pre-clinical

• In vitro data available

Inventors: Hana Golding and Surender Khurana (FDA)

Publication: Khurana S, et al. H5N1–SeroDetect EIA and rapid test: a novel differential diagnostic assay for serodiagnosis of H5N1 infections and surveillance. J Virol. 2011 Dec;85(23):12455–63. [PMID 21957281]

Patent Status: HHS Reference No. E–093–2010/0 — PCT Application No. PCT/US2011/032555 filed 14 Apr 2011, which published as WO 2011/130555 on 20 Oct 2011

Related Technology: HHS Reference No. E–236–2007/3 — U.S. Patent Application No. 12/664,052 filed 10 Dec 2009

Licensing Contact: Kevin W. Chang, Ph.D.; 301–435–5018; *changke@mail.nih.gov*

Parvovirus B19 Codon Optimized Structural Proteins for Vaccine and Diagnostic Applications

Description of Technology: Parvovirus B19 (B19V) is the only known pathogenic human parvovirus. Infection by this viral pathogen can cause transient aplastic crisis in individuals with high red cell turnover, pure red cell aplasia in immunosuppressed patients, and hydrops fetalis during pregnancy. In children, B19V most commonly causes erythema infectiosum, or fifth's disease. Infection can also cause arthropathy and arthralgia. The virus is very erythrotropic, targeting human erythroid (red blood) progenitors found in the blood, bone marrow, and fetal liver. Currently, there are no approved vaccines or antiviral drugs for the treatment or prevention of B19V infection.

The subject technology is a series of plasmid constructs with codon optimized B19 viral capsid genes (VP1 and VP2) that can be expressed in mammalian cells. Transfection of vectors encoding these optimized VP1 and VP2 genes into different mammalian cell lines, including 293, Cos7, and Hela cells produce virus-like particles (VLPs). The vectors include bicistronic plasmids expressing the VP1 and VP2 proteins at different ratios to produce B19V VLPs with optimal antigenicity for vaccine applications. This technology can also be used for diagnostic applications and development of a viral packaging system for producing infectious B19V virus.

Potential Commercial Applications:

• VLPs based vaccines for the prevention and/or treatment of B19V infection

• DNA based vaccines for the prevention and/or treatment of B19V infection

• B19V diagnostics

• Viral packaging system

Competitive Advantages:

• Codon optimized VP1 and VP2 genes for better expression in mammalian cell lines

• Expression of B19V VLPs from ''nonpermissive'' cell lines

Development Stage: In vitro data available

Inventors: Ning Zhi, Sachiko Kajigaya, and Neal S. Young (NHLBI)

Patent Status: HHS Reference No. E–011–2010/0—PCT Application No. PCT/US2011/024199 filed 09 Feb 2011, which published as WO 2011/100330 on 22 Dec 2011

Licensing Contact: Kevin W. Chang, Ph.D.; 301–435–5018; *changke@mail.nih.gov*

Collaborative Research Opportunity: The National Heart Lung and Blood Institute, Hematology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the subject technology. Please contact Cecilia Pazman, Ph.D., at *pazmance@mail.nih.gov* for more information.

Construct for Tetracycline Inducible Podocyte Specific Gene Expression in Mice

Description of Technology: The National Institutes of Health announces the generation of a construct by ligating 2.5kb human podocin promoter sequence to gene encoding reverse tetracycline-controlled transcriptional activator which enables tetracycline-inducible podocyte specific gene of interest expression with another construct consisting of tetracycline responsive element, minimal CMV promoter and gene of interest.

Podocytes are post-mitotic epithelial cells that are positioned on the exterior aspect of the glomerular capillary wall and contribute to the selective molecular permeability of glomeruli. Podocyte damage or dysfunction results in loss of the characteristic foot processes that normally interdigitate and form the selective permeability barriers composed of filtration slits bridged by slit diaphragms. Minimal damage causes proteinuria that in the case of minimal change disease can be reversed by steroid treatment. In focal segmental glomerulosclerosis, more severe loss of podocytes ultimately results in glomerulosclerosis. The podocyte-specific inducible transgene system can be used to identify factors that exacerbate or ameliorate podocyte injury, and can be used to express Cre-recombinase.

Potential Commercial Applications: This technology can be used for the study of renal disease.

Competitive Advantages: The podocyte-specific inducible transgene system can be used to identify factors that exacerbate or ameliorate podocyte injury, and can be used to express Cre-recombinase.

Development Stage: Pre-clinical

Inventors: Jeffrey B. Kopp et al. (NIDDK)

Publication: Shigehara T, et al. Inducible podocyte-specific gene expression in transgenic mice. J Am Soc Nephrol. 2003 Aug;14(8):1998–2003. [PMID 12874453]

Intellectual Property: HHS Reference No. E–299–2007/0 — Research Material. Patent protection has not been pursued for this technology.

Note: The use of Tetracycline controllable expression systems is covered by a series of patents including US #5,464,758 and 5,814,618 which are proprietary to TET systems GmbH & Co. KG. Interested parties are also advised to contact TET Systems, *info@tetsystems.com* or by electronic request at *www.tetsystems.com/main_inquiry.htm*]

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; *Fatima.Sayyid@nih.hhs.gov*

Parallel High Speed Single Molecule Nucleic Acid Sequencing

Description of Technology: This invention entails a new system, methods, and compositions for DNA sequencing, known as Two Dye Sequencing (TDS). The system utilizes Forster Resonance Energy Transfer (FRET). The TDS method consists of the following steps:

(1) Attaching to a microscope chamber, DNA polymerases labeled with a donor fluorophore.

(2) Adding to the chamber DNA molecules annealed to a primer.

(3) Adding four dNTPs, each labeled with a different fluorescent acceptor dye.

(4) Exciting the donor fluorophore with light, causing energy transfer (FRET) to the acceptor fluorophore for a given dNTP, that then radiates light of a different wavelength.

(5) Identifying nucleotides as they are added to the nascent polynucleotide by recording the FRET signals at the location of each DNA polymerase in the microscope field of view.

(6) Converting the sequential signals into a DNA sequence for each DNA molecule in the microscope field of view.

Potential Commercial Applications: High throughput sequencing of single DNA molecules on a substrate.

Competitive Advantages:

- Detection of individual DNA molecule sequences
- Sequences multiple DNA molecules in parallel with one microscope
- Eliminates washing steps, because all four nucleotides are added at once
- Rapid, works at the speed of the DNA polymerase

Development Stage: Early-stage

Inventors: Thomas D. Schneider and Denise Rubins (NCI)

Intellectual Property: HHS Reference No. E–033–1999/0 —

- US Patent No. 6,982,146 issued 03 Jan 2006
- PCT Application No. PCT/US00/23736 filed 29 Aug 2000
- US Application No. 12/886,686 filed 29 Aug 2000

Related Technologies: HHS Reference No. E–194–2005/0 —

- US Patent No. 7,871,777 issued 18 Jan 2011
- EP Patent No. 1960550 issued 15 Sep 2010, validated in DE, FR, and GB
- JP Application No. 2009–545768 filed 12 Dec 2006
- US Application No. 12/980,802 filed 29 Dec 2010

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., MBA; 301–435–4507; *thalhamc@mail.nih.gov*

The Medusa™; Sequencer: A DNA or RNA Sequencing Machine the Size of a Molecule

Description of Technology: Current high-throughput DNA sequencing methods suffer from several limitations. Many methods require multiple fluid handling steps, fixing of molecules on beads or a 2D surface, and provide very short read-lengths. The NIH inventors offer a DNA or RNA sequencing device that drastically simplifies the process by combining all elements for sequence detection in a single molecule, the Medusa™; Sequencer.

The Medusa™; Sequencer utilizes Forster Resonance Energy Transfer (FRET) to read a polynucleotide sequence while synthesizing a complementary strand. The device consists of a DNA (or RNA) polymerase labeled with a FRET donor fluorophore and attached to a set of four flexible arms. The tip of each arm carries a distinct set including one nonhydrolyzable nucleotide and one FRET acceptor fluorophore. While a Medusa™; Sequencer synthesizes a complementary polynucleotide strand, the four different arms continuously ''test'' the polymerase pocket creating a characteristic FRET signal for the correct nucleotide. The series of FRET signals reveals the unknown polynucleotide sequence.

Potential Commercial Applications:

- High-throughput DNA or RNA sequencing
- Alternative to microarrays for expression analysis
- Diagnostics of genetic diseases

Competitive Advantages:

- Single reagent for synthesis and sequencing
- Eliminates repetitive fluid handling steps
- Able to count single mRNA or DNA molecules
- Exceptionally low manufacturing cost
- Could be injected in living cells to read/count mRNA sequences directly
- Low error rate per base
- High speed; one microscope obtains many sequences in parallel
- Can be 3D-arrayed in a gel for ultra-high density
- Use with Sequence Walkers for diagnostics (*http://alum.mit.edu/www/toms/g863a.html*)

Development Stage: Early-stage

Inventors: Thomas D. Schneider, IIya G. Lyakhov, Danielle Needle (NCI)

Publication: The technology is further described at *http://alum.mit.edu/www/toms/patent/medusa.*

Intellectual Property: HHS Reference No. E–194–2005/0 —

• US Patent No. 7,871,777 issued 18 Jan 2011
• EP Patent No. 1960550 issued 15 Sep 2010, validated in DE, FR, and GB
• JP Application No. 2009–545768 filed 12 Dec 2006
• US Application No. 12/980,802 filed 29 Dec 2010

Related Technologies:
HHS Reference No. E–195–2005/0 —
• US Application No. 60/749,858 filed 12 Dec 2005
• US Application No. 11/638,160 filed 12 Dec 2006

HHS Reference No. E–033–1999/0 —
• US Patent No. 6,982,146 issued 03 Jan 2006
• PCT Application No. PCT/US00/23736 filed 29 Aug 2000
• US Application No. 12/886,686 filed 29 Aug 2000

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., MBA; 301–435–4507; *thalhamc@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute, Gene Regulation and Chromosome Biology Laboratory, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize the Medusa™; Sequencer. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov*.

Nanoprobes for Detection or Modification of Molecules

Description of Technology: This invention describes ''Rod-tether Nanoprobes'', devices consisting of a rigid molecular rod with a flexible molecular tether attached at both ends that can detect and/or modify molecules. Each tether tip has a functional group, such as an antibody or oligonucleotide that recognizes a target molecule. In addition, one tip carries a donor fluorophore and the other carries an acceptor fluorophore. The fluorophores form a pair for Forster Resonance Energy Transfer (FRET). In the absence of the target molecule, the rod keeps the tether arms apart, while in the presence of the target molecule, both recognizers bind to the target. This binding holds the donor and acceptor fluorophores close together, allowing a FRET signal. By reducing an ELISA-like assay entirely to the molecular level, complex macroscopic or microfluidic washing and pumping systems can be eliminated. Rod-tether Nanoprobes can detect a wide variety of clinical and biowarfare reagents. The nanoprobes can also rapidly and simply detect, modify, and/or destroy endogenous molecules (e.g., proteins, mRNA) involved in a broad range of diseases. The simplest ssDNA-detecting nanoprobe has been created.

Potential Commercial Applications:
• Instantly detect molecules of interest (e.g., proteins, mRNA) in multiple settings:
—Clinical
—Scientific research
—Biowarfare
• An improved substitute for ELISA assays
• Modify or destroy target molecules, while detecting them
• Detect genetic diseases in the clinic from patient blood samples

Competitive Advantages:
• Only one reagent required for detection
• Entire reaction contained in a single molecule
• Eliminates washing steps
• Complicated and expensive microfluidic chips are eliminated
• High speed
• Exceptionally low cost

Development Stage: Early-stage

Inventors: Thomas D. Schneider, IIya G. Lyakhov, Danielle Needle (NCI)

Publication: The technology is further described at *http://alum.mit.edu/www/toms/patent/nanoprobe/*.

Intellectual Property: HHS Reference No. E–195–2005/0—
• US Application No. 60/749,858 filed 12 Dec 2005
• US Application No. 11/638,160 filed 12 Dec 2006

Related Technologies: HHS Reference No. E–194–2005/0—
• US Patent No. 7,871,777 issued 18 Jan 2011
• EP Patent No. 1960550 issued 15 Sep 2010, validated in DE, FR, and GB
• JP Application No. 2009–545768 filed 12 Dec 2006
• US Application No. 12/980,802 filed 29 Dec 2010

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., MBA; 301–435–4507; *thalhamc@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Gene Regulation and Chromosome Biology Laboratory, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Rod-Tether Nanoprobes. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Immunogenic Peptides (Vaccines) for the Treatment of Prostate and Breast Cancer

Description of Technology: Collectively, cancer is the second leading cause of death in the United States. Current treatments of cancer often involve non-specific strategies (such as chemotherapy) which attack healthy cells as well as diseased cells, leading to harmful side-effects. As a result, the development of more targeted means of treating cancer are highly sought. One option for a targeted treatment is the creation of a vaccine that induces an immune response only against cancer cells. In this sense, vaccination involves the introduction of a peptide into a patient that causes the formation of T cells that recognize the peptide. If those recognize a peptide found in a protein found selectively on cancer cells, those T cells can trigger the death of those cancer cells without harming non-cancer cells. This can result in fewer side effects for the patient. TARP (T cell receptor gamma alternate reading frame protein) is a protein that is selectively expressed on the cells of certain types of prostate and breast cancer. This invention concerns the identification of immunogenic peptides within TARP, and their use to create an anti-cancer immune response in patients. By introducing these peptides into a patient, an immune response against these cancer cells can be initiated by the peptides, resulting in treatment of the cancer. A phase I clinical trial in stage D0 prostate cancer patients is nearing completion. Initial results indicate a statistically significant decrease in the slope of PSA for 48 weeks after vaccination.

Potential Commercial Applications:
• Peptides can be used as cancer vaccines.
• Treatment of any cancer associated with increased or preferential expression of TARP.
• Specific diseases include breast cancer and prostate cancer.

Competitive Advantages: Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer non-specific side-effects and healthier patients.

Development Stage:
• Pre-clinical
• Clinical
• In vivo data available (animal)
• In vivo data available (human)

Publications:

1. Epel M, *et al.* Targeting TARP, a novel breast and prostate tumor-associated antigen, with T cell receptor-like human recombinant antibodies. Eur J Immunol. 2008 Jun;38(6):1706–1720. [PMID 18446790]

2. Oh S, et al. Human CTLs to wild-type and enhanced epitopes of a novel prostate and breast tumor-associated protein, TARP, lyse human breast cancer cells. Cancer Res. 2004 Apr 1;64(7):2610–2618. [PMID 15059918]

Intellectual Property: HHS Reference No. E–116–2003/0—

- US Patent 7,541,035 issued 02 Jun 2009
- US Patent 8,043,623 issued 25 Oct 2011

Licensing Contact: David A. Lambertson, Ph.D.; 301–435–4632; *lambertsond@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Vaccine Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize a prostate cancer vaccine targeting the TARP antigen currently completing phase I clinical trials. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Dated: April 27, 2012.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2012–10637 Filed 5–2–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIEHS.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Environmental Health Sciences, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIEHS.

Date: June 3–5, 2012.

Closed: June 3, 2012, 7:00 p.m. to 10:00 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Doubletree Guest Suites, 2515 Meridian Parkway, Research Triangle Park, NC 27713.

Open: June 4, 2012, 8:30 a.m. to 11:50 a.m.

Agenda: An overview of the organization and research in the Laboratory of Structural Biology.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: June 4, 2012, 11:50 a.m. to 12:35 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: June 4, 2012, 1:30 p.m. to 3:00 p.m.

Agenda: Scientific Presentations and Poster Sessions.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: June 4, 2012, 3:15 p.m. to 3:45 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: June 4, 2012, 3:45 p.m. to 5:25 p.m.

Agenda: Scientific Presentations.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: June 4, 2012, 5:30 p.m. to 6:00 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: June 4, 2012, 8:00 p.m. to 10:00 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Doubletree Guest Suites, 2515 Meridian Parkway, Research Triangle Park, NC 27713.

Open: June 5, 2012, 8:30 a.m. to 10:10 a.m.

Agenda: Scientific Presentations.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: June 5, 2012, 10:25 a.m. to 1:00 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Darryl Zeldin, M.D., Scientific Director & Principal Investigator, Division of Intramural Research, National Institute of Environmental Health Sciences, NIH, 111 TW Alexander Drive, Maildrop A2–09, Research Triangle Park, NC 27709, 919–541–1169, *zeldin@niehs.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS).

Dated: April 26, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–10729 Filed 5–2–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Gastrointestinal Pathophysiology.

Date: May 17, 2012.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Patricia Greenwel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301–435–1169, *greenwep@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR12–010 Alcohol Use Disorders: Treatment, Services Research, and Recovery.

Date: June 1, 2012.

Time: 5:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street NW., Washington, DC 20037.

Contact Person: Jacinta Bronte-Tinkew, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3164, MSC 7770, Bethesda, MD 20892, (301) 806–0009, *brontetinkewjm@csr.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Cellular, Molecular, and Immunobiology Study Section.

Date: June 5–6, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

Contact Person: George M Barnas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, 301–435–0696, *barnasg@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroscience and Neurodegeneration Study Section.

Date: June 5, 2012.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue NW., Washington, DC 20037.

Contact Person: Samuel C Edwards, Ph.D., Chief, Brain Disorders and Clinical Neuroscience, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: CMIP and MEDI.

Date: June 5, 2012.

Time: 1:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301–237–9870, *xuguofen@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Family Smoking Prevention and Tobacco Control.

Date: June 5, 2012.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin National Harbor, 171 Waterfront Street, National Harbor, MD 20745.

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, *riverase@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 26, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–10719 Filed 5–2–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Date: June 5, 2012.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: To discuss administrative details relating to the Council's business and special reports.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Closed: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Contact Person: Laura K. Moen, Ph.D., Director, Division of Extramural Research Activities, NIAMS/NIH, 6700 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301–451–6515, *moenl@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: April 26, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–10717 Filed 5–2–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Tumor Cells Diagnostic Nanotechnology.

Date: May 22, 2012.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Blvd., Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Virginia P. Wray, Ph.D., Deputy Chief, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 8125, Bethesda, MD 20892–8328, 301–496–9236, *wrayv@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Innovative Devices to Protect Radiosensitive Organs.

Date: June 14, 2012.

Time: 11:30 a.m. to 2:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Viatcheslav A Soldatenkov, MD, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd. Room 8057, Bethesda, MD 20892–8329, 301–451–4758 *soldatenkovv@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Cell-Based Imaging.

Date: June 19, 2012.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Clifford W Schweinfest, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 8050a, Bethesda, MD 20892–8329, 301–402–9415 *schweinfestcw@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/sep/sep.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 27, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–10713 Filed 5–2–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Biology.

Date: May 21, 2012.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, *riverase@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR12–048 Prevention and Treatment of Chronic Diseases in Military Populations.

Date: May 25, 2012.

Time: 10:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Fungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–408–9436, *fungai.chanetsa@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR11–301–303: Pediatric Drug Formulations and Drug Delivery.

Date: May 29–30, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: J Scott Osborne, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4114, MSC 7816, Bethesda, MD 20892, (301) 435–1782, *osbornes@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Therapeutic Approaches to Genetic Diseases Study Section.

Date: May 30, 2012.

Time: 8:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, .Bethesda, MD 20814.

Contact Person: Michael K Schmidt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2214, MSC 7890, Bethesda, MD 20892, (301) 435–1147, *mschmidt@mail.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: May 30–31, 2012.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, *luow@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Therapies and Tools for Screenable Disorders.

Date: May 30, 2012.

Time: 2:30 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael K Schmidt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2214, MSC 7890, Bethesda, MD 20892, (301) 435–1147, *mschmidt@mail.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Social Psychology, Personality and Interpersonal Processes Study Section.

Date: May 31–June 1, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.

Contact Person: Monica Basco, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3220, MSC 7808, Bethesda, MD 20892, 301–496–7010, *bascoma@mail.nih.gov.*

Name of Committee: Immunology Integrated Review Group; Hypersensitivity, Autoimmune, and Immune-mediated Diseases Study Section.

Date: May 31–June 1, 2012.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

Contact Person: Bahiru Gametchu, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4204, MSC 7812, Bethesda, MD 20892, 301–408–9329, *gametchb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA RM11–006: Transformative R01 Roadmap Review.

Date: May 31, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: John L. Bowers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4170, MSC 7806, Bethesda, MD 20892, (301) 435–1725, *bowersj@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Molecular and Integrative Signal Transduction Study Section.

Date: May 31–June 1, 2012.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Raya Mandler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5134, MSC 7840, Bethesda, MD 20892, (301) 402–8228, *rayam@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Kidney, Nutrition, Obesity and Diabetes Study Section.

Date: May 31–June 1, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Fungai Chanetsa, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301–408–9436, *fungai.chanetsa@nih.hhs.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Molecular and Cellular Hematology Study Section.

Date: May 31–June 1, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6183, MSC 7804, Bethesda, MD 20892, 301–495–1213, *espinozala@mail.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Psychosocial Development, Risk and Prevention Study Section.

Date: May 31–June 1, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sax Chicago, 333 N. Dearborn, Chicago, IL 60654.

Contact Person: Anna L Riley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301–435–2889, *rileyann@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review, Group; Neuroendocrinology, Neuroimmunology, Rhythms and Sleep Study Section.

Date: May 31–June 1, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *mselmanoff@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA RM11–006: Transformative R01 Roadmap Review.

Date: May 31, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: John L. Bowers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4170, MSC 7806, Bethesda, MD 20892, (301) 435–1725, *bowersj@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Drug Discovery and Molecular Pharmacology Study Section.

Date: May 31–June 1, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

Contact Person: Jeffrey Smiley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301–594–7945, *smileyja@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Virology—-B Study Section.

Date: May 31–June 1, 2012.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Lorien Hotel and Spa, 1600 King Street, Alexandria, VA 22314.

Contact Person: John C Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435–2398, *pughjohn@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 27, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–10701 Filed 5–2–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be open to the public, with attendance limited to pace available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

Date: July 11, 2012.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: Strategic Discussion of NCI's Clinical Trials and Translational Research Programs.

Place: National Institutes of Health, Building 31, C–Wing, 6th Floor, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Contact Person: Sheila A. Prindiville, MD, MPH, Director, Coordinating Center for Clinical Trials, Office of the Director, National Cancer Institute, National Institutes of Health, 6120 Executive Blvd., 3rd Floor Suite, Bethesda, MD 20892, 301–451–5048, *prindivs@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles,

including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 27, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–10699 Filed 5–2–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Ocular Therapeutics Utilizing the Peptide C16Y and Related Peptides

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to ODIN Biotech, a Texas corporation, having a place of business in Dallas, Texas, to practice the inventions embodied in the patents and patent applications belonging to the patent family having HHS Reference Number E–008–2004/0. The exclusive license is one which qualifies under the Start-Up License Agreement program which is in place from October 1, 2011 through September 30, 2012. Specific details regarding the individual patents or patent applications which belong to this patent family are set forth in the table below:

Patent application number	Country	Filing date or international filing date	Status	Publication or patent number
PCT/US2004/04142	PCT	02/12/2004	Expired	WO 2005/087250
10/588,884	US	08/09/2006	Issued	8,039,585 B2
2004317159	AU	02/12/2004	Issued	2004317159 B2
2,555,792	CA	2/12/2004	Pending	2555792 A1
04 710659.6	EP	2/12/2004	Pending	1737479 A1

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be ''worldwide'', and the field of use may be limited to ''use of C16Y and related peptides in the treatment of ocular disease.''

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before May 18, 2012 will be considered.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the patent application(s), inquiries, AND comments relating to the contemplated exclusive license should be directed to: Susan S. Rucker, JD, CLP, Senior Advisor for Intellectual Property Transactions, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4478; Facsimile: (301) 402–0220; Email: *ruckersu@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The technology encompassed by the patents and/or patent applications (IP) to be included in this exclusive license relates to a protein designated C16Y and variations thereof. C16Y is an engineered peptide derived from laminin gamma 1 chain having anti-angiogenic properties. The C16Y peptide is at least 5-fold more potent than the previously described C16S peptide and has been shown to inhibit choroidal neovascularization (CNV) in vivo and inhibit angiogenesis in a tumor bearing mouse model (see Ponce, et al Cancer Research 63: 5060–64 (2003)). The IP covers various C16Y compositions and uses thereof, particularly its use in treating ocular diseases.

The prospective start up exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective start up exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Only applications for a license in the field of use set forth in this notice and filed in response to this notice will be treated as objections to the grant of the contemplated start up exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 27, 2012.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2012–10636 Filed 5–2–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket Number FR–5623–N–01]

Federal Housing Administration (FHA) Healthcare Facility Documents: Proposed Revisions and Updates and Notice of Information Collection

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: Consistent with the Paperwork Reduction Act of 1995 (PRA), HUD is publishing for public comment a comprehensive set of closing and other documents used in connection with transactions involving healthcare facilities (excluding hospitals) that are insured pursuant to section 232 of the National Housing Act (Section 232). In addition to meeting PRA requirements, this notice seeks public comment for the purpose of enlisting input from the lending

industry and other interested parties in the development, updating, and adoption of a set of instruments (collectively, healthcare facility documents) that offer the requisite protection to all parties in these FHA-insured mortgage transactions, consistent with modern real estate and mortgage lending laws and practices. The healthcare facility documents, which are the subject of this notice, can be viewed on HUD's Web site: *www.hud.gov/232forms.* HUD is also publishing today a proposed rule that will submit for public comment certain revisions to FHA's Section 232 regulations for the purpose of ensuring consistency between the program regulations and the revised healthcare facility documents.

DATES: *Comment Due Date:* July 2, 2012.

ADDRESSES: Interested persons are invited to submit comments regarding this proposed rule. Communications must refer to the above docket number and title. There are two methods for submitting public comments:

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Comments may be submitted electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (fax) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an appointment to review the public comments must be scheduled in advance by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

For policy questions contact: John M. Hartung, Director, Policy and Risk Management Division, Office of Residential Care Facilities, Office of Healthcare Programs, Office of Housing, U.S. Department of Housing and Urban Development, 1222 Spruce Street, Room 3.203, St. Louis, MO 63103–2836; telephone (314) 418–5238 (this is not a toll-free number). Persons with hearing or speech disabilities may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

For legal questions contact: Millie Potts, Acting Associate General Counsel, Office of the General Counsel, Room 9230, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410–0500; telephone (202) 708–1274 (this is not a toll-free number). Persons with hearing or speech disabilities may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background and Overview

The issuance of this notice is modeled on the public review and input process that HUD utilized in the updating of its multifamily rental project closing documents. On May 2, 2011, at 76 FR 24363, HUD published a notice announcing HUD's completion of the updates to the multifamily rental project closing documents. The update of HUD's multifamily rental project closing documents involved substantial review of proposed changes to those documents and the opportunity for considerable public comment. Building on the experience of that process, including the changes made to the multifamily rental project closing documents, HUD has revised its healthcare facility documents to utilize, as appropriate, the updated multifamily documents while also developing standardized healthcare facility-specific documents as necessary. This notice solicits comments on this revised set of healthcare facility documents.

The revised healthcare facility documents can be viewed at: *www.hud.gov/232forms.* All of the documents that are the subject of this notice are listed in the Paperwork Reduction Act table found in Section III of this notice. Where healthcare facility documents are based on updated multifamily rental project closing documents, the healthcare facility documents, in addition to being presented in an unmarked format, are presented in redline/strikeout format so that the reviewer can see the changes proposed to be made to the multifamily rental project closing documents in order to make the documents applicable to healthcare facility transactions. Where proposed healthcare facility documents are based on existing healthcare facility documents, the proposed healthcare facility documents, in addition to being presented in an unmarked format, are also presented in redline/strikeout format so that the reviewer can see the changes proposed to the existing healthcare facility documents. Summaries of the major changes to some of the principal documents follow. Where capitalized terms are used, such terms refer to the titles of documents or defined terms in the documents.

The requirements for commitment and endorsement of a mortgage note are provided in HUD's regulations primarily at 24 CFR part 200, subpart A; 24 CFR part 232, and including, in particular, cross-references to general eligibility requirements for the FHA multifamily housing insurance programs in 24 CFR part 207. HUD's regulations provide that where specific documents are referenced in the regulations such documents shall be in a form as prescribed by HUD. The regulations also specify other program requirements that are reflected in the proposed documents. In order to ensure consistency between applicable program regulations and the proposed updated documents, revisions to certain of these regulations will be the subject of a proposed rule that HUD will soon be publishing.

II. Summary of Changes to Selected HUD Healthcare Facility Documents

As detailed more fully below, the overall contractual framework, as set forth in the proposed revised documents, clarifies current policies, and strengthens HUD's oversight. For example, although HUD has always taken the position that an operator, like a borrower, would be subject to regulatory restrictions pursuant to the transaction's regulatory agreements, the revised documents clarify this policy and set forth more specific regulatory restrictions. The revised documents

propose to: maintain operators' currently broad discretion over the use of project funds, provided that quarterly and year-to-date financial reports demonstrate that the healthcare facility is maintaining sufficient working capital; give borrowers greater flexibility in the use of project funds, provided that semi-annual calculations demonstrate positive surplus cash; increase a healthcare facility's ability to weather financial downturns with a debt service reserve; expand information sharing with lenders; clarify requirements for multiple facility portfolios and master lease structures; update terms and standardize provisions across the nation. Although a summary of the revised provisions follows below, HUD encourages interested parties to review the proposed form documents, posted on its Web site at: *www.hud.gov/232forms.*

Regulatory Agreements. The healthcare regulatory agreements are based on the Regulatory Agreement for Multifamily Projects, with three specific regulatory agreements proposed: (1) A borrower's regulatory agreement; (2) an operator's regulatory agreement; and for use where applicable, (3) a master tenant's regulatory agreement. The agreements are proposed to apply to multiple potential deal structures. For example, the operator's regulatory agreement will apply to any operator, whether such operator is a lessee or an operator pursuant to some other contractual arrangement; the borrower's regulatory agreement will apply whether or not the borrower is also the operator, and whether the borrower's operator leases the healthcare facility or operates the facility pursuant to some other contractual arrangement. Borrowers who also operate the healthcare facility will execute both the borrower's and the operator's regulatory agreements.

Substantively, the regulatory agreements provide, without limitation, that: the healthcare facility shall only be used for approved uses and maintained in decent, safe, sanitary condition and good repair; borrowers must maintain a debt service reserve; borrowers may take distributions of project funds so long as semi-annual calculations demonstrate positive surplus cash; non-profit borrowers must maintain residual receipt accounts; project records must be adequately maintained and kept available for inspection; borrowers must submit audited annual financial statements; operators must submit quarterly and year-to-date financial statements; copies of certain notices, reports, surveys and other correspondence relating to the permits and approvals necessary to operate the healthcare facility must be provided to HUD and Lender; HUD's consent must be obtained prior to any change in the operator or management agent; if the healthcare facility's financial or operational viability is at risk, HUD may require the operator to engage an operational consultant; and HUD may terminate an operator's, master tenant's, or sublessee's rights to operate the healthcare facility upon an uncured default.

Management Certification. HUD also invites comments regarding a newly created management certification (''Management Agent's and Owner's or Operator's Certification for Residential Care Facilities for Identity-of-Interest or Independent Management Agents''). HUD recognizes that in most instances the licensed operator, through a contractual relationship with the owner, handles the management activities of the facility. Sometimes, however, that operator (or even the owner itself *as the licensed operator*) contracts with another entity (''management agent'') to handle some management activities. HUD has determined that, in those instances, it is important that the management agent execute a controlling document whereby it makes key certifications/commitments directly to HUD, and through which HUD can directly pursue remedies in the event of noncompliance.

Security Instrument and Security Agreements. The borrower, operator, and, if applicable, master tenant, all provide collateral to the lender as security for the loan. Operators and master tenants provide Uniform Commercial Code (UCC) collateral through security agreements; borrowers provide their interests in both UCC property and real property. Based on the revised multifamily security instrument, the borrower's security instrument is set up with alternative language that can be used as applicable in states where mortgages, deeds of trust, security deeds, or other instrument forms are used. State-specific addenda may be developed by HUD field counsel as required for the various jurisdictions and may need to be appended, comparable to the approach taken in the multifamily rental documents. Collectively, the borrower's security instrument and operator's and master tenant's security agreements provide the lender with security for the loan in all project-related assets. These security documents also incorporate the regulatory agreements and give the lenders rights to enforce the borrower's promises to provide lender with appropriate notices, correspondence, and other applicable reports. In addition to these security documents, borrowers and/or operators, as applicable, will be required to execute form deposit account control agreements, and related documents, to adequately perfect the lender's security interests in the project accounts. Where accounts receivable financing is utilized, the revised form intercreditor agreement sets forth the terms pursuant to which an accounts receivable lender's interest may take priority over the HUD-insured lender's interests.

Healthcare Facility Note. The substantive provisions of the promissory note used for the healthcare facility transactions have not been substantially revised, but the form of note has been revised, adopting the revised multifamily note form. The loan remains a non-recourse loan, as set forth in the note. The borrower's personal assets are not at risk for the repayment of the loan. However, as with the multifamily note posted on HUD's Web site on May 2, 2011, to the extent an individual commits fraud, steals funds from the project, or is otherwise unjustly enriched through improper use of project funds, HUD will pursue recovery of such funds, and certain controlling entities and individuals will be asked to sign the regulatory agreement in acknowledgement of such potential liability.

Master Lease documents. As multi-facility portfolio transactions increase in occurrence, the master lease structure is increasingly utilized. In response to this trend, HUD proposes several form documents to be used in master lease structured transactions. The documents proposed include an Addendum to the master lease which includes provisions protecting the Lender and HUD's interests, a Master Tenant Security Agreement, a Master Tenant Regulatory Agreement, a Subordination Agreement or Subordination Non-Disturbance Agreement, and a Cross-Default Guaranty of Subtenants. The master lease structure allows for any rental deficiencies at one facility to be supported by income from another facility under the master lease. It is important to note that a master lease does not pool the assets of all facilities for underwriting a single mortgage loan for multiple facilities. Each individual loan must meet HUD's underwriting standards on its own merit.

Definitions. Several definitions have been clarified throughout the documents, and several new terms have been added. The terms ''Borrower,'' ''Lender,'' and ''Operator,'' have been added and apply when referencing the respective concepts of borrower/owner/

mortgagor/lessor, lender/mortgagee, and operator/lessee/sub-lessee/sub-tenant. Based on the multifamily concept, the term ''Mortgaged Property'' refers to all of the borrower's interests in any aspect of the project, and includes concepts and interests specific to healthcare programs. Although ''Mortgaged Property'' relates only to the Borrower's interests in the project, the operator's interests in project-related assets are separately conveyed as collateral through the operator's security agreement. In order to capture all of borrowers' and operators' interests and assets related to the development and operation of the healthcare facility, including those that, in the strictest legal interpretations may not be a part of the healthcare facility itself, the terms ''Healthcare Facility'' and ''Project'' have been set forth as very closely related but distinct concepts: ''Project'' has been defined as ''any and all assets of whatever nature or wherever situated related to the Loan, including without limitation, the Mortgaged Property, any Improvements, and any collateral owned by operators securing the Loan;'' whereas ''Healthcare Facility'' has been defined as ''any portions of the Project (both tangible, and intangible), operated on the Land as a Nursing Home, Intermediate Care Facility, Board and Care Home, Assisting Living Facility or any other healthcare facility authorized to receive mortgage insurance pursuant to Section 232 of the National Housing Act, as amended, or other applicable federal law.'' Several other definitions have been revised, added, or deleted, as appropriate.

Finally, a decision was made to adopt more consistency in the numbering system for the program documents, *e.g.* HUD Form 9XXXX–OHP. Greater consistency should reduce confusion because the documents will appear in the same group wherever HUD publishes the documents, *e.g.* HUDCLIPS at *http://www.hud.gov/hudclips.*

III. Paperwork Reduction Act

The proposed new information collection requirements contained in this notice have been submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Under this Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number. The public reporting burden for this new collection of information is estimated to include the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Information on the estimated public reporting burden is provided in the following table:

New form number	Form name	Number of respondents	Freq. of resp.	Resp. per annum	Avg. burden per hour per resp.	Annual burden hours	Avg. hourly cost per resp.	Annual cost
HUD–901–OHP.	Firm Application Checklist Section 232—223a7 Refinance.	30	2.5	75	0.67	50	$62	$3,083
HUD–902–OHP.	Firm Application Checklist Section 232—223f Refinance.	30	7.5	225	0.83	188	62	11,563
HUD–903–OHP.	Firm Application Checklist Section 232—241a Supplemental Loan.	4	1	4	0.83	3	62	206
HUD–904–OHP.	Firm Application Checklist Section 232—New Construction—Single Stage.	10	2	20	1.17	23	62	1,439
HUD–905a–OHP.	Firm Application Checklist Section 232—New Construction—2 Stage—Final Submittal.	10	2	20	0.67	13	62	822
HUD–905–OHP.	Firm Application Checklist Section 232—New Construction—2 Stage—Initial Submittal.	10	2	20	0.83	17	62	1,028
HUD–906–OHP.	Firm Application Checklist Section 232—Substantial Rehabilitation—Single Stage.	4	1	4	1.17	5	62	288
HUD–907–OHP.	Firm Application Checklist Section 232—Substantial Rehabilitation—2 Stage—Initial Submittal.	4	1	4	0.83	3	62	206
HUD–907a–OHP.	Firm Application Checklist Section 232—Substantial Rehabilitation—2 Stage—Final Submittal.	4	1	4	0.83	3	62	206
HUD–908–OHP.	Firm Application Checklist Section 232—Blended Rate—Single Stage.	4	1	4	0.83	3	62	206

New form number	Form name	Number of respondents	Freq. of resp.	Resp. per annum	Avg. burden per hour per resp.	Annual burden hours	Avg. hourly cost per resp.	Annual cost
HUD–909–OHP.	Firm Application Checklist Section 232—232(i)—Fire Safety Protection Loan for Projects Not Currently Insured.	5	2	10	0.67	7	62	411
HUD–9010–OHP.	Firm Application Checklist Section 232—232(i)—Fire Safety Protection Loan for Projects Currently Insured.	5	2	10	0.67	7	62	411
HUD–9011–OHP.	Firm Application Checklist Section 232—223(d)—Operating Loss Loan.	1	2	2	0.67	1	62	82
HUD–9012–OHP.	Post-Commitment Early Start of Construction Checklist.	7	1	7	0.50	4	62	216
HUD–9001–OHP.	Lender Narrative 223a7—Main.	30	2.5	75	22.00	1650	75	123,750
HUD–9001a–OHP.	Lender Narrative 223a7—Addenda—PCNA.	30	2.5	75	1.50	113	75	8,438
HUD–9001b–OHP.	Lender Narrative 223a7.223d.232i—Addenda—Survey.	30	2.5	75	0.25	19	75	1,406
HUD–9001c–OHP.	Lender Narrative 223a7—Addenda—4128.	30	2.5	75	0.25	19	75	1,406
HUD–9001d–OHP.	Lender Narrative 223a7—Addenda—Indebtedness.	30	2.5	75	0.25	19	75	1,406
HUD–9001e–OHP.	Lender Narrative 223a7.223d.232i—Addenda—Principal of Mortgagor.	30	2.5	75	0.50	38	75	2,813
HUD–9001f–OHP.	Lender Narrative 223a7.223d.232i—Addenda—Operator.	20	2.5	50	0.50	25	75	1,875
HUD–9001g–OHP.	Lender Narrative 223a7.223d.232i—Addenda—Management Agent.	12	2.5	30	0.50	15	75	1,125
HUD–9001h–OHP.	Lender Narrative 223a7.223d.232i—Addenda—Operating Lease.	30	2.5	75	0.50	38	75	2,813
HUD–9001i–OHP.	Lender Narrative 223a7.223d.232i—Addenda—Management Agreement.	30	2.5	75	0.25	19	75	1,406
HUD–9001j–OHP.	Lender Narrative 223a7.223d—Addenda—AR Financing.	15	2.5	37.5	0.50	19	75	1,406
HUD–9002–OHP.	Lender Narrative 223f	30	7.5	225	70.00	15750	75	1,181,250
HUD–9003–OHP.	Lender Narrative 241a—Main.	4	1	4	73.33	293	75	22,000
HUD–9003a–OHP.	Lender Narrative 241a—Addenda—Phase 1 Environmental.	4	1	4	4.00	16	75	1,200
HUD–9004–OHP.	Lender Narrative New Construction—Single Stage.	10	2	20	86.67	1733	75	130,000
HUD–9005a–OHP.	Lender Narrative New Construction 2 Stage Final Submittal.	10	2	20	53.33	1067	75	80,000
HUD–9005–OHP.	Lender Narrative New Construction 2 Stage Initial Submittal.	10	2	20	63.33	1267	75	95,000

New form number	Form name	Number of respondents	Freq. of resp.	Resp. per annum	Avg. burden per hour per resp.	Annual burden hours	Avg. hourly cost per resp.	Annual cost
HUD–9006–OHP.	Lender Narrative Substantial Rehabilitation—Single Stage.	4	1	4	93.33	373	75	28,000
HUD–9007–OHP.	Lender Narrative Substantial Rehabilitation 2 Stage Initial Submittal.	4	1	4	70.00	280	75	21,000
HUD–9007a-OHP.	Lender Narrative Substantial Rehabilitation 2 Stage Final Submittal.	4	1	4	70.00	280	75	21,000
HUD–9008–OHP.	Lender Narrative—Blended Rate.	4	1	4	70.00	280	62	17,267
HUD–9009–OHP.	Lender Narrative 232(i) Not Currently Insured.	5	2	10	0.67	7	62	411
HUD–90010–OHP.	Lender Narrative 232(i) Currently Insured.	5	2	10	0.67	7	62	411
HUD–90011–OHP.	Lender Narrative 223(d)—Main.	1	2	2	0.67	1	62	82
HUD–9444–OHP.	Lender Narrative Cost Certification Supplement.	2	2	4	6.67	27	75	2,000
HUD–90001–OHP.	Firm Commitment—223a7.	30	2.5	75	0.42	31	83	2,604
HUD–90002–OHP.	Firm Commitment—223f	30	7.5	225	0.42	94	83	7,813
HUD–90003a–OHP.	Firm Commitment—New Construction or Substantial Rehabilitation—2 Stage—Final Submittal (Amended and Restated).	12	2	24	0.42	10	83	833
HUD–90003–OHP.	Firm Commitment—New Construction or Substantial Rehabilitation—2 Stage—Initial Submittal.	12	2	24	0.42	10	83	833
HUD–90004–OHP.	Firm Commitment—New Construction or Substantial Rehabilitation—Single Stage.	12	2	24	0.42	10	83	833
HUD–90005–OHP.	Firm Commitment—241a	12	2	24	0.42	10	83	833
HUD–90006–OHP.	Firm Commitment—232(i)	5	2	10	0.67	7	62	411
HUD–90007–OHP.	Firm Commitment—223(d).	1	2	2	0.67	1	62	82
HUD–90012–OHP.	Consolidated Certification—Lender.	30	2.5	75	0.58	44	67	2,917
HUD–90013–OHP.	Consolidated Certification—Mortgagor.	77	1	77	1.33	103	75	7,700
HUD–90014–OHP.	Consolidated Certification—Principal of the Mortgagor.	38	2	76	1.33	101	75	7,600
HUD–90015–OHP.	Consolidated Certification—Operator.	35	2	70	1.33	93	75	7,000
HUD–90016–OHP.	Consolidated Certification—Parent of Operator.	35	2	70	1.33	93	75	7,000
HUD–90017–OHP.	Consolidated Certification—Management Agent.	35	2	70	1.33	93	75	7,000

New form number	Form name	Number of respondents	Freq. of resp.	Resp. per annum	Avg. burden per hour per resp.	Annual burden hours	Avg. hourly cost per resp.	Annual cost
HUD–90018–OHP.	Consolidated Certification—Contractors.	4	1	4	1.33	5	75	400
HUD–90019–OHP.	Auditor Certification 223d	3	1	3	0.58	2	67	117
HUD–90021–OHP.	Certification FHA Retyped Forms.	35	10	350	0.28	99	83	8,264
HUD–90022–OHP.	Certification for Electronic Submittal.	35	10	350	0.28	99	67	6,611
HUD–9445–OHP.	Certification of Outstanding Obligations.	35	10	350	1.25	438	83	36,458
HUD–91118–OHP.	Owner's Certification—Completion of Critical Repairs.	240	1	240	0.58	140	75	10,500
HUD–92434–OHP.	Lender Certification	35	10	350	0.75	263	75	19,688
HUD–91130–OHP.	Building Code Certification.	26	2	52	0.33	17	83	1,444
HUD–91131–OHP.	Zoning Certification	30	11.7	351	0.67	234	75	17,550
HUD–91123–OHP.	Design Professional's Certification of Liability Insurance.	26	2	52	0.33	17	83	1,444
HUD–91124–OHP.	Design Architect Certification.	26	2	52	0.33	17	83	1,444
HUD–91127–OHP.	Financial Statement Certification GC.	26	2	52	0.37	19	67	1,271
HUD–92408–OHP.	HUD Amendment to B108.	26	2	52	0.28	15	75	1,105
HUD–95379–OHP.	HUD Representative's Trip Report.	26	28	728	0.83	607	75	45,500
HUD–91129–OHP.	Lender Certification for New Construction Cost Certifications.	10	5.2	52	3.33	173	75	13,000
HUD–9441–OHP.	Lenders Preconstruction Conference Agenda.	10	5	50	4.67	233	75	17,500
HUD–9442–OHP.	Memo for Post-Commitment Early Start of Construction Request.	3	2	6	0.70	4	75	315
HUD–92415–OHP.	Request for Permission to Commence Construction Prior to Initial Endorsement for Mortgage Insurance (Post-Commitment Early Start of Construction).	3	2	6	0.30	2	83	150
HUD–93305–OHP.	Agreement and Certification.	10	5.2	52	0.50	26	75	1,950
HUD–92441–OHP.	Building Loan Agreement	10	5.2	52	1.00	52	75	3,900
HUD–92441a–OHP.	Building Loan Agreement Supplemental.	10	5.2	52	1.00	52	75	3,900
HUD–92450–OHP.	Completion Assurance	10	5.2	52	0.50	26	75	1,950
HUD–92442–OHP.	Construction Contract	10	5.2	52	1.00	52	75	3,900

New form number	Form name	Number of respondents	Freq. of resp.	Resp. per annum	Avg. burden per hour per resp.	Annual burden hours	Avg. hourly cost per resp.	Annual cost
HUD–92554–OHP.	Construction Contract Supplemental.	10	5.2	52	0.20	10	217	2,253
HUD–92456–OHP.	Escrow Agreement for Incomplete Construction.	3	2	6	0.50	3	75	225
HUD–92479–OHP.	Offsite Bond	5	3	15	0.50	8	75	563
HUD–92452A–OHP.	Payment Bond	5	5.2	26	0.50	13	75	975
HUD–92452–OHP.	Performance bond Dual Obligee.	5	5.2	26	0.50	13	217	2,817
HUD–92455–OHP.	Request for Endorsement	10	5.2	52	0.75	39	75	2,925
HUD–92023–OHP.	Request for Final Endorsement.	10	5.2	52	1.00	52	75	3,900
HUD–92477–OHP.	Sponsors Bond	1	1	1	0.50	1	75	38
HUD–92412–OHP.	Working Capital Escrow	10	5.2	52	0.50	26	75	1,950
HUD–91125–OHP.	Staffing Schedule	30	5.83	175	1.00	175	62	10,792
HUD–91708–OHP.	Agreement for Payment of Real Property Taxes.	1	1	1	0.67	1	83	56
HUD–92576A–OHP.	Certificate of Need for Health Facility.	3	2	6	0.30	2	83	150
HUD–90023–OHP.	Check Transmittal Letter Template.	30	11.7	351	0.28	99	62	6,133
HUD–90024–OHP.	Contact Sheet	35	10	350	0.67	233	67	15,556
HUD–91121–OHP.	Deposit Account Control Agreement (DACA).	30	5	150	3.67	550	217	119,167
HUD–91122–OHP.	Deposit Account Instructions and Service Agreement (DAISA).	30	5	150	3.50	525	217	113,925
HUD–91126–OHP.	Financial Statement Certification.	150	7	1050	0.37	385	67	25,667
HUD–92264–OHP.	Healthcare Facility Summary Appraisal Report.	26	2	52	41.33	2149	75	161,200
HUD–91116–OHP.	Addendum to Operating Lease.	30	6.5	195	0.50	98	217	21,125
HUD–941–OHP.	Lenders FHA Number Request Form.	30	11.7	351	0.37	129	62	7,937
HUD–92264a–OHP.	Maximum Insurable Mortgage.	30	11.7	351	1.25	439	83	36562.5
HUD–92477–OHP.	Property Insurance Requirements.	35	10	350	0.87	303	75	22,750
HUD–2–OHP.	Request for Waiver of Housing Directive.	20	8	160	1.00	160	75	12,000
HUD–91119–OHP.	Schedule of Facilities Owned Operated or Managed.	35	10	350	1.33	467	75	35,000

New form number	Form name	Number of respondents	Freq. of resp.	Resp. per annum	Avg. burden per hour per resp.	Annual burden hours	Avg. hourly cost per resp.	Annual cost
HUD–91110–OHP.	Subordination, Non-Disturbance and Attornment Agreement of Operating Lease (SNDA).	30	11.7	351	2.33	819	233	191,100
HUD–91111–OHP.	Survey Instructions and Owners Certification.	180	1.5	270	0.53	144	83	12,000
HUD–91112–OHP.	Request of Overpayment of Firm Application Exam Fee.	15	5.13	76.95	0.50	38	67	2,565
HUD–9839–OHP.	Management Certification—Residential Care Facility.	5	1	5	0.50	3	75	188
HUD–92466–OHP.	Regulatory Agreement—Owner of Residential Care Facility.	35	10	350	0.83	292	217	63,194
HUD–92466A–OHP.	Regulatory Agreement—Operator (non-lessee) of Residential Care Facility.	10	2	20	0.83	17	217	3,611
HUD–94000–OHP.	Security Instrument/Mortgage/Deed of Trust.	35	10	350	1.00	350	217	75,833
HUD–92070–OHP.	Lease Addendum	2	1	2	0.50	1	217	217
HUD–94001–OHP.	Healthcare Facility Note	35	10	350	1.00	350	75	26,250
HUD–91710–OHP.	Residual Receipts Note Non Profit Mortgagor.	5	2	10	0.50	5	75	375
HUD–92420–OHP.	Subordination Agreement	7	2	14	0.50	7	217	1,517
HUD–9223–OHP.	Surplus Cash Note	7	2	14	0.50	7	75	525
HUD–91128–OHP.	Initial Operating Deficit Escrow Calculation Template.	11	5	55	1.25	69	83	5,729
HUD–92414–OHP.	Latent Defects Escrow	20	12	240	0.50	120	75	9,000
HUD–9443–OHP.	Minor Moveable Escrow	26	2	52	0.92	48	83	3,972
HUD–92476–OHP.	Escrow Agreement Non-critical Deferred Repairs.	20	12	240	0.50	120	75	9,000
HUD–92476A–OHP.	Escrow Agreement Additional Contribution by Sponsors.	1	1	1	0.50	1	217	108
HUD–92476B–OHP.	Escrow Agreement for Operating Deficits.	12	4.8	57.6	0.50	29	75	2,160
HUD–92464–OHP.	Request Approval Advance of Escrow Funds.	35	15	525	1.00	525	75	39,375
HUD–92266–OHP.	Application for Transfer of Physical Assets (TPA).	25	2	50	1.17	58	83	4,861
HUD–93331–OHP.	Asset Management Submission Section 232 Accounts Receivable Checklist.	25	2	50	1.17	58	83	4,861
HUD–93332–OHP.	Certification of Exigent Health & Safety (EH&S) Issues.	456	1	456	0.75	342	75	25,650
HUD–93333–OHP.	Certification Physical Condition in Compliance.	208	1	208	0.50	104	83	8,667

New form number	Form name	Number of respondents	Freq. of resp.	Resp. per annum	Avg. burden per hour per resp.	Annual burden hours	Avg. hourly cost per resp.	Annual cost
HUD–93486–OHP.	Computation of Surplus Cash HUD 93486.	70	1	10	0.25	18	62	1,085
HUD–9250–OHP.	Funds Authorizations, HUD–9250.	500	5.6	2800	1.00	2800	75	210,000
HUD–92114–OHP.	Loan Modification Lender Submission Checklist.	5	3	15	0.58	9	75	656
HUD–92228–OHP.	Model Form Bill of Sale and Assignment.	20	2	40	0.67	27	83	2,222
HUD–92115–OHP.	Mortgagor Certification and Request Detail—Attach 1.	15	2	30	1.00	30	75	2,250
HUD–92116–OHP.	Modified Master Lease Checklist—Asset Management.	15	2	30	1.00	30	75	2,250
HUD–92117–OHP.	Owner's Certification—Completion of Non-Critical Repairs.	250	2	500	0.58	292	75	21,875
HUD–92417–OHP.	Personal Financial and Credit Statement, form HUD–92417.	175	6	1050	3.50	3675	83	306,250
HUD–92118–OHP.	Partial Payment of Claim Model.	15	30	450	2.00	900	75	67,500
HUD–93479–OHP.	Schedule A Monthly Report for Establishing Net Income.	60	2	120	1.17	140	75	10,500
HUD–93480–OHP.	Schedule B Schedule of Disbursements.	60	12	720	1.00	720	75	54,000
HUD–93481–OHP.	Schedule C Schedule of Accounts Payable.	60	12	720	1.00	720	75	54,000
HUD–92119–OHP.	TPA Checklist (Full and Modified, Lessee Operator, Management Agent).	11	5	55	0.58	32	75	2,406
HUD–90020–OHP.	A/R Financing Certification.	50	3	150	0.67	100	217	21,667
HUD–92321–OHP.	Blocked Account Agreement.	35	10	350	2.00	700	200	140,000
HUD–92322–OHP.	Intercreditor Agreement (for AR Financed Projects).	30	5	150	2.00	300	200	60,000
HUD–92323–OHP.	Operator Security Agreement.	30	6.5	195	2.00	390	200	78,000
HUD–92324–OHP.	Rider to Intercreditor Agreement (for AR Financed Projects).	30	5	150	2.00	300	200	60,000
HUD–92211–OHP.	Master Lease Addendum	5	5	25	1.00	25	217	5,417
HUD–92331–OHP.	Subtenants Cross Guaranty.	30	5.83	175	1.00	175	217	37,895
HUD–92333–OHP.	Master Lease SNDA	30	5.83	175	1.00	175	217	37,895
HUD–92334–OHP.	Subordination Agreement—Operating Lease.	30	5.83	175	2.00	350	217	75,790
HUD–92335–OHP.	Master Tenants Attorneys Opinion.	30	5.83	175	1.00	175	217	37,895
HUD–92337–OHP.	Master Tenant Regulatory Agreement.	30	5.83	175	2.00	350	217	75,790

New form number	Form name	Number of respondents	Freq. of resp.	Resp. per annum	Avg. burden per hour per resp.	Annual burden hours	Avg. hourly cost per resp.	Annual cost
HUD–92339–OHP.	Master Lease Estoppel Agreement.	30	5.83	175	0.50	87	217	18,948
HUD–92340–OHP.	Master Tenant Security Agreement.	30	5.83	175	1.00	175	217	37,895
HUD–91117–OHP.	Operator Estoppel Certificate.	100	2	200	0.75	150	275	41,250
HUD–91725–INST–OHP.	Counsels Opinion Instructions.	35	10	350	2.00	700	217	151,667
HUD–91725–CERT–OHP.	Opinion of Borrower's Counsel Certification—Exhibit A.	35	10	350	2.00	700	217	151,667
HUD–91725–OHP.	Guide for Opinion of Borrower's Counsel.	35	10	350	2.00	700	217	151,667
HUD–92325–OHP.	Guide for Opinion of Operator's Counsel and Certification.	30	6.5	195	3.00	585	200	117,000
Totals ...	.....	5115	708	23958	855	51,868	15,252	4,966,799

In accordance with 5 CFR 1320.8(d)(1), HUD is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Interested persons are invited to submit comments regarding the information collection requirements in this proposal. Comments must be received by July 2, 2012. Comments must refer to the proposal by name and docket number (FR–5354–N–01) and must be sent to:

HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503, Fax number: (202) 395–6947, and Colette Pollard, Office of the Chief Information Officer, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4178, Washington, DC 20410.

IV. Solicitation of Public Comments

HUD welcomes public comments from industry and other interested members of the public on this most recent issuance of revised documents, posted at: *www.hud.gov/232forms.*

Dated: April 12, 2012.

Carol J. Galante,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2012–10687 Filed 5–2–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

National Environmental Policy Act: Implementing Procedures; Addition to Categorical Exclusions for Bureau of Indian Affairs (516 DM 10)

AGENCY: Department of the Interior.

ACTION: Notice.

SUMMARY: This notice announces a proposed addition to the categorical exclusions included in the Departmental Manual 516 DM 10. The proposed categorical exclusion pertains to the leasing and funding for single-family homesites on Indian land, including associated improvements and easements, which encompass five acres or less of contiguous land.

DATES: Comments are due by June 4, 2012.

ADDRESSES: Send comments to Marvin Keller, NEPA Coordinator—Indian Affairs, 2051 Mercator Drive, Reston, VA 20191, email: *Marv.Keller@bia.gov.*

FOR FURTHER INFORMATION CONTACT: Marvin Keller, NEPA Coordinator—Indian Affairs, (703) 390–6470.

SUPPLEMENTARY INFORMATION:

Background

The National Environmental Policy Act (NEPA) requires Federal agencies to consider the potential environmental consequences of their decisions before deciding whether and how to proceed. The Council on Environmental Quality encourages Federal agencies to use categorical exclusions to protect the environment more efficiently by; (a) reducing the resources spent analyzing proposals which generally do not have potentially significant environmental impacts, and (b) focusing resources on proposals that may have significant environmental impacts. The appropriate use of categorical exclusions allow the NEPA review to be concluded without preparing either an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) (40 CFR 1500.4(p) and 40 CFR 1508.4).

The need for adequate housing is critical on most Indian reservations. Several hundred actions associated with new home construction are processed each year and this is expected to continue at the same level. The Bureau

of Indian Affairs (BIA) has typically conducted NEPA reviews of actions associated with single-family homes by preparing EAs; the addition of a categorical exclusion to cover these actions will allow for a more efficient NEPA review.

Proposed Categorical Exclusion

The Department of the Interior proposes to add a categorical exclusion to the Departmental Manual at 516 DM 10.5 for approval of leases or funds for single-family homesites, including associated improvements and easements on Indian land. This category includes Federal actions that may include BIA lease approval or funding for a single-family homesite, which would include a residence with one to four dwelling units, as well as other improvements such as a garage, barn or corral. In addition to building construction, associated easements may also need BIA approval on adjacent lands for an access road and utilities, such as gas, electric and fiber optics. The categorical exclusion would be limited to single-family homesites where the total area to be disturbed by construction of homes, associated structures, and related easements must be five acres or less; do not adversely affect any tribal cultural resources or historic properties; and are in compliance with applicable federal and tribal laws. As a final review, each proposed approval of a lease or funding for a single-family homesite must also be reviewed for extraordinary circumstances that would preclude use of this categorical exclusion. The Department's list of extraordinary circumstances under which a normally excluded action would require further analysis and documentation in an EA or EIS is found at 43 CFR 46.215.

Analysis

The intent of this categorical exclusion is to improve the efficiency of a routine environmental review process for approval of new home construction on Indian land. The BIA environmental staff: (1) Reviewed other agencies' NEPA procedures to determine if similar categorical exclusions were in effect; (2) reviewed EAs of homesites previously prepared by BIA to verify that no significant impacts had been identified; and (3) conducted a post-construction reviews of individual homesites to determine if any unanticipated impacts had occurred as a result of house construction.

The BIA reviewed other agencies' NEPA procedures and identified comparable categorical exclusions currently used by the Department of the Army, Indian Health Service, and Rural Development Program. These categorical exclusions are comparable because they are for structures that provide housing or office space; they have a size limitation on the area to be disturbed; they are not restricted to an environmental setting or geographic region of the country; and they are subject to review for extraordinary circumstances.

On Indian reservations across the country, the BIA and tribal environmental staff routinely conduct NEPA analysis of single-family homesites by preparing EAs. These EAs, which have been prepared over the years in a variety of environmental and geographic areas, consistently result in Findings of No Significant Impact (FONSI).

To verify these findings the BIA environmental professionals reviewed 159 EAs completed between 2009 and 2011 that covered 643 individual homesites. These EAs ranged in scope from a single homesite to a programmatic EA covering over 100 scattered homesites. The review confirmed that FONSIs were reached in all cases. The BIA environmental professionals also conducted post-construction reviews on 117 homesites where construction had already occurred. No unanticipated environmental effects were identified in any of these areas, and the conclusions of the original EAs and FONSIs were confirmed. The most typical site specific mitigation measures that limited site selections involved modifying or moving the location of the homesite lease in order avoid cultural resources or historic properties. The analysis conducted by BIA environmental staff concluded that a sufficient administrative record exists to demonstrate the construction of scattered homesites would normally not have a significant impact on the human environment, with the following limitations: The area of disturbance of the home site and any associated facilities must have a five acre limitation; and each homesite must be reviewed for extraordinary circumstances, which not only includes a review for historic properties and other relevant federal and tribal laws, but also the effect to other resources such as wetlands, and endangered species. The review for extraordinary circumstances, which BIA normally conducts for all categorical exclusions, insures that measures would continue to be taken to identify and reduce any significant impacts.

Public Comments

To be considered, any comments on this proposed addition to the list of categorical exclusions in the Departmental Manual must be received by the date listed in the **DATES** section of this notice at the location listed in the **ADDRESSES** section. Comments received after that date will be considered only to the extent practicable. Comments, including names and addresses of respondents, will be part of the public record and available for public review at the BIA address shown in the **ADDRESSES** section, during business hours, 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Text of Proposed Addition to 516 DM 10

10.5 Categorical Exclusions

M. *Other.*

(7) Approval of leases, easements or funds for single-family homesites and associated improvements, including but not limited to homes, outbuildings, access roads, and utility lines, which encompass five (5) acres or less of contiguous land, provided that such sites and associated improvements do not adversely affect any tribal cultural resources or historic properties and are in compliance with applicable federal and tribal laws.

Dated: April 20, 2012.

Willie R. Taylor,

Director, Office of Environmental Policy and Compliance.

[FR Doc. 2012–10696 Filed 5–2–12; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

[Docket No. ONRR–2012–0003]

U.S. Extractive Industries Transparency Initiative Stakeholder Assessment and Multi-Stakeholder Group Options

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior (Interior) has retained an independent facilitator, the Consensus

Building Institute (CBI), to conduct a stakeholder assessment as part of the U.S. Extractive Industries Transparency Initiative (USEITI) implementation process. On May 18, 2012, Interior will receive and publish CBI's findings regarding options for forming a U.S. multi-stakeholder group that will be responsible for determining how USEITI will be implemented. By this notice, Interior is providing the public advance notice of the opportunity to comment between May 18 and June 29, 2012 on CBI's assessment and findings. Comments may be provided in writing or in person at public listening sessions and a public workshop. Details will be provided by **Federal Register** Notice at a later date.

DATES: The public listening sessions, webinar and workshop dates are:

Session 1—Anchorage, Alaska Public Listening Session, May 30, 2012.

Session 2—Public Webinar, June 1, 2012.

Session 3—Pittsburgh, Pennsylvania Public Listening Session, June 11, 2012.

Session 4—New Orleans, Louisiana Public Listening Session, June 12, 2012.

Session 5—Washington, DC Public Workshop, June 22, 2012.

FOR FURTHER INFORMATION CONTACT: Ben Nussdorf, telephone (202) 254–5573, fax number (202) 254–5589, email *benjamin.nussdorf@onrr.gov.*

SUPPLEMENTARY INFORMATION: On February 24th, 2012, Interior published a notice in the **Federal Register** seeking public comment on the formation of a multi-stakeholder group to implement USEITI (74 FR 11151). In that notice, Interior stated that it would hold a series of public listening sessions to provide additional opportunities for public comment. In March, Interior held those listening sessions in St. Louis, Missouri; Denver, Colorado; Houston, Texas; and Washington, DC. CBI analyzed the input from these four public listening sessions, interviews with potential stakeholders, and written comments that were submitted to Interior. This input will form the basis of CBI's independent stakeholder assessment and findings regarding options for establishing the U.S. multi-stakeholder group, which will be responsible for implementing USEITI.

In response to feedback received during the first public comment period, once Interior receives the assessment from CBI on May 18, 2012, it will be published and made available online at *www.doi.gov/EITI.* Alternatively, you may request a copy of the assessment from Ben Nussdorf, whose contact information is listed previously in this notice. We encourage stakeholders and members of the public to participate in the additional public comment period held from May 18–June 29, 2012, to gather feedback on the stakeholder assessment and recommended options for establishing the U.S. multi-stakeholder group. During the May 18–June 29 public comment period, three public listening sessions, a public webinar, and a public workshop will be held as listed previously in this notice. Further details regarding specific times and locations will be provided in advance via **Federal Register** Notice and online at *www.doi.gov/EITI.*

Background: In September 2011, President Barack Obama announced the United States' commitment to participate in the Extractive Industries Transparency Initiative. EITI is a signature initiative of the U.S. National Action Plan for the international Open Government Partnership and offers a voluntary framework for governments and companies to publicly disclose in parallel the revenues paid and received for extraction of oil, gas and minerals owned by the state. The design of each framework is country-specific, and is developed through a multi-year, consensus based process by a multi-stakeholder group comprised of government, industry and civil society representatives. On October 25, President Obama named Secretary of the Interior Ken Salazar as the U.S. Senior Official responsible for implementing USEITI. In response, Secretary Salazar posted a White House blog the same day, committing to work with industry and civil society to implement USEITI. For further information on EITI, please visit the USEITI Web page at *http://www.doi.gov/EITI.*

Dated: April 27, 2012.

Amy Holley,

Acting Assistant Secretary, Policy, Management and Budget.

[FR Doc. 2012–10663 Filed 5–2–12; 8:45 am]

BILLING CODE 4310–T2–P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

Sunshine Act Meeting

F.C.S.C. Meeting and Hearing Notice No. 04–12.

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

Wednesday, May 16, 2012: 2:30 p.m.—Issuance of Proposed Decisions in claims against Libya.

Thursday, May 17, 2012: 9:00 a.m.—Issuance of Proposed Decisions in claims against Libya.

Status: Open.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Judith H. Lock, Executive Officer, Foreign Claims Settlement Commission, 600 E Street NW., Suite 6002, Washington, DC 20579. Telephone: (202) 616–6975.

Jaleh F. Barrett,

Chief Counsel.

[FR Doc. 2012–10748 Filed 5–1–12; 11:15 am]

BILLING CODE 4410–BA–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–029 and 52–030; NRC–2008–0558]

Progress Energy Florida; Final Environmental Impact Statement for Combined Licenses for Levy Nuclear Plant Units 1 and 2

Notice is hereby given that the U.S. Nuclear Regulatory Commission (NRC or the Commission) and the U.S. Army Corps of Engineers, Jacksonville District, as a cooperating agency, have published a final environmental impact statement (EIS), NUREG–1941, ''Environmental Impact Statement for Combined Licenses (COLs) for Levy Nuclear Plant Units 1 and 2.'' The site comprises of approximately 3,105 acres in Levy County, Florida.

On August 13, 2010 (75 FR 49539), the NRC published a notice of availability for the draft EIS. The purpose of this notice is to inform the public that the final EIS is available for public inspection in the NRC's Public Document Room (PDR) located at One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852 or from NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC's Web site at *www.nrc.gov/reading-rm/adams.html.* The ADAMS accession numbers for the final EIS are ML12100A063, ML12100A068, and ML12100A070. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the PDR reference staff by telephone at 1–800–397–4209 and 1–301–415–4737 or by sending an email to

pdr.resource@nrc.gov. The final EIS may also be viewed online at: *http://www.nrc.gov/reactors/new-reactors/col/levy.html.* In addition, the following four public libraries have agreed to make the final EIS available to the public: the Citrus County Coastal Region Library, located at 8619 West Crystal Street, Crystal River, Florida; the Dunnellon Branch Library, located at 20351 Robinson Road, Dunnellon, Florida; the AF Knotts Public Library, located at 11 56th Street, Yankeetown, Florida; and the Bronson Public Library, located at 600 Gilbert Street, Bronson.

FOR FURTHER INFORMATION CONTACT: Mr. Douglas Bruner, Environmental Projects Branch 1, U.S. Nuclear Regulatory Commission, Mail Stop T6C20M, Washington, DC, 20555–0001. Mr. Bruner may be contacted by telephone at 301–415–2730 or via email at *Douglas.Bruner@nrc.gov.*

Dated at Rockville, Maryland, this 26th day of April, 2012.

For The Nuclear Regulatory Commission.

David B. Matthews,

Director, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2012–10695 Filed 5–2–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[[Docket No. 50–133; License DPR–007; NRC–2012–0101]

Exemption of Material for Proposed Disposal Procedures for the Humboldt Bay Power Plant, Unit 3, Eureka, CA

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact.

FOR FURTHER INFORMATION CONTACT: John Hickman, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Mail Stop: T8F5, Washington, DC 20555–00001, telephone: (301) 415–3017, email: *john.hickman@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) staff is considering a request dated June 7, 2011, as supplemented E–Mail dated January 9, 2012, by Pacific Gas and Electric Company (PG&E, the licensee) for alternate disposal of approximately 2,000,000 cubic feet of hazardous waste containing low-activity radioactive debris, at the US Ecology Idaho (USEI) Resource Conservation and Recovery Act (RCRA) Subtitle C hazardous disposal facility located near Grand View, Idaho. This request was made under the alternate disposal provision contained in Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2002, and the exemption provision in 10 CFR 30.11.

This Environmental Assessment (EA) has been developed in accordance with the requirements of 10 CFR 51.21.

II. Environmental Assessment

Identification of Proposed Action

On July 2, 1976, Humboldt Bay Power Plant (HBPP) Unit 3 was shut down for annual refueling and to conduct seismic modifications. In 1983, updated economic analyses indicated that restarting Unit 3 would probably not be cost-effective, and in June 1983, Pacific Gas and Electric Company (PG&E) announced its intention to decommission the unit. On July 16, 1985, the U.S. Nuclear Regulatory Commission (NRC) issued Amendment No. 19 to the HBPP Unit 3 Operating License to change the status to possess-but-not-operate. In December of 2008, the transfer of spent fuel from the fuel storage pool to the dry-cask Independent Spent Fuel Storage Installation was completed, and the decontamination and dismantlement phase of HBPP Unit 3 decommissioning commenced.

PG&E requested NRC authorization for the disposal of waste from the HBPP at the US Ecology Idaho (USEI) facility in accordance with 10 CFR 20.2002. This waste would be generated during the decommissioning of the nuclear Unit 3. This waste consists of approximately 2,000,000 cubic feet (56,634 cubic meters) of hazardous waste, soil, and debris containing low-activity radioactive debris generated during the demolition of structures and remediation activities at Unit 3.

The waste would be transported by truck from HBPP in Eureka, CA to the USEI facility, Grand View, Idaho in the Owyhee Desert. The USEI facility is a Subtitle C RCRA hazardous waste disposal facility permitted by the State of Idaho. The USEI site has both natural and engineered features that limit the transport of radioactive material. The natural features include the low precipitation rate [i.e., 18.4 cm/y (7.4 in. per year)] and the long vertical distance to groundwater (i.e., 61-meter (203-ft) thick on average unsaturated zone below the disposal zone). The engineered features include an engineered cover, liners and leachate monitoring systems. Because the USEI facility is not licensed by the NRC, this proposed action would require the NRC to exempt the low-contaminated material authorized for disposal from further AEA and NRC licensing requirements.

Need for Proposed Action

The subject waste material consists of hazardous waste, soil, and debris containing low-activity radioactive debris generated during the demolition of structures and remediation activities at Unit 3. This proposed alternate disposal would conserve low-level radioactive waste disposal capacity.

Environmental Impacts of the Proposed Action

The NRC staff has reviewed the evaluation performed by the Licensee to demonstrate compliance with the 10 CFR 20.2002 alternate disposal criteria. Under these criteria, a licensee may seek NRC authorization to dispose of licensed material using procedures not otherwise authorized by the NRC's regulations. A licensee's supporting analysis must show that the radiological doses arising from the proposed 10 CFR 20.2002 disposal will be as low as reasonably achievable and within the 10 CFR part 20 dose limits.

PG&E performed a radiological assessment in consultation with USEI. Based on this assessment, PG&E concludes that potential doses to members of the public, including workers involved in the transportation and placement of this waste will be approximately one millirem total effective dose equivalent (TEDE) in one calendar year for this project, and well within the ''few millirem'' criteria that the NRC has established.

The staff evaluated activities and potential doses associated with transportation, waste handling and disposal as part of the review of this 10 CFR 20.2002 application. The projected doses to individual transportation and USEI workers have been appropriately estimated and are demonstrated to meet the NRC's alternate disposal requirement of contributing a dose of not more than ''a few millirem per year'' to any member of the public. Independent review of the post-closure and intruder scenarios confirmed that the maximum projected dose over a period of 1,000 years is also within ''a few millirem per year.'' Additionally, the proposed action will not significantly increase the probability or consequences of accidents and there is no significant increase in occupational or public radiation exposures.

With regard to potential non-radiological impacts, the proposed action does not have a potential to affect any historic sites. The proposed action does not affect non-radiological plant effluents, air quality or noise.

The proposed action and attendant exemption of the material from further AEA and NRC licensing requirements will not significantly increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released off site, and there is no significant increase in occupational or public radiation exposure.

Environmental Impacts of the Alternatives to the Proposed Action

Due to the very small amounts of radioactive material involved, the environmental impacts of the proposed action are small. Therefore, the only alternative the staff considered is the no-action alternative, under which the staff would deny the disposal request. This denial of the request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are therefore similar and the no-action alternative is accordingly not further considered.

Conclusion

The NRC staff has concluded that the proposed action will not significantly impact the quality of the human environment, and that the proposed action is the preferred alternative.

Agencies and Persons Consulted

The NRC provided a draft of this Environmental Assessment to the State of Idaho Department of Environmental Quality for review on February 29, 2012. The State had no comments.

The NRC staff has determined that the proposed action is of a procedural nature, and will not affect listed species or critical habitat. Therefore, no further consultation is required under Section 7 of the Endangered Species Act. The NRC staff has also determined that the proposed action is not the type of activity that has the potential to cause effects on historic properties. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act.

III. Finding of No Significant Impact

The NRC staff has prepared this EA in support of the proposed action. On the basis of this EA, the NRC finds that there are no significant environmental impacts from the proposed action, and that preparation of an environmental impact statement is not warranted. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

IV. Further Information

Documents related to this action, including the application and supporting documentation, are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents related to this action are listed below, along with their ADAMS numbers.

(1) Letter dated June 7, 2011, ''Humboldt Bay Power Plant Unit 3, Request for 10 CFR 20.2002 Alternate Disposal Approval and 10 CFR 30.11 Exemption of Humboldt Bay Power Plant Waste for Disposal at US Ecology Idaho [ADAMS Accession Number ML11160A211].

(2) E–Mail dated January 9, 2012, providing responses to a request for additional information and corrected information for the prior submittal [ADAMS Accession Number ML120330349].

(3) NRC letter dated November 2, 2010, approving prior request from Humboldt Bay for 10 CFR 20.2002 alternate disposal and 10 CFR 30.11 exemption [ADAMS Accession Number ML102870344].

If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr@nrc.gov.* These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

For the U.S. Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 25th day of April, 2012.

Paul Michalak,

Acting Deputy Director, Decommissioning and Uranium Recovery Licensing Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2012–10700 Filed 5–2–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–269, 50–270, and 50–287; NRC–2012–0088]

Duke Energy Carolinas, LLC., Oconee Nuclear Station, Units 1, 2, and 3 Exemption

1.0 Background

Duke Energy Carolinas, LLC (the licensee) is the holder of Renewed Facility Operating Licenses DPR–38, DPR–47, and DPR–55, which authorize operation of the Oconee Nuclear Station, Units 1, 2 and 3 (ONS, Units 1, 2, and 3). The licenses provide, among other things, that the facilities are subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, the Commission) now or hereafter in effect.

The facility consists of three pressurized water reactors located in Oconee County in South Carolina.

2.0 Request/Action

Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, Appendix G, ''Fracture Toughness Requirements,'' requires that fracture toughness requirements for ferritic materials of pressure-retaining components of the reactor coolant pressure boundary of light water nuclear power reactors provide adequate margins of safety during any condition of normal operation, including anticipated operational occurrences and system hydrostatic tests, to which the pressure boundary may be subjected over its service lifetime; and 10 CFR 50.61, ''Fracture Toughness Requirements for Protection Against Pressurized Thermal Shock Events,'' provides fracture toughness requirements for protection against pressurized thermal shock (PTS) events.

By letter dated August 3, 2011 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML11223A010), the licensee requested exemptions from certain requirements of 10 CFR 50.61 and 10 CFR Part 50, Appendix G. The exemptions would allow use of alternate initial RT_{NDT} (reference nil ductility temperature), as described in the NRC-approved topical reports (TRs), BAW–2308, ''Initial RT_{NDT} of Linde 80 Weld Materials,'' Revisions 1–A and 2–A, for determining the adjusted RT_{NDT} of Linde 80 weld materials present in the beltline region of the ONS, Units 1, 2, and 3 reactor vessels (RVs).

The licensee requested an exemption from Appendix G to 10 CFR Part 50 to replace the required use of the existing

Charpy V-notch (C_v) and drop weight-based methodology and allow the use of an alternate methodology to incorporate the use of fracture toughness test data for evaluating the integrity of the ONS, Units 1, 2, and 3 reactor vessel (RV) beltline welds based on the use of the 1997 and 2002 editions of American Society for Testing and Materials (ASTM) Standard Test Method E 1921, ''Standard Test Method for Determination of Reference Temperature T_0, for Ferritic Steels in the Transition Range,'' and American Society of Mechanical Engineers (ASME), *Boiler and Pressure Vessel Code* (Code), Code Case N–629, ''Use of Fracture Toughness Test Data to Establish Reference Temperature for Pressure Retaining Materials of Section III, Division 1, Class 1.'' The exemption is required since Appendix G to 10 CFR Part 50, through reference to Appendix G to Section XI of the ASME Code pursuant to 10 CFR 50.55a, requires the use of a methodology based on C_v and drop weight data.

The licensee also requested an exemption from 10 CFR 50.61(a)(5) to use an alternate methodology to allow the use of fracture toughness test data for evaluating the integrity of the ONS, Units 1, 2, and 3 for RV beltline welds based on the use of the 1997 and 2002, editions of ASTM E 1921, and ASME Code Case N–629. The exemption is required since the methodology for evaluating RV material fracture toughness in 10 CFR 50.61 requires the use of the C_v and drop weight data for establishing the PTS reference temperature (RT_{PTS}).

3.0 Discussion

Pursuant to 10 CFR 50.12(a), the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public health or safety, are consistent with the common defense and security; and (2) when special circumstances are present. These circumstances include the special circumstances that allow the licensee an exemption from the use of the C_v and drop weight-based methodology required by 10 CFR Part 50, Appendix G and 10 CFR 50.61. This exemption only modifies the methodology to be used by the licensee for demonstrating compliance with the requirements of 10 CFR Part 50, Appendix G and 10 CFR 50.61, and does not exempt the licensee from meeting any other requirement of 10 CFR Part 50, Appendix G and 10 CFR 50.61.

Authorized by Law

These exemptions would allow the licensee to use an alternate methodology to make use of fracture toughness test data for evaluating the integrity of the ONS, Units 1, 2, and 3 RV beltline welds, and would not result in changes to operation of the plant. Section 50.60(b) of 10 CFR Part 50 allows the use of alternatives to the described requirements in 10 CFR Part 50, Appendix G, or portions thereof, when an exemption is granted by the Commission under 10 CFR 50.12. In addition, 10 CFR 50.60(b) of 10 CFR Part 50 permits different NRC approved methods for use in determining the initial material properties. As stated above, 10 CFR 50.12(a) allows the NRC to grant exemptions from the requirements of 10 CFR Part 50, Appendix G and 10 CFR 50.61. The NRC staff has determined that granting of the licensee's proposed exemptions will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemptions are authorized by law.

No Undue Risk to Public Health and Safety

The underlying purpose of Appendix G to 10 CFR Part 50 is to set forth fracture toughness requirements for ferritic materials of pressure-retaining components of the reactor coolant pressure boundary of light water nuclear power reactors to provide adequate margins of safety during any condition of normal operation, including anticipated operational occurrences and system hydrostatic tests, to which the pressure boundary may be subjected over its service lifetime. The methodology underlying the requirements of Appendix G to 10 CFR Part 50 is based on the use of C_v and drop weight data. The licensee proposes to replace the use of the existing C_v and drop weight-based methodology by a fracture toughness-based methodology to demonstrate compliance with Appendix G to 10 CFR Part 50. The NRC staff has concluded that the exemptions are justified based on the licensee utilizing the fracture toughness methodology specified in BAW–2308, Revisions 1–A [1] and 2–A, which include the conditions and limitations delineated in the NRC staff's safety evaluations (SEs), dated August 4, 2005 (ADAMS Accession No. ML052070408), and March 24, 2008 (ADAMS Accession No. ML080770349). The use of the methodology specified in the NRC staff's SEs will ensure that pressure-temperature limits developed for the ONS, Units 1, 2, and 3 RVs will continue to be based on an adequately conservative estimate of RV material properties and ensure that the pressure-retaining components of the reactor coolant pressure boundary retain adequate margins of safety during any condition of normal operation, including anticipated operational occurrences and system hydrostatic tests. This exemption only modifies the methodology to be used by the licensee for demonstrating compliance with the requirements of Appendix G to 10 CFR Part 50, and does not exempt the licensee from meeting any other requirement of Appendix G to 10 CFR Part 50.

The underlying purpose of 10 CFR 50.61 is to establish requirements for evaluating the fracture toughness of RV materials to ensure that a licensee's RV will be protected from failure during a PTS event. The licensee seeks an exemption from 10 CFR 50.61 to use a methodology for the determination of adjusted/indexing reference temperatures. The licensee proposes to use ASME Code Case N–629 and the methodology outlined in its submittal, which are based on the use of fracture toughness data, as an alternative to the C_v and drop weight-based methodology required by 10 CFR 50.61 for establishing the initial, unirradiated properties when calculating RT_{PTS} values. The NRC staff has concluded that the exemption is justified based on the licensee utilizing the methodology specified in TRs BAW–2308, Revisions 1–A and 2–A. These TRs established an alternative method for determining initial (unirradiated) material reference temperatures for RV welds manufactured using Linde 80 weld flux (i.e., ''Linde 80 welds'') and established weld wire heat-specific and Linde 80 weld generic values of this reference temperature. These weld wire heat-specific and Linde 80 weld generic values may be used in lieu of the RT_{NDT} determined as specified by paragraph NB–2331 of Section III of the ASME Code. Regulations associated with the determination of RV material properties involving protection of the RV from brittle failure or ductile rupture includes Appendix G to 10 CFR Part 50 and 10 CFR 50.61, the PTS rule. These regulations require that the initial (unirradiated) material reference temperature, RT_{NDT}, be determined in accordance with the provisions of the ASME Code, and provide the process for

[1] **Note,** a revision number including a ''-A'' denotes an NRC-staff approved version of the TR which includes the NRC staff's final safety evaluation.

determination of RT_{PTS}, the reference temperature RT_{NDT}, evaluated for the end of license fluence.

In TR BAW–2308, Revision 1, the Babcock and Wilcox Owners Group (B&WOG) proposed to perform fracture toughness testing based on the application of the Master Curve evaluation procedure, which permits data obtained from sample sets tested at different temperatures to be combined, as the basis for redefining the initial (unirradiated) material properties of Linde 80 welds. NRC staff evaluated this methodology for determining Linde 80 weld initial (unirradiated) material properties and uncertainty in those properties, as well as the overall method for combining unirradiated material property measurements based on T_o values (i.e., IRT_{To}), with property shifts from models in Regulatory Guide (RG) 1.99, Revision 2, ''Radiation Embrittlement of Reactor Vessel Materials,'' which are based on C_v testing and a defined margin term to account for uncertainties in the NRC staff SE. Table 3 in the NRC staff's August 4, 2005 SE of BAW–2308, Revision 1, contains the NRC staff-accepted IRT_{TO} and initial margin (denoted as σ_i) for specific Linde 80 weld wire heat numbers. In accordance with the conditions and limitations outlined in the NRC staff's August 4, 2005 SE of TR BAW–2308, Revision 1, for utilizing the values in Table 3: the licensee's proposed methodology has (1) utilized the appropriate NRC staff-accepted IRT_{To} and σ_i values for Linde 80 weld wire heat numbers; (2) applied chemistry factors greater than 167 °F (the weld wire heat-specific chemical composition, via the methodology of RG 1.99, Revision 2, indicated that higher chemistry factors are applicable); (3) applied a value of 28 °F for $\sigma\Delta$ in the margin term; and (4) submitted values for ΔRT_{NDT} and the margin term for each Linde 80 weld in the RV through the end of the current operating license. Additionally, the NRC's SE for TR BAW–2308, Revision 2 concludes that the revised IRT_{T0} and σ_i values for Linde 80 weld materials are acceptable for referencing in plant-specific licensing applications as delineated in TR BAW–2308, Revision 2 and to the extent specified under Section 4.0, Limitations and Conditions, of the SE., which states: ''Future plant-specific applications for RPVs [reactor pressure vessels] containing weld heat 72105, and weld heat 299L44, of Linde 80 welds must use the revised IRT_{To} and σ_i, values in TR BAW–2308, Revision 2.'' The NRC staff notes that heat 299L44 is used in one ONS 1 RV beltline weld and one ONS 2 RV beltline weld and heat. The NRC staff also notes heat 72105 is used in an ONS 3 beltline weld. The NRC staff verified that the revised IRT_{T0} and σ_i values from TR BAW–2308, Revision 2 were used for these three welds. The licensee also used the revised IRT_{To} and σ_i, values in TR BAW–2308, Revision 2 for the other weld heats. Although the revised IRT_{To} values for the weld heats other than 72105 and 299L44 are lower than the values given in the NRC staff's SE of BAW–2308, Revision 1, these values are acceptable because the NRC staff determined in its SE for BAW–2308, Revision 2, that the modified methodology used to calculate these values is acceptable, and more accurate than the methodology used to generate the values given in the NRC staff's SE of BAW–2308, Revision 1. Therefore, all conditions and limitations outlined in the NRC staff SEs for TRs BAW–2308, Revisions 1 and 2, have been met for ONS, Units 1, 2, and 3.

The use of the methodology in TRs BAW–2308, Revisions 1–A and 2–A, will ensure the PTS evaluation developed for the ONS, Units 1, 2, and 3 RVs will continue to be based on an adequately conservative estimate of RV material properties, and ensure the RV will be protected from failure during a PTS event. Also, when additional fracture toughness data relevant to the evaluation of the ONS, Units 1, 2, and 3 RV welds is acquired as part of the surveillance program, these data must be incorporated into the evaluation of the ONS, Units 1, 2, and 3 RV fracture toughness requirements.

Based on the above, no new accident precursors are created by allowing an exemption to use an alternate methodology to comply with the requirements of 10 CFR 50.61 in determining adjusted/indexing reference temperatures, thus, the probability of postulated accidents is not increased. Also, based on the above, the consequences of postulated accidents are not increased. Therefore, there is no undue risk to public health and safety. On February 3, 2010, a new rule, 10 CFR 50.61a, ''Alternate Fracture Toughness Requirements for Protection Against [PTS] Events,'' became effective. The NRC staff reviewed this new rule against the licensee's exemption request and determined that there is no effect on the exemption request. The new rule does not modify the requirements from which the licensee has sought an exemption, and the alternative provided by the new rule does not address the scope of issues associated with both 10 CFR 50.61 and 10 CFR Part 50, Appendix G that the requested exemption does.

Consistent With Common Defense and Security

The proposed exemption would allow the licensee to use an alternate methodology to allow the use of fracture toughness test data for evaluating the integrity of the ONS, Units 1, 2, and 3 RV beltline welds. This change has no relation to security issues. Therefore, the common defense and security is not impacted by these exemptions.

Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR Part 50, Appendix G and 10 CFR 50.61 is to protect the integrity of the reactor coolant pressure boundary by ensuring that each reactor vessel material has adequate fracture toughness. Therefore, since the underlying purpose of 10 CFR Part 50, Appendix G and 10 CFR 50.61 is achieved by an alternative methodology for evaluating RV material fracture toughness, the special circumstances required by 10 CFR 50(a)(2)(ii) for the granting of an exemption from portions of the requirements of 10 CFR Part 50, Appendix G and 10 CFR 50.61 exist.

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants Duke Energy Carolinas, LLC an exemption from certain requirements of Appendix G to 10 CFR Part 50 and 10 CFR 50.61, to allow an alternative methodology to incorporate the use of fracture toughness test data for evaluating the integrity of the ONS, Units 1, 2, and 3 reactor vessel (RV) beltline welds that is based on using fracture toughness test data to determine initial, unirradiated properties.

Pursuant to 10 CFR 51.32, ''Finding of no significant impact,'' the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment 77 FR 21594.

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 25th day of April 2012.

For The Nuclear Regulatory Commission.

Michele G. Evans,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2012–10698 Filed 5–2–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–288; NRC–2011–0172]

Reed College, Reed Research Nuclear Reactor, Renewed Facility Operating License No. R–112

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance.

ADDRESSES: Please refer to Docket ID NRC–2011–0172 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly-available, using the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2011–0172. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly-available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For details with respect to the application for renewal, see the licensee's letter dated August 29, 2007 as supplemented by letters dated January 26, July 30, October 15, 2010, and May 20, August 3, December 12, 2011, and January 27, and March 26, 2012, is available electronically under ADAMS Accession Nos. ML092310567, ML100610121, ML102360016, ML102990489, ML111520559, ML11222A026, ML113630145, ML12039A147 and ML12100A075. Also see the license's annual reports for years 2003–2004 (ADAMS Accession No. ML043620310), 2004–2005 (ADAMS Accession No. ML052930194), 2005–2006 (ADAMS Accession No. ML062850518), 2006–2007 (ADAMS Accession No. ML073040191), 2007–2008 (ADAMS Accession No. ML082890533), 2008–2009 (ADAMS Accession No. ML092720865), 2009–2010 (ADAMS Accession No. ML102440042), and 2010–2011 (ADAMS Accession No. ML11221A161).

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Geoffrey Wertz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Rockville, MD 20852. Telephone: (301) 415–0893; fax number: (301) 415–3031; email: *Geoffrey.Wertz@nrc.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Nuclear Regulatory Commission (NRC or the Commission) has issued renewed Facility Operating License No. R–112, held by Reed College (the licensee), which authorizes continued operation of the Reed Research Reactor (RRR), located in Portland, Oregon. The RRR is a pool-type, natural convection, light-water cooled, and shielded TRIGA (Training, Research, Isotope Production, General Atomics) reactor fuel. The RRR is licensed to operate at a steady-state power level of 250 kilowatts thermal power. The renewed Facility Operating License No. R–112 will expire 20 years from its date of issuance.

The renewed facility operating license complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's regulations in Title 10, Chapter 1, ''Nuclear Regulatory Commission,'' of the *Code of Federal Regulations* (10 CFR), and sets forth those findings in the renewed facility operating license. The agency afforded an opportunity for hearing in the Notice of Opportunity for Hearing published in the **Federal Register** on August 19, 2011 (76 FR 52018–52022). The NRC received no request for a hearing or petition for leave to intervene following the notice.

The NRC staff prepared a safety evaluation report for the renewal of Facility Operating License No. R–112 and concluded, based on that evaluation, the licensee can continue to operate the facility without endangering the health and safety of the public. The NRC staff also prepared an Environmental Assessment and Finding of No Significant Impact for the renewal of the facility operating license, noticed in the **Federal Register** on March 30, 2012 (77 FR 19362–19366), and concluded that renewal of the facility operating license will not have a significant impact on the quality of the human environment.

Dated at Rockville, Maryland, this 25th day of April, 2012.

For the Nuclear Regulatory Commission.

Jessie F. Quichocho,

Chief, Research and Test Reactors Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2012–10705 Filed 5–2–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–338 and 50–339; NRC–2012–0051; License Nos. NPF–4 and NPF–7]

Virginia Electric and Power Company

AGENCY: Nuclear Regulatory Commission.

ACTION: Director's Decision; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is giving notice that the Director of the Office of Nuclear Reactor Regulation (NRR) has issued a Director's Decision with regard to a petition dated September 8, 2011, filed by Mr. Thomas Saporito, hereinafter referred to as the ''petitioner.''

ADDRESSES: Please refer to Docket ID NRC–2012–0051 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, using the following methods:

• *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0051. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.

• *NRC's PDR:* You may examine and purchase copies of public documents at

the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

SUPPLEMENTARY INFORMATION:

Notice is hereby given that the Director, NRR, has issued a Director's Decision with regard to a petition dated September 8, 2011 (ADAMS Accession No. ML11256A019), filed by Mr. Thomas Saporito. The petition was supplemented on September 8, 2011 (ADAMS Accession No. ML11334A152), September 29, 2011 (ADAMS Accession No. ML11332A046), October 21, 2011 (ADAMS Accession No. ML11308A016), and November 7, 2011 (ADAMS Accession No. ML113530035). The petition concerns the operation of the North Anna Power Station, Units 1 and 2 (North Anna 1 and 2), by the Virginia Electric and Power Company (VEPCO or the licensee). The petition requested that the NRC:

(1) Take escalated enforcement action against the licensee and suspend, or revoke, the operating licenses for North Anna 1 and 2;

(2) Issue a notice of violation against the licensee with a proposed civil penalty in the amount of 1 million dollars; and

(3) Issue an order to the licensee requiring the licensee to keep North Anna 1 and 2, in a ''cold shutdown'' mode of operation until such time as a series of actions described in the petition are completed.

As the basis for this request, the petitioner states in summary that:

(1) On August 23, 2011, North Anna 1 and 2, automatically tripped offline as a direct result of ground motion caused by an earthquake centered in Mineral, Virginia, approximately 10 miles from North Anna 1 and 2. The licensee has not determined the root cause of this event, nor has it explained why the reactor tripped on ''negative flux rate'' rather than on loss of offsite power.

(2) Subsequent to the earthquake, the licensee initiated various inspection activities and tests to discover the extent of damage to the nuclear facility, but these inspection and testing activities continue and remain incomplete and non-validated.

(3) The licensee had set an overly aggressive schedule for restarting North Anna 1 and 2, that was based on economic considerations rather than safety.

(4) The licensee needs to amend its licensing documents, including its licenses and the updated final safety analysis report. As a result, of ground motion experienced at, and damage sustained to, North Anna 1 and 2, due to the earthquake of August 23, 2011, which is greater than the licensee's design and safety bases, North Anna 1 and 2, are in an unanalyzed condition and current licensing documents are erroneous and incomplete. As a result, the licensee cannot rely on them to provide reasonable assurance to the NRC that these nuclear reactors can be operated in a safe and reliable manner to protect public health and safety.

(5) The licensee needs to conduct new seismic and geological evaluations of the North Anna 1 and 2, site that are independent. These evaluations should ascertain the degree and magnitude of future earthquake events and address a ''worst case'' earthquake.

(6) There are numerous issues with the seismic instrumentation at North Anna 1 and 2, including lack of free field instrumentation, issues associated with conversion of analog data to digital data, issues with lack of on-site personnel with sufficient training in seismic measurements, and potential skewing of ground motion data due to the location of the ''scratch plates.''

(7) Retrofitting of North Anna 1 and 2, is required due to damage to North Anna 1 and 2, from the earthquake of August 23, 2011.

(8) There are concerns with the impact of the August 23, 2011, earthquake on the North Anna 1 and 2, Independent Spent Fuel Storage Installation (ISFSI) including the fact that 25 casks weighing over 115 tons were not supposed to shift as much as 4.5 inches during an earthquake, validation of the integrity of the seals inside the spent fuel casks, assessing whether spent nuclear fuel storage facilities could topple or otherwise sustain significant damage resulting in a release, and assessing whether the licensee's emergency plans adequately addressed damage to the ISFSI as a result of a severe earthquake.

(9) The petitioner is concerned that the licensee cannot be trusted to communicate reliable information to the public or the regulator based on the fact that the licensee in the 1970s failed to promptly disclose the discovery of geological information and was subjected to a monetary fine for the violation.

On September 29, 2011, and November 7, 2011, the petitioner and the licensee met with the NRC staff's petition review board via telephone conference (meeting transcripts at ADAMS Accession Nos. ML11332A046 and ML113530035) regarding the petition. These meetings gave the petitioner and the licensee an opportunity to provide additional information and to clarify issues raised in the petition.

The NRC sent a copy of the proposed Director's Decision to the petitioner and the licensee for comment by letter dated February 22, 2012 (ADAMS Accession No. ML11356A164), and February 28, 2012 (ADAMS Accession No. ML11357A117), respectively. The licensee provided comments by letter dated March 12, 2012 (ADAMS Accession No. ML120720519). The comments and the NRC staff's response to them are included in the Director's Decision, the complete text of which is available in ADAMS under Accession No. ML12094A250.

The NRC staff has evaluated the petitioner's requests to: (1) Take escalated enforcement action against the licensee and suspend, or revoke, the operating licenses for North Anna 1 and 2, and (2) issue a notice of violation against the licensee with a proposed civil penalty in the amount of 1 million dollars. With respect to these two requests, the evaluations of two NRC inspection teams as documented in inspection reports dated October 31, 2011 (ADAMS Accession No. ML113040031), and November 30, 2011 (ADAMS Accession No. ML113340345), did not find any violation of NRC regulations that would merit such enforcement actions. Further detail regarding this decision on these two requests is provided in the Director's Decision. With respect to the petition's third request for enforcement action: ''to issue an order to the licensee requiring the licensee to keep North Anna 1 and 2, in a ''cold shutdown'' mode of operation until such time as a series of actions described in the petition are completed,'' the NRC staff concluded that it had partially granted that request in Confirmatory Action Letter (CAL) No. 2–2011–001 dated September 30, 2011 (ADAMS Accession No. ML11273A078), which stated the following:

> This Confirmatory Action Letter (CAL) confirms that NAPS [North Anna Power Station] Units 1 and 2 will not enter Modes 1–4 (as defined in the technical specifications), until the Commission has completed its review of your information, performed confirmatory inspections, and completed its safety evaluation review. The permission to resume operations will be formally communicated to Virginia Electric and Power Company (VEPCO) in a written correspondence.
>
> VEPCO shall submit to the NRC all documentation requested by the NRC as being necessary to demonstrate that NAPS Units 1 and 2 can be operated safely following the seismic event that exceeded the safe shutdown event analyzed in the current revision of the Updated Final Safety Analysis Report.
>
> This CAL will remain in effect until the NRC has (1) reviewed your information,

including responses to staff's questions and the results of your evaluations, and (2) the staff communicates to you in written correspondence that it has concluded that NAPS can be operated without undue risk to the health and safety of the public or the environment.''

This CAL, therefore, confirmed the licensee's understanding that North Anna 1 and 2, could not be restarted unless and until the licensee had demonstrated to the NRC staff's satisfaction that ''* * * no functional damage has occurred to those features necessary for continued operation without undue risk to the health and safety of the public,'' consistent with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR), Part 100, Appendix A, Section V(a)(2). Restart was contingent upon addressing a number of issues before startup, many of which had been identified, in whole or in part, in the petition as concerns.

Issues in the petition, previously identified and discussed as concerns 1, 2, 3, 5, 6, 7, and 8, were discussed and substantially addressed, either in the inspection reports issued October 31, 2011, and November 30, 2011, or in the NRC technical evaluation dated November 11, 2011. The activities by the NRC staff were completed before restart to ensure that, before resuming operations, the licensee had demonstrated no functional damage had occurred to those features at North Anna 1 and 2, necessary for continued operation without undue risk to the health and safety of the public. In that respect, these concerns described in the petition as requiring completion before the restart of North Anna 1 and 2, were addressed before restart, consistent with the third request for enforcement action described in the petition. Issues in the petition, previously identified and discussed as concerns 4 and 9, were evaluated by the NRC staff before restart of North Anna 1 and 2, but disposition of these concerns by the NRC staff differed from the course of action requested in the petition. In that respect, these aspects of the petition were denied.

A copy of the Director's Decision will be filed with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206 of the Commission's regulations. As provided for by this regulation, the Director's Decision will constitute the final action of the Commission 25 days after the date of the decision, unless the Commission, on its own motion, institutes a review of the Director's Decision in that time.

Dated at Rockville, Maryland, this 27th day of April 2012.

For the Nuclear Regulatory Commission.

Bruce A. Boger,

Deputy Director, Reactor Safety Programs, Office of Nuclear Reactor Regulation.

[FR Doc. 2012–10707 Filed 5–2–12; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Board of Governors Sunshine Act Meeting

Board Votes to Close April 25, 2012, Meeting

By telephone vote on April 25, 2012, members of the Board of Governors of the United States Postal Service met and voted unanimously to close to public observation its meeting held in Washington, DC, via teleconference. The Board determined that no earlier public notice was possible.

ITEMS CONSIDERED:

1. Strategic Issues.

GENERAL COUNSEL CERTIFICATION: The General Counsel of the United States Postal Service has certified that the meeting was properly closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION: Requests for information about the meeting should be addressed to the Secretary of the Board, Julie S. Moore, at (202) 268–4800.

Julie S. Moore,

Secretary.

[FR Doc. 2012–10852 Filed 5–1–12; 4:15 pm]

BILLING CODE 7710–12–P

POSTAL SERVICE

Board of Governors; Sunshine Act Meeting

Board Votes to Close April 26, 2012, Meeting

By telephone vote on April 26, 2012, members of the Board of Governors of the United States Postal Service met and voted unanimously to close to public observation its meeting held in Washington, DC, via teleconference. The Board determined that no earlier public notice was possible.

ITEMS CONSIDERED:

1. Strategic Issues.
2. Financial Matters.

GENERAL COUNSEL CERTIFICATION: The General Counsel of the United States Postal Service has certified that the meeting was properly closed under the Government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION: Requests for information about the meeting should be addressed to the Secretary of the Board, Julie S. Moore, at (202) 268–4800.

Julie S. Moore,

Secretary.

[FR Doc. 2012–10854 Filed 5–1–12; 4:15 pm]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66871; File No.10–206]

In the Matter of the Application of BOX Options Exchange LLC for Registration as a National Securities Exchange Findings, Opinion, and Order of the Commission

April 27, 2012.

I. Introduction

On December 19, 2011, BOX Options Exchange LLC (''BOX Exchange'' or ''Exchange'') submitted to the Securities and Exchange Commission (''Commission'') an Application for Registration as a National Securities Exchange (''Form 1 Application'') [1] under Section 6 of the Securities Exchange Act of 1934 (''Act'').[2] On December 28, 2011, BOX Exchange submitted Amendment No. 1 to its Form 1 Application.[3] Notice of the Form 1 Application, as modified by Amendment No. 1, was published for comment in the **Federal Register** on January 31, 2012.[4] The Commission has not received any comment letters regarding the Form 1 Application. On April 2, 2012, BOX Exchange submitted Amendment No. 2 to the Form 1 Application.[5]

[1] On January 26, 2012, the Commission issued an order granting BOX Exchange exemptive relief, subject to certain conditions, in connection with the filing of its Form 1 Application. *See* Securities Exchange Act Release No. 66241, 77 FR 4845 (January 31, 2012). Because BOX Exchange's Form 1 Application was incomplete without the exemptive relief, the date of filing of such application is January 26, 2012.

[2] 15 U.S.C. 78f.

[3] Amendment No. 1, among other things, provides the unconsolidated financial statements for certain affiliates of BOX Exchange that are required in Exhibit D to Form 1 but were not included in BOX Exchange's initial Form 1 Application. In its initial Form 1 Application, BOX Exchange only submitted consolidated financials for certain of these affiliates.

[4] *See* Securities Exchange Act Release No. 66242 (January 26, 2012), 77 FR 4841 (''Notice'').

[5] In Amendment No. 2, BOX Exchange, among other things: (1) Amends the BOX Exchange Bylaws to provide: (a) That at least one public, non-industry director of BOX Exchange will not be associated with a broker or dealer, as required by Section 6(b)(3) of the Act; (b) that BOX Exchange will have a chief regulatory officer (''CRO'') with general day-to-day supervision over BOX Exchange's regulatory operations; (c) that a majority of the members of the BOX Exchange nominating

Continued

BOX Options Exchange Group, LLC (''BOX Group LLC'') currently operates the Boston Options Exchange options trading platform (''BOX'') as a facility of Nasdaq OMX BX, Inc. (''BX''). In January 2004, the Boston Stock Exchange, Inc. (''BSE'') (n/k/a BX) established BOX as its options trading facility.[6] BOX Group LLC was formed to operate BOX. Bourse de Montréal Inc. (''Bourse''), BSE, and Interactive Brokers Group LLC (''IB'') each held more than a 20% interest in BOX Group LLC, and none of the remaining owners of BOX Group LLC held more than a 5% interest.[7] Subsequently, the Bourse transferred its 31.37% ownership interest in BOX Group LLC to Bourse's wholly-owned subsidiary, MX US 2, Inc. (''MX US 2'').[8] As a result of a merger in 2008 involving Bourse and a subsidiary of TSX Group, Inc., a company incorporated in Ontario, Canada (n/k/a TMX Group, Inc.), MX US 2 became an indirect wholly-owned subsidiary of TMX Group, Inc. (''TMX'').

In August 2008, The Nasdaq OMX Group, Inc. (''Nasdaq'') acquired BSE but did not acquire any interest in BOX Group LLC. As part of that acquisition, BSE transferred its ownership interest in BOX Group LLC to MX US 2.[9] MX US 2 thereafter held over 50% ownership interest in BOX Group LLC.[10] Although BX (f/k/a BSE) no longer holds an ownership interest in BOX Group LLC, BOX continues to be a facility of BX, and, as such, BX is responsible for regulating this facility and ensuring that it operates in compliance with the federal securities laws.[11]

BOX Exchange has filed to register as a national securities exchange pursuant to the Form 1 Application that is the subject of this Order. As a registered national securities exchange, BOX Exchange will be a self-regulatory organization (''SRO'') under the Act.[12] BOX Exchange will be responsible for the operation and oversight of BOX as its facility [13] following commencement of operations of BOX Exchange as a national securities exchange. In contemplation of this registration, the owners of BOX Group LLC formed the following three entities: BOX Exchange; BOX Market LLC (''BOX Market''); and BOX Holdings Group LLC (''BOX Holdings''). As noted above, BOX Exchange will be the registered national securities exchange and SRO. BOX Market will be the successor-in-interest to the current BOX Group LLC and will own and operate BOX as a facility of BOX Exchange. BOX Holdings will be the sole owner of BOX Market.

II. Discussion

Under Sections 6(b) and 19(a) of the Act,[14] the Commission shall by order grant an application for registration as a national securities exchange if the Commission finds, among other things, that the proposed exchange is so organized and has the capacity to carry out the purposes of the Act and can comply, and can enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of the exchange.

As discussed in greater detail below, the Commission finds that BOX Exchange's application for exchange registration meets the requirements of the Act and the rules and regulations thereunder. Further, the Commission finds that the proposed rules of BOX Exchange are consistent with Section 6 of the Act in that, among other things, they are designed to: (1) Assure fair representation of the exchange's members in the selection of its directors and administration of its affairs and provide that, among other things, one or more directors shall be representative of investors and not be associated with the exchange, or with a broker or dealer; [15] (2) prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, and remove impediments to and perfect the mechanisms of a free and open market and a national market system; [16] (3) not permit unfair discrimination between customers, issuers, or dealers; [17] and (4) protect investors and the public interest.[18] Finally, the Commission finds that the proposed rules of BOX Exchange do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[19]

A. Governance of BOX Exchange

1. BOX Exchange Board of Directors

The BOX Exchange Board will be the governing body of the Exchange and will possess all of the powers necessary for the management of the property, business and affairs of BOX Exchange and the governing of BOX Exchange as a SRO. The BOX Exchange Board will initially be comprised of five directors, and must have at least five, but no more than eleven, directors.[20] Under the BOX Exchange Bylaws, the BOX Exchange Board will be required to include:

- A majority non-industry directors; [21]
- At least one public director; [22] and

committee will be non-industry representatives; (d) that the CRO will report to the regulatory oversight committee and to the President of BOX Exchange; (e) that the compensation committee of BOX Exchange will set, among other things, the CRO's compensation, taking into consideration any recommendations made by the President of BOX Exchange; and (f) that the regulatory oversight committee will make hiring and termination decisions with respect to the CRO, taking into consideration any recommendations made by the President of BOX Exchange; (2) represents that the regulatory oversight committee will meet regularly with the CRO to review regulatory matters; (3) represents that the only individual entitled to observation rights on the BOX Exchange Board to attend board or committee meetings if the BOX Holdings Director is unable to attend is the person appointed by the BOX Holdings Director (as defined below); (4) provides further information regarding BOX Exchange's regulatory services agreement (''RSA'') with the Financial Industry Regulatory Authority (''FINRA''); (5) states the names of the initial BOX Exchange Board and describes the process for selecting such initial board; (6) updates Exhibit I to the Form 1 Application; and (7) updates the ownership schedule of BOX Exchange in Schedule 1 to the BOX Exchange LLC Agreement.

[6] *See* Securities Exchange Act Release No. 49068 (January 13, 2004), 69 FR 2775 (January 20, 2004) (establishing, among other things, BOX as an options trading facility of BSE).

[7] *See* Securities Exchange Act Release No. 49067 (January 13, 2004), 69 FR 2761 (January 20, 2004) (approving the operating agreement of BOX Group LLC).

[8] *See* Securities Exchange Act Release No. 57713 (April 25, 2008), 73 FR 24327 (May 2, 2008).

[9] *See* Securities Exchange Act Release No. 58324 (August 7, 2008), 73 FR 46936 (August 12, 2008) (approving, among other things, the acquisition of BSE by Nasdaq and the transfer of BSE's ownership interest in Boston Group LLC to MX US 2).

[10] *See id.*

[11] BX regulates BOX through its wholly-owned regulatory subsidiary, the Boston Options Exchange Regulation, LLC (''BOXR'').

[12] *See* 15 U.S.C. 78c(a)(26) (defining a ''self-regulatory organization'' to include a national securities exchange).

[13] *See* 15 U.S.C. 78c(a)(2) (defining ''facility'').

[14] 15 U.S.C. 78f(b) and 15 U.S.C. 78s(a), respectively.

[15] *See* 15 U.S.C. 78f(b)(3).

[16] *See* 15 U.S.C. 78f(b)(5).

[17] *See id.*

[18] *See id.*

[19] *See* 15 U.S.C. 78f(b)(8).

[20] *See* BOX Exchange Bylaws Section 4.02.

[21] *See* BOX Exchange Bylaws Section 1.01(q). A non-industry director is defined as a person who is a public director or is not an industry representative. An industry representative is an individual who is an officer, director or employee of a broker or dealer or who has been employed in any such capacity at any time within the prior three years, as well as an individual who has, or has had, a consulting or employment relationship with BOX Exchange or any affiliate of BOX Exchange, within the prior three years. *See* BOX Exchange Bylaws Section 1.01(m). Because BOX Market is an affiliate of BOX Exchange, anyone affiliated with BOX Market will not be considered a non-industry director. This definition generally is consistent with that approved with regard to other exchanges. *See e.g.,* Securities Exchange Act Release Nos. 61698 (March 12, 2010), 75 FR 13151 (March 18, 2010) (''DirectEdge Exchanges Order'') and 58375 (August 18, 2008), 73 FR 49498 (August 21, 2008) (''BATS Order'').

[22] *See* BOX Exchange Bylaws Section 1.01(v). Public Director means a person who has no material

• One director appointed by BOX Holdings (''BOX Holdings Director''), who will be an officer or director of BOX Holdings, MX US 2, or an affiliate of MX US 2.[23]

In addition, at least 20% of the BOX Exchange Board must be officers, directors, or employees of a firm that is a BOX Options Participant (each a ''Participant Director'').[24]

Prior to the commencement of operations as an exchange, BOX Exchange will submit the name of its nominee for the Participant Director[25] to all current BOX Options Participants. BOX Options Participants will thereafter be allowed the same periods for submitting the names of alternative candidates and to vote (14 days and 5 days, respectively) that are provided in the BOX Exchange Bylaws.[26] All other interim directors except for the Participant Director will be appointed and elected by the owners of BOX Group LLC, which persons will be the owners of BOX Exchange, and must meet the BOX Exchange board composition requirements as set forth in the BOX Exchange Bylaws.[27] This interim board will serve until BOX Exchange elects a new Board pursuant to the full nomination, petition, and voting process set forth in the BOX Exchange Bylaws.[28] BOX Exchange will complete such election within 90 days after BOX Exchange's application for registration as a national securities exchange is granted.[29]

BOX Exchange owners will elect those candidates nominated by the nominating committee as BOX Exchange Board directors subsequent to the initial Board election process set forth above.[30] The owners of BOX Exchange that together hold a majority of voting percentage interest in BOX Exchange will have the right to object to any director nominee, but only if the nominee had been disciplined by a securities regulatory authority or the nominee would be subject to statutory disqualification under the Act.[31] If there is no objection to the proposed director nominees, then they would take office at the annual meeting.[32]

The Commission believes that the requirement in the BOX Exchange Bylaws that 20% of the directors be Participant Directors and the means by which they will be chosen by BOX Options Participants provide for the fair representation of members in the selection of directors and the administration of BOX Exchange and is consistent with the requirement in Section 6(b)(3) of the Act.[33] As the Commission has previously noted, this requirement helps to ensure that members have a voice in the use of self-regulatory authority, and that an exchange is administered in a way that is equitable to all those who trade on its market or through its facilities.[34]

The Commission has previously stated that the inclusion of public, non-industry representatives on exchange oversight bodies is critical to an exchange's ability to protect the public interest.[35] Further, public, non-industry representatives can help to ensure that no single group of market participants has the ability to systematically disadvantage other market participants through the exchange governance process. The Commission believes that public directors can provide unique, unbiased perspectives, which are designed to enhance the ability of the BOX Exchange Board to address issues in a non-discriminatory fashion and foster the integrity of BOX Exchange.[36] The Commission believes that the composition of the BOX Exchange Board satisfies the requirements in Section 6(b)(3) of the Act,[37] which requires in part that one or more directors be representative of issuers and investors and not be associated with a member of the exchange, or with a broker or dealer.[38]

The Commission believes that the process for electing the initial interim board, as proposed, is consistent with the requirements of the Act, including that the rules of the exchange assure fair representation of the exchange's members in the selection of its directors and administration of its affairs.[39] The initial members of BOX Exchange will likely consist substantially of the current BOX Options Participants.[40] As noted, prior to the commencement of operations as an exchange, BOX Exchange will provide all current BOX Options Participants the opportunity to participate in the selection of a Participant Director consistent with the BOX Exchange Bylaws. Further, BOX Exchange represents that it will complete the full nomination, petition, and voting process as set forth in the BOX Exchange Bylaws, which will provide persons that are approved as BOX Options Participants after the effective date of this Order with the opportunity to participate in the selection of a Participant Director(s), within 90 days of when BOX Exchange's application for registration as a national securities exchange is granted. The Commission therefore believes BOX Exchange's initial interim board will provide member representation sufficient to allow the Exchange to commence operations for an interim period prior to going through the process to elect a new Board pursuant to the full nomination, petition, and

business relationship with BOX Exchange or any affiliate of BOX Exchange, or any BOX Options Participant or any affiliate of any BOX Options Participant; provided, however, that an individual who otherwise qualifies as a Public Director shall not be disqualified from serving in such capacity solely because such individual is a director of BOX Exchange and/or the Chairman or Vice Chairman of the Board.

[23] The BOX Holdings Director will be on each committee of the BOX Exchange Board except the compensation committee and the regulatory oversight committee, unless he or she declines. *See* BOX Exchange Bylaws Section 6.01.

[24] A BOX Options Participant cannot have more than one officer, director or partner serving as a member of the BOX Exchange Board at any time. *See* BOX Exchange Bylaws Section 4.02.

[25] For the initial interim BOX Exchange Board, the BOX Exchange owners will propose James Boyle of UBS Americas Inc. as the initial Participant Director nominee.

[26] Current BOX Options Participants will be permitted to nominate alternative Participant Directors candidates by submitting a petition naming an alternative candidate signed by not less than 10% of all current BOX Options Participants. Each BOX Options Participant will then have one vote to elect the Participant Director and the Participant Director with the majority of votes will be included as a member of the initial BOX Exchange Board elected by the owners of BOX Exchange. *See* Amendment No. 2.

[27] *See* Amendment No. 2.

[28] *See* Amendment No. 2. *See* also BOX Exchange Bylaws Section 4.02.

[29] *See* BOX Exchange Bylaws Sections 4.02 and 4.06. *See also* Securities Exchange Act Release No. 61152 (December 10, 2009), 74 FR 66699 (December 16, 2009) (''C2 Order'') (allowing CBOE to appoint the initial board members and to issue a circular to trading permit holders identifying a slate of representative directors within 45 days from the date on which trading commenced on C2).

[30] *See* BOX Exchange Bylaws Section 4.06(d)(iv). *See infra* Section II.A.2. for discussion of the nominating committee.

[31] *See* BOX Exchange Bylaws Section 4.06(e)(iv).

[32] *Id.*

[33] 15 U.S.C. 78f(b)(3).

[34] *See, e.g.,* Securities Exchange Act Release No. 53128 (January 13, 2006), 71 FR 3550 (January 23, 2006 (granting the exchange registration of Nasdaq Stock Market, Inc.) (''Nasdaq Order''), and BATS Order, *supra* note 21. *See also* Securities Exchange Act Release No. 53382 (February 27, 2006), 71 FR 11251 (March 6, 2006) (''NYSE/Archipelago Merger Approval Order'').

[35] *See, e.g.,* Regulation of Exchanges and Alternative Trading Systems, Securities Exchange Act Release No. 40760 (December 8, 1998), 63 FR 70844 (December 22, 1998) (''Regulation ATS Release'').

[36] *See* Nasdaq Order and NYSE/Archipelago Merger Approval Order, *supra* note 34, and BATS Order, *supra* note 21.

[37] 15 U.S.C. 78f(b)(3).

[38] *See* BOX Exchange Bylaws Section 4.02 and Amendment No. 2 (representing that at least one director will not be associated with a member of BOX Exchange or with a broker or dealer, as required by Section 6(b)(3) of the Act).

[39] 15 U.S.C. 78f(b)(3).

[40] *See* Amendment No. 2.

voting process set forth in the BOX Exchange Bylaws.[41]

2. Exchange Committees

In the BOX Exchange Bylaws, BOX Exchange has proposed to establish several standing committees of the BOX Exchange Board. The standing committees of the BOX Exchange Board will be the audit, compensation, and regulatory oversight committees, and if applicable, the executive committee. The audit committee will consist of three to five directors, a majority of which will be required to be non-industry directors.[42] Each of the compensation and regulatory oversight committees will consist of three to five directors, all of which will be required to be non-industry directors.[43] The BOX Exchange Board will have the authority to appoint an executive committee, which will be required to have a majority of non-industry directors and at least 20% Participant Directors.[44] The BOX Holdings Director will sit on each committee of the BOX Exchange Board except the compensation and regulatory oversight committees, unless he or she declines.[45]

In addition, the BOX Exchange Bylaws provide that a nominating committee will be established to select nominees for the BOX Exchange Board.[46] The nominating committee will be a committee of BOX Exchange but will not be a committee of the BOX Exchange Board. The nominating committee will have at least five members.[47] The nominating committee will nominate candidates for each director position on the BOX Exchange Board.[48] BOX Options Participants also will be able to nominate alternate candidates for the Participant Directors through a petition process and vote by BOX Options Participants.[49] If no candidates are nominated pursuant to the petition process, then the nominating committee will nominate its nominees for the Participant Director positions.[50] If a petition process produces additional candidates, then the candidates nominated pursuant to the petition process, together with those nominated by the nominating committee, will be presented to BOX Options Participants for a vote to determine the final list of nominees for the Participant Director positions.[51]

The Commission believes that BOX Exchange's proposed committees, which are similar to the committees maintained by other exchanges,[52] are designed to help enable BOX Exchange to carry out its responsibilities under the Act and are consistent with the Act.

B. Regulation of BOX Exchange and BOX

Following BOX Exchange's commencement of operations as a national securities exchange, BOX Exchange will have all the attendant regulatory obligations under the Act. In particular, BOX Exchange will be responsible for the operation and regulation of BOX, its options trading facility. Certain provisions in the BOX Exchange, BOX Market, and BOX Holdings governance documents are designed to facilitate the ability of BOX Exchange and the Commission to fulfill their regulatory obligations. The discussion below summarizes some of these key provisions.

1. Changes in Control

a. Ownership Structure of BOX Exchange, BOX Holdings, and BOX Market

BOX Exchange will issue Economic Units, as well as Voting Units, to each of its owners, or Members.[53] Economic Units, comprising all interests in the profits and losses of BOX Exchange and all rights to receive distributions from BOX Exchange, will not have any voting rights.[54] Voting Units will have voting rights and not include any right to, or interest in, any profits and losses of BOX Exchange, distributions from BOX Exchange, assets of BOX Exchange or other economic value in BOX Exchange.[55] The total number of Voting Units will be equal to the total number of Economic Units. Voting Units cannot be transferred separately from their related Economic Units.

The Members of BOX Exchange and their respective interests are: MX US 2 (40.000% of Economic Units and 20.000% of Voting Units); IB (20.000% of Economic Units and 20.000% of Voting Units); Citadel Securities LLC (6.445% of Economic Units and 12.179% of Voting Units); Citigroup Financial Products (6.445% of Economic Units and 12.179% of Voting Units); Strategic Investments II Inc. (6.445% of Economic Units and 4.990% of Voting Units); UBS Americas Inc. (6.253% of Economic Units and 4.990% of Voting Units); CSFB Next Fund Inc. (6.123% of Economic Units and 10.00% of Voting Units); LabMorgan Corp. (6.123% of Economic Units and 11.570% of Voting Units); and Aragon Solutions Ltd. (2.166% of Economic Units and 4.092% of Voting Units).

As noted above, BOX Holdings will own 100% of BOX Market. Unlike BOX Exchange, BOX Holdings will issue one class of units. The Members of BOX Holdings[56] and their respective interests are: MX US 2 (53.83%); IB (20.09%); Citadel Securities LLC (4.20%); Citigroup Financial Products (4.20%); Strategic Investments II Inc. (4.20%); UBS Americas Inc. (4.08%); CSFB Next Fund Inc. (3.99%); LabMorgan Corp. (3.99%); and Aragon Solutions Ltd. (1.41%).

As stated above, MX US 2 is a Member in both BOX Exchange (40% of Economic Units and 20% of Voting Units) and BOX Holdings (53.83%). Further, MX US 2 is a wholly-owned indirect subsidiary of the Bourse.[57] The

[41] *See* BOX Exchange Bylaws Sections 4.02 and 4.06. *See* C2 Order, supra note 29 at 66701 (December 16, 2009) (noting that because C2's initial permit holders will likely consist substantially of current CBOE members, ''the Commission believes C2's initial Board will provide member representation sufficient to allow the Exchange to commence operations.'').

[42] *See* BOX Exchange Bylaws Section 6.05.

[43] *See* BOX Exchange Bylaws Section 6.06 and 6.07.

[44] *See* BOX Exchange Bylaws Section 6.04.

[45] *See* BOX Exchange Bylaws Section 6.01.

[46] The BOX Exchange owners will appoint the initial nominating committee, which will serve until the first annual meeting. Thereafter, prior to each annual meeting, the sitting nominating committee will select individuals for the next nominating committee. BOX Exchange owners will then vote on the full slate of the nominating committee at the annual meeting. If the full slate fails to obtain the required vote of BOX Exchange owners, then the nominating committee will select a new slate and the process will be repeated. *See* BOX Exchange Bylaws Section 4.06.

[47] BOX Holdings will have the right to appoint one representative to sit on the nominating committee, at least 20% of the nominating committee will be composed of representatives of BOX Options Participants, and a majority of the members of the BOX Exchange nominating committee will be non-industry representative. *See* BOX Exchange Bylaws Section 4.06(a) and Amendment No. 2.

[48] *See id.*

[49] *See* BOX Exchange Bylaws Section 4.06(e). Specifically, the Secretary of BOX Exchange must provide to each BOX Options Participant the name of the nominating committee's nominees for the Participant Director positions. BOX Options Participants may nominate alternative candidates for election to the Participant Director positions by submitting a petition signed by not less than 10% of all then-current BOX Options Participants. *Id.*

[50] *Id.*

[51] *Id.*

[52] *See, e.g.,* BATS Order, *supra* note 21, and Nasdaq Order, *supra* note 34.

[53] BOX Exchange's limited liability company agreement (''BOX Exchange LLC Agreement'') refers to the owners of BOX Exchange as ''Members.''

[54] *See* Article 2.5(a) of the BOX Exchange LLC Agreement.

[55] *See* Article 2.5(b) of the BOX Exchange LLC Agreement.

[56] BOX Holdings' limited liability company agreement (''BOX Holdings LLC Agreement'') refers to the owners of BOX Holdings as ''Members.''

[57] Specifically MX US 2 is a wholly-owned direct subsidiary of MX US 1, Inc. (''MX US 1''), a company incorporated in Delaware and a wholly-owned direct subsidiary of the Bourse.

Bourse, a company incorporated in Quebec, Canada, is a wholly-owned direct subsidiary of TMX, a company incorporated in Ontario, Canada. Therefore, MX US 1, the Bourse, and TMX (collectively, the ''Controlling Upstream Owners'') will be indirect owners of BOX Exchange, BOX Holdings, and BOX Market.

b. BOX Exchange Ownership and Voting Limits

The BOX Exchange LLC Agreement contains limits on the ownership of Economic Units and Voting Units, and on the voting of Voting Units.[58] Specifically, with respect to the limits on the Economic Units, no person, either alone or together with any related persons (including affiliates) may own, directly or indirectly, of record or beneficially, Economic Units representing a percentage interest of more than 40%.[59] In addition, BOX Options Participants, alone or together with any related persons (including affiliates) may not own, directly or indirectly, of record or beneficially, Economic Units representing a percentage interest of more than 20%.[60] With respect to limits on the Voting Units, no person, either alone or together with any related person (including affiliates), may own, directly or indirectly, of record or beneficially, Voting Units representing a percentage interest of more than 20%, have the power to vote, direct the vote or give any consent or proxy in excess of the 20% voting limit, or enter into any agreement, plan or other arrangement that would result in the Voting Units that are subject to such agreement, plan or other arrangement not being voted on any matter or matters or any proxy relating thereto being withheld, where the effect would be to enable any person, either alone or together with any related persons (including affiliates), to vote, possess the right to vote or cause the voting of, Voting Units in excess of the 20% voting limit.[61]

Notwithstanding the limits described above, the BOX Exchange Board may waive the 40% ownership limit for Economic Units if it makes certain determinations.[62] The BOX Exchange Board also may waive the 20% ownership limit for Voting Units if it makes certain determinations.[63] However, BOX Options Participants will be subject to the 20% ownership limit for Economic Units and the 20% ownership limit for Voting Units and will not be eligible for a waiver to exceed such thresholds.[64]

The BOX Exchange LLC Agreement also contains a provision designed to ensure that no owner of BOX Exchange will exceed the applicable ownership limit on Voting Units. Specifically, if an owner of BOX Exchange owns Voting Units in excess of the applicable voting limit, then the excess Voting Units will be distributed, *pro rata* according to Economic Units percentage, to the other owners so that the owner does not exceed the applicable voting limit.[65] In addition, the BOX Exchange LLC Agreement provides that, if an owner of BOX Exchange subsequently becomes a BOX Options Participant, and that owner's Economic Units or Voting Units percentage exceeds 20%, then such owner will have no voting rights on the Voting Units that exceeds the voting limit.[66]

The BOX Exchange LLC Agreement contains other provisions that are designed to safeguard the Economic Units and Voting Units limits. For example, any transfer that would violate the BOX Exchange LLC Agreement, such as exceeding the limits, will be void.[67] Moreover, any owner involved in a transaction in which a person, either alone or together with any related person (including affiliates), would exceed 5% ownership in Economic Units or Voting Units will be required to provide written notice to BOX Exchange fourteen days before the transaction that would exceed the 5% limit.[68] BOX Exchange will then be required to provide written notice to the Commission ten days before the transaction.[69] In addition, each person or entity that acquires 5% or more in Economic Units or Voting Units will be required to immediately notify BOX Exchange in writing and will need to update BOX Exchange if the ownership limits applicable to the person or entity are exceeded. Further, in addition to these notices, owners of BOX Exchange have agreed that any transfer of units that results in the acquisition and holding by any person, alone or with its related persons, of a percentage interest that meets or crosses the threshold level of 20% or any successive 5% percentage interest will be subject to the rule filing process of Section 19 of the Act.[70]

[58] These provisions are consistent with ownership and voting limits approved by the Commission for other exchanges. *See, e.g.,* DirectEdge Exchanges Order and BATS Order, *supra* note 21. *See also* C2 Order, *supra* note 29 and Nasdaq Order, *supra* note 34.

[59] *See* Article 7.3(f) of the BOX Exchange LLC Agreement.

[60] *Id.*

[61] *See* Article 7.3(g)(i) of the BOX Exchange LLC Agreement. An owner of BOX Exchange may also voluntarily impose a lower voting restriction on itself. *Id.* Strategic Investments II Inc. and UBS Americas Inc. each have voluntary imposed a lower voting limit of 4.99%. *See* Amendment No. 2.

[62] *See* Article 7.3(f) of the BOX Exchange LLC Agreement. The required determinations are that (A) such waiver will not impair the ability of BOX Exchange to carry out its functions and responsibilities under the Act and the rules and regulations promulgated thereunder, (B) such waiver is otherwise in the best interests of BOX Exchange and its owners, (C) such waiver will not impair the ability of the Commission to enforce the Act and (D) if applicable, the transferee in such transfer and its related persons are not subject to any applicable ''statutory disqualification'' (within the meaning of Section 3(a)(39) of the Act). *Id.* The Commission has previously approved the rules of other exchanges that provide for the ability of the exchange to waive the ownership and voting limitations discussed above for non-members of the exchange. *See, e.g.,* DirectEdge Exchanges Order, *supra* note 21.

[63] *See* Article 7.3(g)(i) of the BOX Exchange LLC Agreement. The required determinations for waiving the voting limitation are the same as the required determinations for waiving the ownership limitation.

[64] *See* Articles 7.3(f) and 7.3(g)(i) of the BOX Exchange LLC Agreement.

[65] *See* Article 7.3(g)(ii) of the BOX Exchange LLC Agreement. Pursuant to this provision, upon any transfer of Economic Units, each owner's Voting Units percentage will be reset to equal its percentage of Economic Units. Should any owner, after the Voting Units reset, exceed the voting limit, then the excess Voting Units will be distributed *pro rata* according to Economic Units percentage, to the other owners so that the owner does not exceed the applicable voting limit. *Id.*

[66] *See* Article 7.3(i) of the BOX Exchange LLC Agreement. Any Voting Units that exceed the voting limit will be voted in the same proportion as the Voting Units held by the other owners of BOX Exchange are voted. *Id.*

[67] *See* Article 7.3(d) of the BOX Exchange LLC Agreement.

[68] *See* Article 7.3(e) of the BOX Exchange LLC Agreement.

[69] *Id.* This provision is consistent with the current operating agreement of BOX Group LLC. *See* Section 8.4(e) of the Sixth Amended and Restated Operating Agreement of BOX Group LLC.

[70] *Id.* The BOX Exchange LLC Agreement also requires a ''controlling person'' of a BOX Exchange owner to execute an amendment to the BOX Exchange LLC Agreement agreeing to be bound by that agreement upon establishing a controlling interest in any BOX Exchange owner that, alone or together with its related persons, holds BOX Exchange Economic Units or Voting Units representing a percentage interest equal to or greater than 20%. *See* Article 7.3(h) of the BOX Exchange LLC Agreement. As noted above, MX US 2 is an owner of BOX Exchange (40% of Economic Units and 20% of Voting Units). In addition, as noted above, MX US 2 (through MX US 1) is a wholly-owned indirect subsidiary of the Bourse and the Bourse is a wholly-owned direct subsidiary of TMX. Under the BOX Exchange LLC Agreement, each of MX US 1, Bourse, and TMX will be required to become parties to the BOX Exchange LLC Agreement through such an amendment and will have all the rights and responsibilities of the owners of BOX Exchange. This will be effectuated pursuant to Instruments of Accession. If in the future there is another such ''controlling person,'' it also will be required to execute an Instrument of Accession, which will be an amendment to the BOX Exchange LLC Agreement that is required to be filed with the Commission. *See* Article 7.3(h)(iv) of the BOX Exchange LLC Agreement. The BOX Exchange LLC Agreement further provides that ''[t]he rights and privileges, including all voting rights, of the Member in whom a controlling interest is held

Continued

The Commission believes that these provisions are consistent with the requirements of the Act. These limitations are designed to help prevent any owner of BOX Exchange from exercising undue control over the operation of BOX Exchange and to help assure that BOX Exchange is able to effectively carry out its regulatory obligations under the Act. In addition, these limitations are designed to address the conflicts of interests that might result from a member of a national securities exchange owning interests in the exchange. As the Commission has noted in the past, a member's interest in an exchange could become so large as to cast doubts on whether the exchange may fairly and objectively exercise its self-regulatory responsibilities with respect to such member.[71] A member that is a controlling shareholder of an exchange could seek to exercise that controlling influence by directing the exchange to refrain from, or the exchange may hesitate to, diligently monitor and conduct surveillance of the member's conduct or diligently enforce the exchange's rules and the federal securities laws with respect to conduct by the member that violates such provisions. As such, these requirements are expected to minimize the potential that a person or entity can improperly interfere with or restrict the ability of BOX Exchange to effectively carry out its regulatory oversight responsibilities under the Act.

c. BOX Holdings and BOX Market

The BOX Holdings limited liability company agreement (''BOX Holdings LLC Agreement'') and the BOX Market limited liability company agreement (''BOX Market LLC Agreement'') also contain provisions related to direct and indirect changes in control.

Specifically, any owner involved in a transaction in which the owner's percentage interest in BOX Holdings, either alone or together with any related person (including affiliates), will meet or cross the threshold level of 5% or the successive 5% percentage levels of 10% and 15% will be required to provide written notice to BOX Holdings fourteen days before the transaction.[72] BOX Holdings will then be required to provide written notice to BOX Exchange and the Commission ten days before the transaction.[73] In addition any person that, either alone or together with any related person [74] (including affiliates) owns, directly or indirectly, of record or beneficially, 5% or more of BOX Holdings will be required to immediately notify in writing BOX Holdings upon acquiring knowledge of such ownership.[75] In addition to these notices, owners of BOX Holdings have agreed that any transfer of units that results in the acquisition and holding by any person, alone or with its related persons, of a percentage interest that meets or crosses the threshold level of 20% or any successive 5% percentage interest will be subject to the rule filing process of Section 19 of the Act.[76] Further, any transfer that would be in contravention of these notification and filing provisions will be void.[77]

In addition, if an owner of BOX Holdings or any of its related persons is approved as a BOX Options Participant, and if such owner, alone or together with the related persons, own more than 20% of BOX Holdings, then such owner and any director of BOX Holdings designated by such owner will not have any voting rights with respect to any units owned in excess of 20%.[78] Further, the owner will not be entitled to give any proxy with respect to any units owned in excess of 20%.[79] IB, however, will have an exemption until January 1, 2014, from the voting limitation described in this paragraph, but only with respect to any votes regarding a merger, consolidation or dissolution of BOX Holdings or a sale of all or substantially all of the assets of BOX Holdings.[80]

The BOX Holdings LLC Agreement also provides that a ''controlling person'' [81] of a BOX Holdings owner is required to execute an amendment to the BOX Holdings LLC Agreement agreeing to be bound by the BOX Holdings LLC Agreement upon establishing a controlling interest in any BOX Holdings owner [82] that, alone or together with its related persons, holds BOX Holdings units representing a percentage interest equal to or greater than 20%.[83] As noted above, MX US 2 is an owner of BOX Holdings (53.83%). In addition, as noted above, MX US 2 (through MX US 1) is a wholly-owned indirect subsidiary of the Bourse and the Bourse is a wholly-owned direct subsidiary of TMX. Under the BOX Holdings LLC Agreement, each of MX US 1, Bourse, and TMX will be required to become a party to the BOX Holdings LLC Agreement through such an amendment and will have all the rights and responsibilities of the owners of BOX Holdings.[84] The BOX Holdings LLC Agreement further provides that ''[t]he rights and privileges, including all voting rights, of the Member in whom a controlling interest is held * * * shall be suspended until such time as the amendment * * * [to the Agreement] has become effective pursuant to Section 19 of the Exchange Act or the Controlling Person no longer holds a controlling interest in the Member.'' [85]

The BOX Market LLC Agreement does not explicitly include change of control provisions that are similar to those in the BOX Holdings LLC Agreement. However, the BOX Market LLC Agreement explicitly provides that BOX Holdings is the sole Member of BOX Market.[86] Thus, if BOX Holdings were no longer the sole Member of BOX Market, BOX Market will be required to amend the BOX Market LLC Agreement, which will be required to be filed with

* * * shall be suspended until such time as the amendment * * * [to the Agreement] has become effective pursuant to Section 19 of the Exchange Act or the Controlling Person no longer holds a controlling interest in the Member.'' *See* Section 7.4(h)(iv) of the BOX Exchange LLC Agreement.

[71] *See, e.g.,* DirectEdge Exchanges Order and BATS Order, *supra* note 21.

[72] *See* Article 7.4(e) of the BOX Holdings LLC Agreement.

[73] *Id.* This provision is consistent with the current operating agreement of BOX Group LLC. *See* Section 8.4(e) of the Sixth Amended and Restated Operating Agreement of BOX Group LLC.

[74] *See* Article 1.1 of the BOX Holdings LLC Agreement for a definition of ''related person.''

[75] *See id.* The notice will require the person's full legal name; the number of units owned, directly or indirectly, of record or beneficially, by the person together with any related person; and whether the person has power, directly or indirectly, to direct the management or policies of BOX Holdings.

[76] *See* Article 7.4(f) of the BOX Holdings LLC Agreement.

[77] *See* Article 7.4(d) of the BOX Holdings LLC Agreement.

[78] *See* Article 7.4(h) of the BOX Holdings LLC Agreement.

[79] *Id.*

[80] *Id.*

[81] A ''controlling person'' is defined as a Person who, alone or together with any related persons of such person, holds a controlling interest in an owner of BOX Holdings. *See* Article 7.4(g)(v) of the BOX Holdings LLC Agreement.

[82] A ''controlling interest'' is defined as the direct or indirect ownership of 25% or more of the total voting power of all equity securities of an owner of BOX Holdings (other than voting rights solely with respect to matters affecting the rights, preferences, or privileges of a particular class of equity securities), by any person, alone or together with any related persons of such person. *See* Article 7.4(g)(v) of the BOX Holdings LLC Agreement.

[83] *See* Article 7.4(g) of the BOX Holdings LLC Agreement.

[84] This will be effectuated pursuant to Instruments of Accession included in the Form 1. If in the future there is another such ''controlling person,'' it too will be required to execute an Instruments of Accession, which will be an amendment to the BOX Holdings LLC Agreement that is required to be filed with the Commission. *See* Article 7.4(g)(iv) of the BOX Holdings LLC Agreement.

[85] *See* Section 7.4(g)(iv) of the BOX Holdings LLC Agreement.

[86] *See* Article 1.1 of the BOX Market LLC Agreement.

and approved by the Commission before such amendment may be effective.[87]

Although BOX Holdings and BOX Market are not independently responsible for regulation, their activities with respect to the operation of BOX must be consistent with, and not interfere with, the self-regulatory obligations of BOX Exchange. The Commission believes that the requirements in the BOX Holdings LLC Agreement and the BOX Market LLC Agreement applicable to direct and indirect changes in control of BOX Holdings and BOX Market described above, as well as the voting limitation imposed on owners of BOX Holdings who also are BOX Options Participants described above, are appropriate to help ensure that BOX Exchange is able to effectively carry out its self-regulatory responsibilities, including over BOX, and are consistent with the requirements of the Act. In addition, the Commission believes that the exemption from the BOX Options Participant voting limitation granted to IB is appropriate and is not expected to limit BOX Exchange's ability to effectively carry out its self-regulatory responsibilities. The Commission also notes that IB was provided with a similar exemption with respect to its current ownership of BOX Group LLC.[88]

2. Regulatory Independence

BOX Exchange, BOX Market, and BOX Holdings propose to adopt certain provisions in their respective governing documents designed to help maintain the independence of the regulatory functions of BOX Exchange. These proposed provisions are substantially similar to those included in the governing documents of exchanges that recently have been granted registration.[89] Specifically:

- The owners, directors, officers, employees, and agents of BOX Exchange, BOX Market, and BOX Holdings must give due regard to the preservation of the independence of the self-regulatory function of BOX Exchange and must not take actions that would interfere with the effectuation of decisions by the BOX Exchange Board relating to its regulatory functions or that would interfere with BOX Exchange's ability to carry out its responsibilities under the Act.[90]

- Each of BOX Exchange, BOX Market, and BOX Holdings and their respective owners must comply with federal securities laws and the rules and regulations promulgated thereunder and agree to cooperate with the Commission and BOX Exchange pursuant to and to the extent of their respective regulatory authority.[91]

- BOX Exchange, BOX Market, and BOX Holdings, and the owners, officers, directors, employees and agents of each, must submit to the jurisdiction of the U.S. federal courts and the Commission for any action, suit or proceeding arising out of or related to BOX Exchange activities.[92]

- All books and records of BOX Exchange reflecting confidential information pertaining to the self-regulatory function of BOX Exchange (including but not limited to disciplinary matters, trading data, trading practices, and audit information) shall be retained in confidence by BOX Exchange and its personnel, including any individuals entitled to information pursuant to Board observation rights, and will not be used by BOX Exchange for any non-regulatory purpose and shall not be made available to persons (including, without limitation, any owners of BOX Exchange) other than to those personnel of BOX Exchange, to members of the BOX Exchange Board and any observer, to the extent necessary or appropriate to properly discharge the self-regulatory function of BOX Exchange, or unless required by court order or applicable law.[93]

- The books and records of BOX Exchange and BOX Market and, to the extent related to the operation or administration of BOX Exchange and BOX Market, the books and records of BOX Holdings, must be maintained in the United States and will be subject at all times to inspection and copying by the Commission.[94]

- Furthermore, for so long BOX Holdings directly or indirectly controls BOX Market, and to the extent related to the operation or administration of BOX Exchange or the BOX Market, the books, records, premises, officers, directors, employees and agents of BOX Holdings and its owners will be deemed to be the books, records, premises, officers, directors, employees and agents of BOX Exchange.[95]

- BOX Exchange, BOX Market, and BOX Holdings will take such action as is necessary to ensure that their officers, directors and employees, and each owner's officers, directors, and employees, consent to the applicability of provisions regarding books and records, confidentiality, jurisdiction, and regulatory obligations, to the extent related to the operation or administration of BOX Exchange.[96]

As noted above, each of the Controlling Upstream Owners will be required to become a party to the BOX Exchange LLC Agreement and the BOX Holdings LLC Agreement and will have all the rights and obligations of the owners of BOX Exchange and BOX Holdings. Thus, for example, as a party to the BOX Exchange LLC Agreement and the BOX Holdings LLC Agreement, each Controlling Upstream Owner will be required to comply with the U.S. federal securities laws and the rules and regulations thereunder and cooperate with the Commission and BOX

[87] *See* Article 14.1 of the BOX Market LLC Agreement. A proposed rule change can also become effective by operation of law. *See* 15 U.S.C. 78s(b)(2).

[88] *See* Securities Exchange Act Release No. 49607 (January 13, 2004), 69 FR 2761, 2767 (January 20, 2004) (approving a limited temporary exemption for IB from the voting limitation provisions in the limited liability company agreement of BOX Group LLC and noting that the exemption is designed to afford IB some ability to protect its investment but also to limit the possibility that BSE's ability to carry out its self-regulatory responsibilities would be impaired). This exemption is substantially similar to an exemption granted to founder members of the International Securities Exchange (''ISE''). See Securities Exchange Act Release Nos. 45803 (April 23, 2002), 67 FR 21306, 21307 (April 30, 2002) (approval of SR–ISE–2002–01) (conversion of ISE from an LLC to a corporation); and 42455 (February 24, 2000), 65 FR 11388, 11391–92 (March 2, 2000) (File No. 10–127) (approval of registration of ISE as a national securities exchange) (''ISE Order'').

[89] *See e.g.,* DirectEdge Exchanges Order and BATS Order, *supra* note 21, and C2 Order, *supra* note 29.

[90] *See* Article 4.6(a) of the BOX Exchange LLC Agreement, Article 4.12(a) of the BOX Market LLC Agreement, and Article 4.12(a) of the BOX Holdings LLC Agreement.

[91] *See* Article 4.6(b) of the BOX Exchange LLC Agreement, Article 4.12(b) of the BOX Market LLC Agreement, and Article 4.12(b) of the BOX Holdings LLC Agreement.

[92] *See* Article 18.6(b) of the BOX Exchange LLC Agreement, Article 14.6(b) of the BOX Market LLC Agreement, and Article 18.6(a) of the BOX Holdings LLC Agreement.

[93] *See* BOX Exchange Bylaws Section 5.02. The Commission notes that the BOX Exchange LLC Agreement, the BOX Market LLC Agreement and the BOX Holdings LLC Agreement also provide that confidential information pertaining to regulatory matters related to BOX Exchange, BOX Market and BOX Holdings will be subject to confidentiality restrictions. *See* Article 15.5 of the BOX Exchange LLC Agreement, Article 12.6 of the BOX Market LLC Agreement, and Article 15.6 of the BOX Holdings LLC Agreement.

[94] *See* Article 11.1 and 18.6(a) of the BOX Exchange LLC Agreement, Article 9.1 of the BOX Market LLC Agreement, and Article 11.1 of the BOX Holdings LLC Agreement.

[95] *See* Article 11.1 of the BOX Holdings LLC Agreement.

[96] *See* Article 18.6(c) of the BOX Exchange LLC Agreement, Article 14.6(c) of the BOX Market LLC Agreement, and Article 18.6(b) of the BOX Holdings LLC Agreement.

Exchange [97] and will be required to take such action as is necessary to ensure that its directors, officers and employees consent to complying with the U.S. federal securities laws and the rules and regulations thereunder and cooperating with the Commission and BOX Exchange to the extent related to the operation or administration of the BOX Exchange or BOX Market.[98] Moreover, each Controlling Upstream Owner, its officers, directors, employees and agents will irrevocably submit to the jurisdiction of the U.S. federal courts and the Commission for purposes of any action arising out of, or relating to, activities of BOX Exchange and/or BOX Market.[99] Further, TMX, Bourse, and MX US 1 (and any future controlling upstream owner of BOX Market), by becoming parties to the BOX Holdings LLC Agreement and having the responsibilities of BOX Holdings' owners, will agree (to the extent related to the operation or administration of BOX Exchange or the BOX Market) that their books and records must be maintained within the United States and shall be subject at all times to inspection and copying by the Commission and BOX Exchange; and that their books, records, premises, directors, officers, employees and agents shall be deemed to be those of the Exchange for the purposes of, and subject to oversight pursuant to, the Act.

In addition, each Controlling Upstream Owner must give due regard to the preservation of the independence of the self-regulatory function of BOX Exchange and must not take any action that would interfere with the effectuation of decisions by the BOX Exchange Board or interfere with BOX Exchange's ability to carry out its responsibilities under the Act.[100] Each Controlling Upstream Owner also is required to take such action as is necessary to ensure that its directors, officers and employees consent to giving due regard to the preservation of the independence of the self-regulatory function of BOX Exchange and to not taking any action that would interfere with the effectuation of decisions by the BOX Exchange Board or interfere with BOX Exchange's ability to carry out its responsibilities under the Act to the extent related to the operation or administration of the BOX Exchange or BOX Market.[101]

The Commission believes that the provisions discussed in this section, which are designed to help maintain the independence of BOX Exchange's regulatory function, are appropriate and consistent with the requirements of the Act, particularly with Section 6(b)(1), which requires, in part, an exchange to be so organized and have the capacity to carry out the purposes of the Act.[102] The Commission notes that, even in the absence of these provisions, Section 20(a) of the Act (as applied to the BOX entities) provides that any person with a controlling interest in BOX Exchange or BOX Market would be jointly and severally liable with and to the same extent that BOX Exchange or BOX Market, as the case may be, is liable under any provision of the Act, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action. In addition, Section 20(e) of the Act creates aiding and abetting liability for any person who knowingly provides substantial assistance to another person in violation of any provision of the Act or rule thereunder. Further, Section 21C of the Act authorizes the Commission to enter a cease-and-desist order against any person who has been ''a cause of'' a violation of any provision of the Act through an act or omission that the person knew or should have known would contribute to the violation. These provisions are applicable to all entities' dealings with BOX Exchange and BOX Market, including the Controlling Upstream Owners.

3. Regulation of BOX

As a prerequisite for the Commission's granting of an exchange's application for registration, an exchange must be organized and have the capacity to carry out the purposes of the Act.[103] Specifically, an exchange must be able to enforce compliance by its members, and persons associated with its members, with the federal securities laws and the rules of the exchange.[104] The discussion below summarizes how BOX Exchange proposes to conduct and structure its regulatory operations.

a. Regulatory Oversight Committee

The regulatory operations of BOX Exchange will be monitored by the regulatory oversight committee of the BOX Exchange Board. The regulatory oversight committee will consist of at least three directors, all of whom will be non-industry directors. The regulatory oversight committee generally will be responsible for overseeing the adequacy and effectiveness of BOX Exchange's regulatory and SRO responsibilities, assessing BOX Exchange's regulatory performance, and assisting the BOX Exchange Board (and committees of the BOX Exchange Board) in reviewing BOX Exchange's regulatory plan and the overall effectiveness of BOX Exchange's regulatory functions.[105] Further, a CRO of BOX Exchange will have general day-to-day supervision over BOX Exchange's regulatory operations.[106] The regulatory oversight committee will be charged with all hiring and termination decisions over the CRO, taking into account the recommendation of the President of BOX Exchange.[107] The CRO will report to both the regulatory oversight committee and the President of BOX Exchange.[108]

To help assure the Commission that it has and will continue to have adequate funding to be able to meet its responsibilities under the Act, BOX Exchange represented that, upon the granting of its application as a national securities exchange and prior to commencing operations as such, BOX Group LLC will contribute sufficient operational assets to the Exchange, including furnishings, equipment and servers previously used in connection with the regulation of BOX, and industry and regulatory memberships. In addition, BOX Exchange stated that it has received from BOX Group LLC a loan of $1,000,000.[109] In addition, because BOX Exchange would be the registered national securities exchange, BOX Exchange would be entitled to receive all fees, including regulatory fees and trading fees, payable by BOX Option Participants, as well as any

[97] *See* Article 4.6(b) of the BOX Exchange LLC Agreement and Article 4.12(b) of the BOX Holdings LLC Agreement.

[98] *See* Articles 4.6(b) and 18.6(c) of the BOX Exchange LLC Agreement and Articles 4.12(b) and 18.6(b) of the BOX Holdings LLC Agreement.

[99] *See* Article 18.6(b) of the BOX Exchange LLC Agreement and Article 18.6(a) of the BOX Holdings LLC Agreement.

[100] *See* Article 4.6(a) of the BOX Exchange LLC Agreement and Article 4.12(a) of the BOX Holdings LLC Agreement.

[101] *See* Articles 4.6(a) and 18.6(c) of the BOX Exchange LLC Agreement and Articles 4.12(a) and 18.6(b) of the BOX Holdings LLC Agreement.

[102] 15 U.S.C. 78f(b)(1).

[103] *See* Section 6(b)(1) of the Act, 15 U.S.C. 78f(b)(1).

[104] *Id. See also* Section 19(g) of the Act, 15 U.S.C. 78s(g).

[105] *See* BOX Exchange Bylaws Section 6.07.

[106] *See* BOX Exchange Bylaws Section 7.01. *See also* Amendment No. 2.

[107] *See* BOX Exchange Bylaws Section 6.07. *See also* Amendment No. 2.

[108] *See* BOX Exchange Bylaws Section 7.01. *See also* Amendment No. 2.

[109] *See* Amendment No. 2. In addition, BOX Exchange represents that the $1,000,000 loan it received from BOX Group LLC will be sufficient to cover the expenses of BOX Exchange until BOX Exchange begins receiving revenues from transaction fees, market data fees and regulatory fees. *See* letter from Lisa Fall, President, BOX Exchange, to Heather Seidel, Associate Director, Division, Commission, dated April 2, 2012 (''April 2 Letter'').

funds received from any applicable market data fees and Options Price Reporting Authority tape revenue.[110] Any excess funds, as determined solely by BOX Exchange, will be remitted to BOX Market.[111] To the extent BOX Exchange's assets were not sufficient, BOX Market (and BOX Holdings, to the extent it holds BOX Market funds) will reimburse BOX Exchange.[112] Further, any revenues received by BOX Exchange from fees derived from its regulatory function or regulatory penalties will not be used for non-regulatory purposes.[113]

b. Rule 17d–2 Agreements and Regulatory Contract

Rule 17d–2 of the Act[114] permits SROs to propose joint plans allocating regulatory responsibilities concerning members, as such term is defined in Section 3(a)(3) of the Act, of more than one SRO (''Common Members'').[115] These agreements, which must be filed with and approved by the Commission, generally cover such regulatory functions as personnel registration and sales practices. Commission approval of a Rule 17d–2 plan relieves the specified SRO of those regulatory responsibilities allocated by the plan to another SRO.[116] Many SROs have entered into Rule 17d–2 agreements.[117] BOX Exchange has represented to the Commission that it intends to become a party to the existing multiparty options Rule 17d–2 plans concerns sales practice regulation and market surveillance.[118] Under these agreements, the examining SROs examine firms that are common members of BOX Exchange and the particular examining SRO for compliance with certain provisions of the Act, certain rules and regulations adopted thereunder, and certain BOX Exchange Rules.

In addition, BOX Exchange has entered into an RSA with FINRA, under which FINRA will perform certain regulatory functions on behalf of BOX Exchange.[119] Specifically, BOX Exchange states that FINRA will: assist BOX Exchange in conducting investigations of potential violations of BOX Exchange rules and/or federal securities laws related to activity on the Exchange; conduct examinations related to BOX Option Participants' conduct on BOX Exchange; assist BOX Exchange with disciplinary proceedings pursuant to BOX Exchange rules, including issuing charges and conducting hearings; and provide dispute resolution services to BOX Option Participants on behalf of BOX Exchange, including operation of the BOX Exchange's arbitration program.[120] Notwithstanding the RSA, BOX Exchange acknowledges it will retain ultimate legal responsibility for the regulation of its members and its market.[121]

The Commission believes that it is consistent with the Act for BOX Exchange to contract with FINRA to perform certain examination, enforcement, and disciplinary functions.[122] These functions are fundamental elements of a regulatory program, and constitute core self-regulatory functions. The Commission believes that FINRA has the expertise and experience to perform these functions on behalf of BOX Exchange.[123]

BOX Exchange, unless relieved by the Commission of its responsibility,[124] bears the ultimate responsibility for self-regulatory responsibilities and primary liability for self-regulatory failures, not the SRO retained to perform regulatory functions on the Exchange's behalf. In performing these regulatory functions, however, the SRO retained to perform regulatory functions may nonetheless bear liability for causing or aiding and abetting the failure of BOX Exchange to perform its regulatory functions.[125] Accordingly, although FINRA will not act on its own behalf under its SRO responsibilities in carrying out these regulatory services for BOX Exchange, as the SRO retained to perform regulatory functions, FINRA may have secondary liability if, for example, the Commission finds that the contracted functions are being performed so inadequately as to cause a violation of the federal securities laws by BOX Exchange.[126]

4. Regulatory Oversight Over BOX Market

There is an inherent tension between a national securities exchange's role as a regulator and as the operator of a market, and between its role as a regulator and as a membership organization.[127] The existence of a shareholder class separate from membership adds yet another constituency with interests potentially in conflict with the regulatory

[110] BOX Exchange acknowledged this fact in Amendment No. 2.

[111] *See* Form 1 Application, Exhibit I. BOX Exchange represents that, in determining the excess funds to remit to BOX Market, it will exercise prudent financial management (including cash flow management) and may retain funds for anticipated and unanticipated expenses. *See* April 2 Letter, *supra* note 109.

[112] *See* Form 1 Application, Exhibit I.

[113] Article 8.1 of the BOX Exchange LLC Agreement.

[114] *See* Section 17(d)(1) of the Act and Rule 17d–2 thereunder, 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d–2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO. Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members.

[115] 17 CFR 240.17d–2. Section 19(g)(1) of the Act requires every SRO to examine its members and persons associated with its members and to enforce compliance with the federal securities laws and the SRO's own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d) of the Act. Section 17(d) was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication with respect to Common Members. *See* Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976) (''Rule 17d–2 Adopting Release'').

[116] *See id.*

[117] *See, e.g.,* Securities Exchange Act Release Nos. 59218 (January 8, 2009), 74 FR 2143 (January 14, 2009) (File No. 4–575) (FINRA/Boston Stock Exchange, Inc.); 58818 (October 20, 2008), 73 FR 63752 (October 27, 2008) (File No. 4–569) (FINRA/BATS Exchange, Inc.); 55755 (May 14, 2007), 72 FR 28057 (May 18, 2007) (File No. 4–536) (National Association of Securities Dealers, Inc. (''NASD'') n/k/a FINRA and CBOE concerning the CBOE Stock Exchange); 55367 (February 27, 2007), 72 FR 9983 (March 6, 2007) (File No. 4–529) (NASD/ISE); and 54136 (July 12, 2006), 71 FR 40759 (July 18, 2006) (File No. 4–517) (NASD/Nasdaq).

[118] *See* Securities Exchange Act Release Nos. 61589 (February 25, 2010), 75 FR 9976 (March 4, 2010) (File No. S7–966) (notice of filing and order approving and declaring effective an amendment to the multiparty 17d–2 plan concerning options-related sales practice matters); 61588 (February 25, 2010), 75 FR 9970 (March 4, 2010) (File No. 4–551) (notice of filing and order approving and declaring effective an amendment to the multiparty 17d–2 plan concerning options-related market surveillance).

[119] *See* Form 1 Application, Exhibit L.

[120] *See* BOX Exchange IM–12150–1 and Amendment No. 2, *supra* note 5.

[121] *See* Amendment No. 2, *supra* note 5.

[122] *See, e.g.,* Regulation ATS Release, *supra* note 35. *See also* Securities Exchange Act Release Nos. 50122 (July 29, 2004), 69 FR 47962 (August 6, 2004) (SR–Amex–2004–32) (order approving rule that allowed Amex to contract with another SRO for regulatory services) (''Amex Regulatory Services Approval Order''); 57478 (March 12, 2008), 73 FR 14521 (March 18, 2008) (SR–NASDAQ–2007–004) (''NOM Approval Order''); Nasdaq Order, *supra* note 34; and BATS Order, *supra* note 21.

[123] *See, e.g.,* Amex Regulatory Services Approval Order, *supra* note 122; NOM Approval Order, *supra* note 122; and Nasdaq Order, *supra* note 34. The Commission notes that the RSA is not before the Commission and, therefore, the Commission is not acting on it.

[124] *See supra* note 114.

[125] For example, if failings by the SRO retained to perform regulatory functions have the effect of leaving an Exchange in violation of any aspect of the exchange's self-regulatory obligations, the exchange will bear direct liability for the violation, while the SRO retained to perform regulatory functions may bear liability for causing or aiding and abetting the violation. *See, e.g.,* Nasdaq Order, *supra* note 34; BATS Order, *supra* note 21; and ISE Order, supra note 88.

[126] *Id.*

[127] *See* Securities Exchange Act Release No. 50699, 69 FR 71126, 71141 (December 8, 2004) (File No. S7–39–04).

responsibilities of the SRO.[128] An exchange should have in place a structure and be operated in a manner designed to mitigate any potential conflicts between its commercial interests and its regulatory responsibilities so as to assure that it is able to carry out its responsibilities in compliance with the Act.[129]

As noted above, BOX Exchange and BOX Market will be separate corporate entities, and BOX Market will not be a wholly-owned subsidiary of BOX Exchange.[130] The structural separation of the entity responsible for regulation from the entity that operates the trading platform may serve to mitigate to some degree the influence of commercial interests on regulation. However, although BOX Exchange will be structurally separate from BOX Market as the entity that operates the trading platform, the ultimate owners of such entities are the same, albeit in different percentages.[131] In particular, as outlined above, in addition to being owners of BOX Exchange, MX US 2 directly owns (and TMX, Bourse and MX US 1 indirectly own) 53.83% of BOX Holdings. BOX Holdings has certain rights with respect to BOX Exchange that, in conjunction with this overlapping ownership structure, raise questions regarding the ability of BOX Holdings and its controlling owner to exert undue influence over BOX Exchange's regulatory functions. Specifically, the BOX Exchange Bylaws provides that BOX Holdings may appoint one director on the BOX Exchange Board and each board committee (including the nominating committee but excluding the regulatory oversight committee and the compensation committee).[132]

The Commission believes that this right potentially increases the likelihood that the owners of BOX Holdings, particularly MX US 2 (and its controlling owners, TMX, Bourse and MX US 1), can exercise undue influence over BOX Exchange's regulatory functions through the BOX Holdings Director. However, the following provisions in the BOX Exchange governing documents are designed to mitigate such concern: (1) BOX Holdings is permitted to appoint only one director to the BOX Exchange Board; [133] (2) because a majority of the BOX Exchange Board will be non-industry directors and 20% will be representative of BOX Options Participants,[134] there will at most be one other director that can potentially be selected by MX US 2; [135] (3) the BOX Holdings Director can not constitute more than 20% of the nominating committee; [136] and (4) the compensation committee and the regulatory oversight committee will not include the BOX Holdings Director.[137]

The separation of BOX Exchange and BOX Market also raises questions as to how effectively BOX Exchange will be kept informed about BOX Market's commercial operations that might be of regulatory concern, and whether BOX Exchange will be sufficiently empowered, and have the ability, to assure that the trading platform and related services are operated in accordance with the Act. To help address these concerns, the BOX Market LLC Agreement includes several provisions that are specifically designed to help facilitate the ability of BOX Exchange to oversee the BOX options trading facility and BOX Market as the operator of the BOX facility. Specifically:

- BOX Exchange must receive notice of, and will be required to affirmatively approve, any planned or proposed changes of BOX Market including, but not limited to, any planned or proposed changes to BOX, the sale by BOX Market of any material portion of its assets, and any action to effect a voluntary, or which would precipitate an involuntary, dissolution or winding up of BOX Market; [138]
- BOX Market is prohibited from implementing any such changes until they are approved by the BOX Exchange Board; [139]
- BOX Exchange has the right to direct BOX Market to make any modifications to prevent or eliminate a regulatory deficiency; [140] and
- BOX Exchange will have the right to designate a non-voting director to serve on the BOX Market board of directors, as long as BOX remains a facility of BOX Exchange (''regulatory director'').[141]

The Commission believes that the provisions discussed above, which are designed to facilitate the ability of BOX Exchange to oversee BOX Market and BOX, are appropriate and consistent with the requirements of the Act, particularly with Section 6(b)(1), which requires in part an exchange to be so organized and have the capacity to carry out the purposes of the Act.[142] As noted, the BOX Market LLC Agreement will require BOX Market to notify and receive prior approval from BOX Exchange of planned or proposed changes related to BOX Market or the BOX options trading facility.[143] In addition, BOX Exchange has full discretion to direct BOX Market to modify any proposed or planned changes to BOX to prevent or eliminate a regulatory deficiency.[144] Further, the

[128] *Id.*

[129] *See id* at 71141–2 (stating that national securities exchanges and associations should have policies and procedures that provide for the independence of their regulatory programs from the operation or administration of their trading facilities and other businesses; that the proposals should require that the exchange's or association's regulatory program be either structurally separated from the exchange's or association's market operations and other commercial interests, by means of separate legal entities or functionally separated within the same legal entity from the exchange's or association's market operations and other commercial interests; and that, in Commission's view, such separation must be designed to permit the regulatory program to function independently from the market operations and other commercial interests of the exchange or association).

[130] There is precedent for this type of structure in the current structure of BOX, with BOX being a facility of BX, as well as a prior structure when Archipelago Exchange was operated as the equity trading facility of the Pacific Exchange (''PCX''). *See* Securities Exchange Act Release Nos. 49068, *supra* note 6 (establishing, among other things, BOX as an options trading facility of BSE), and 44983 (October 25, 2001), 66 FR 55225 (November 1, 2001) (approving PCX's use of the Archipelago Exchange as its equity trading facility).

[131] The owners of BOX Holdings are indirect owners of BOX Market because BOX Market is a wholly-owned subsidiary of BOX Holdings.

[132] *See* BOX Exchange Bylaws Section 4.02.

[133] *Id.*

[134] *Id.*

[135] *Id.*

[136] *See* BOX Exchange Bylaws Section 4.06.

[137] *See* BOX Exchange Bylaws Sections 6.06 and 6.07.

[138] Changes relating solely to one or more of the following will not be subject to this notice requirement: marketing; administrative matters; personnel matters; social or team-building events; meetings of the owner of BOX Market; communication with the owner of BOX Market; finance; location and timing of board meetings; market research; real property; equipment; furnishings; personal property; intellectual property; insurance; contracts unrelated to the operation of the BOX Market; and de minimis items. *See* Article 3.2(a)(ii) of the BOX Market LLC Agreement.

[139] *See id.*

[140] *See* Articles 3.2(a)(iii) and (iv) of the BOX Market LLC Agreement. A ''regulatory deficiency'' means the operation of BOX or the BOX Market in a manner that is not consistent with the rules of BOX Exchange and/or the rules of the Commission governing the BOX Market or BOX Options Participants, or that otherwise impedes the ability of BOX Exchange to regulate the BOX Market or BOX Options Participants or to fulfill its obligations under the Act as an SRO. *See* Article 1.1 of the BOX Market LLC Agreement.

[141] This regulatory director will have not the right to vote or to serve on a committee, but will have the right to attend all meetings of the BOX Market board of directors, receive equivalent notice of such meetings, and receive a copy of all meeting materials provided to the other directors. *See* Article 4.1(a) of the BOX Market LLC Agreement.

[142] 15 U.S.C. 78f(b)(1).

[143] *See* Article 3.2(a)(ii) of the BOX Market LLC Agreement.

[144] *See* Article 3.2(a)(iii) and (iv) of the BOX Market LLC Agreement.

inclusion of the regulatory director on the BOX Market board of directors is designed to help facilitate the ability of BOX Exchange to become informed about the operations of the BOX trading platform and any proposed changes thereto.

Section 6(b)(1) of the Act [145] requires an exchange—including BOX Exchange—to be so organized and have the capacity to be able to carry out the purposes of the Act. In addition, Section 19(g)(1) of the Act [146] requires an exchange—including BOX Exchange—to comply with the provisions of the Act, the rules and regulations thereunder, and its own rules, and, absent reasonable justification or excuse, to enforce compliance by its members with such provisions. At this time, the Division believes that the overall corporate and governance structure proposed by BOX Exchange is designed to help facilitate the ability of BOX Exchange to carry out its responsibility and operate in a manner consistent with the Exchange Act.[147] Whether BOX Exchange operates in compliance with the Act, however, depends on how BOX Exchange and BOX Market in practice implement the governance and other provisions that are the subject of this Order.[148]

Section 19(h)(1) of the Act [149] provides the Commission with the authority ''to suspend for a period not exceeding twelve months or revoke the registration of [an SRO], or to censure or impose limitations upon the activities, functions, and operations of [an SRO], if [the Commission] finds, on the record after notice and opportunity for hearing, that [the SRO] has violated or is unable to comply with any provision of the Act, the rules or regulations thereunder, or its own rules or without reasonable justification or excuse has failed to enforce compliance'' with any such provision by its members (including associated persons thereof).[150] If Commission staff were to find, or become aware of, through staff review and inspection or otherwise, facts indicating any violations of the Act, including without limitation Sections 6(b)(1) and 19(g)(1), these matters could provide the basis for a disciplinary proceeding under Section 19(h)(1) of the Act.

C. Trading Host

1. Order Display, Execution, and Priority

As noted above, BOX Market will operate the automated trading system used for the trading of options contracts (the ''Trading Host'').[151] The Trading Host includes a fully automated electronic order book (''BOX Book'') for orders to buy or sell securities. BOX Options Participants are entitled to enter orders into and receive executions through the electronic order book. Liquidity is derived from orders to buy and sell submitted electronically by BOX Options Participants in remote locations. There will be no physical trading floor.

BOX Options Participants' Limit Orders submitted to the Trading Host will be ranked and maintained in the BOX Book according to price/time priority, such that within each price level, all orders will be organized by the time of entry.[152] No distinction is made to this priority with regard to account designation (Public Customer, Broker-Dealer or Market Maker). The number of orders and the total quantity at each of the five best price levels in the BOX Book will be displayed to all BOX Options Participants on an anonymous basis.[153]

BOX Options Participants may submit the following types of orders: Limit; BOX-Top; [154] Market-on-Opening; Market; and Intermarket Sweep Order (''ISO'').[155] Options Participants can add the designation of Good 'Til Cancelled, Fill and Kill, or Session Order [156] to each of the above mentioned order types.[157] These order types and designations are substantially similar to the order types currently offered by BOX.[158]

BOX Exchange also permits Order Flow Providers (''OFPs'') [159] to utilize Directed Orders.[160] A ''Directed Order'' refers to a Customer Order that an OFP directs to a particular BOX market maker. Unlike all other orders submitted to the Trading Host, Directed Orders are not anonymous. A market maker who wishes to accept Directed Orders must systemically indicate that it wishes to receive Directed Orders, must be willing to accept Directed Orders from all OFPs, may receive Directed Orders only through the Trading Host, and may not reject Directed Orders.[161]

Trades will execute when orders or quotations on the BOX Book match one another. The priority of orders at the same price will be determined by time of order entry. An order entered into the Trading Host that matches an order in the Trading Host will trade at the price of the order in the Trading Host up to the available size.[162]

With the exception of Improvement Orders and Primary Improvement Orders submitted during a Price Improvement Period (''PIP'') auction,[163] Directed Orders,[164] and ISOs,[165] all

[145] 15 U.S.C. 78f(b)(1).

[146] 15 U.S.C. 78s(g)(1).

[147] The Commission notes that it is reviewing the various standards and processes it uses to facilitate the registration of national securities exchanges and other entities required to register with the Commission and plans to issue a concept release designed to collect information and evaluate different aspects of these registration standards and processes, including the policy objectives of registration, how best to achieve those policy objectives through registration and other means, and the relative benefits and costs of the various means available. *See* Securities Exchange Act Release No. 65543 (October 12, 2011), 76 FR 65784, 65786 fn. 13 (October 24, 2011).

[148] According to Amendment No. 2, the person that will initially be the Chief Executive Officer of BOX Exchange also will be the Chief Executive Officer of BOX Market, and the person that will initially be the President of BOX Exchange also will be the Executive Vice President, Chief Legal Officer and Company Secretary of BOX Market. *See* Amendment No. 2. Thus, senior executives of BOX Exchange also will hold senior executive positions at BOX Market. Further, BOX Exchange's CRO will, in addition to reporting to BOX Exchange's regulatory oversight committee, report to the President of BOX Exchange. *See* BOX Exchange Bylaws Section 7.01. The CRO will have general day-to-day supervision over BOX Exchange's regulatory operations. *See id.* The compensation committee of BOX Exchange will set the CRO's compensation and the regulatory oversight committee, in its sole discretion, will make hiring and termination decisions with respect to the CRO, in each case taking into consideration any recommendations made by the President of BOX Exchange. *See* BOX Exchange Bylaws Sections 6.06 and 6.07.

[149] *See* 15 U.S.C. 78s(h)(1).

[150] *Id.*

[151] BOX Exchange's proposed trading rules are substantially similar to the current rules of BOX, which rules have been subject to the rule filing process under Section 19(b) of the Act.

[152] *See* BOX Exchange Rule 7130(a).

[153] *See* BOX Exchange Rule 7130(a)(2).

[154] BOX-Top orders that are entered into the BOX Book are executed at the best price available in the market for the total quantity available from any contra bid (offer). Any residual volume left after part of a BOX-Top Order has been executed is automatically converted to a limit order at the price at which the original BOX-Top Order was executed. *See* BOX Exchange Rule 7110(c)(2).

[155] *See* BOX Exchange Rule 7110(c).

[156] An order with a Session Order designation will remain active in the BOX trading system until certain triggering events occur (*e.g.,* disconnection of the connection between the BOX Options Participant and BOX). *See* BOX Exchange Rule 7110(e)(iii).

[157] *See* BOX Exchange Rule 7110(e).

[158] *See* Chapter V, Section 14 of the current BOX Rules.

[159] An OFP means those BOX Options Participants representing as agent customer orders on the Trading Host and those non-market-maker BOX Options Participants conducting proprietary trading. *See* BOX Exchange Rule 100(a)(45).

[160] *See* BOX Exchange Rule 8040. This rule is substantially similar to Chapter VI, Section 5(c) of the current BOX Rules.

[161] *See* BOX Exchange Rule 8040(d).

[162] *See* BOX Exchange Rule 7130(a)(4).

[163] These orders will be processed in accordance with BOX Exchange Rule 7150.

[164] Directed Orders will be processed in accordance with BOX Exchange Rule 8040.

[165] *See* BOX Exchange Rule 7110(c)(5).

orders submitted to the Trading Host will be filtered by the Trading Host prior to entry on the BOX Book, which is designed to ensure that such orders will not execute at a price outside of the current NBBO.[166]

BOX Exchange will limit an OFP's ability to trade as principal with an order it represents as agent, unless the agency order is first given the opportunity to interact with other trading interest on the Exchange. Specifically, an OFP may not execute as principal an order it represents as agent unless: (i) The agency order is first exposed to the BOX Book for at least one second; (ii) the OFP has been bidding or offering on the BOX Book for a least one second prior to receiving an agency order that is executable against such bid or offer; (iii) the OFP sends the agency order to the PIP; or (iv) the OFP sends the agency order to the Facilitation Auction.[167]

BOX Exchange Rules also will prohibit the disclosure of information about agency orders to third parties. Specifically, prior to submitting an order to the PIP, the Facilitation Auction, or the Solicitation Auction, a BOX Options Participant cannot inform another BOX Options Participant or any other third party of any of the terms of the order, except as provided for in the rules regarding Directed Orders.[168]

The PIP process may be used by BOX Options Participants seeking to execute their agency orders as principal. BOX Exchange's PIP rule is the same as BOX Group LLC's current PIP rule.[169] Under the PIP rule, Customer Orders designated for the PIP (''PIP Orders'') will be submitted to BOX with a matching contra order (''Primary Improvement Order'') equal to the full size of the PIP Order. The Primary Improvement Order must be on the opposite side of the market than that of the PIP Order and represent either: (1) A single price that is equal to or better than that of the NBBO at the time of the commencement of the PIP; or (2) an auto-match submission that will automatically match both the price and size of all competing quotes and orders at any price level achieved during the PIP or only up to a limit price. The Primary Improvement Order will designate the PIP auction start price, which must be equal to or better than the NBBO at the time of commencement of the PIP. BOX Exchange will commence a PIP by broadcasting a message to Options Participants, and the exposure period will last for one hundred milliseconds. At the conclusion of the auction, the PIP Order will be matched on price/time priority with orders on the opposite side (with the Initiating Participant retaining priority for 40% of the order),[170] subject to certain conditions.[171]

BOX Exchange will have no minimum size requirement for orders entered into the PIP, for a pilot period to expire July 18, 2012.[172] During the pilot period, BOX Exchange will submit certain data, periodically as required by the Commission, to help evaluate whether, among other things: (1) There is meaningful competition for all size PIP orders; and (2) there is significant price improvement for all orders executed through the PIP.[173] This data is expected to aid the Commission in evaluating the PIP during the pilot period to determine whether it would be beneficial to customers and to the options market as a whole to approve any proposal requesting permanent approval to permit orders of fewer than 50 contracts to be submitted to the PIP.

BOX Exchange's proposed Facilitation Auction is the same as BOX Group LLC's current Facilitation Auction.[174] The Facilitation Auction is a process by which an OFP seeks either to facilitate a block-size order it represents as agent, or to execute an order it solicited to execute against the agency order. OFPs must be willing to execute the entire size of agency orders entered into the Facilitation Auction through the submission of a contra ''Facilitation Order.'' [175] BOX Exchange also is proposing to have a Solicitation Auction, which is the same as BOX Group LLC's current Solicitation Auction.[176] The Solicitation Auction allows an OFP to seek to execute orders of 500 or more contracts it represents as agent against contra orders that it has solicited (''Solicited Order'').[177]

---

[166] *See* BOX Exchange Rule 7130(b) (noting that BOX will ''filter'' or check to ensure that the order will not: (i) in the case of a sell order, execute at a price below the NBBO bid price or (ii) in the case of a buy order, the execute at a price above the NBBO offer execute at a price above the NBBO offer price). This rule is substantially similar to Chapter V, Section 16(b) of the current BOX Rules.

[167] *See* BOX Exchange IM–7140–3.

[168] *See* BOX Exchange IM–7140–4.

[169] *See* Chapter V, Section 18 of the current BOX Rules.

[170] *See* BOX Exchange Rule 7150(g). At its option, the Initiating Participant may designate a lower amount for which it retains certain priority and trade allocation privileges upon the conclusion of the PIP than the forty percent (40%) of the PIP Order to which it is entitled. *See* Rule 7150(g)(5).

[171] *See* BOX Exchange Rule 7150.

[172] *See* BOX Exchange IM–7150–1.

[173] *See* Form 1 Application, Exhibit B. This data is substantially the same data currently provided to the Commission by BOX Group LLC. *See* Securities and Exchange Commission Release Nos. 61805 (March 31, 2010), 75 FR 17454 (April 6, 2010); 60337 (July 17, 2009), 74 FR 36805 (July 24, 2009); 51821 (June 10, 2005), 70 FR 35143 (June 16, 2005); and 49068, *supra* note 6.

[174] *See* Chapter V, Section 31(a) of the current BOX Rules.

[175] Upon the entry of an agency order and Facilitation Order into the Facilitation Auction, a broadcast message will be sent and Options Participants will be given an opportunity to enter responses with the prices and sizes at which they will be willing to participate in the facilitation of the agency order. At the end of the one second period for the entry of responses, the agency order will be automatically executed. Unless there is sufficient size to execute the entire Agency Order at a price better than the facilitation price, Public Customer bids (offers) and Public Customer responses on BOX at the time the agency order is executed that are price higher (lower) than the facilitation price will be executed at the facilitation price. Non-Public Customer and Market Maker bids (offers) and Non-Public Customer and Market Maker Response on BOX at the time the Agency Order is executed that are priced higher (lower) than the facilitation price will be executed against the agency order at their stated price. The facilitating OFP will execute at least forty percent (40%) of the original size of the Facilitation Order, but only after better-priced bids (offers) and auction responses on BOX, as well as Public Customer bids (offers) and responses at the facilitation price, are executed in full, based upon price/time priority. Thereafter, Non-Public Customer and Market Maker bids (Offers) and Non-Public Customer and Market Maker responses on BOX at the facilitation price will participate in the execution of the agency order based upon price/time priority. *See* BOX Exchange Rule 7270(a).

[176] *See* Chapter V, Section 31(b) of the current BOX Rules.

[177] Each agency order entered into the Solicitation Auction must be all-or-none. When a proposed solicited cross is entered into the Solicitation Auction, a broadcast message will be sent and Options Participants will be given an opportunity to enter responses with the prices and sizes at which they will be willing to participate in the execution of the agency order. At the end of the one second period for the entry of responses, the agency order will be automatically executed in full or cancelled. The agency order will be executed against the solicited order at the proposed execution price unless (1) there is sufficient size to execute the entire agency order at a better price or prices, or (2) there is a Public Customer order resting on the BOX Book at a price equal to or better than the proposed execution price within the depth of the BOX Book that would have traded with the agency order if the agency order had been submitted to the BOX Book instead of to the Solicitation Mechanism (''Book Priority Public Customer Order''). If there is sufficient size to execute the entire agency order at a better price or prices, the agency order will be executed at the improved price(s) and the Solicited Order will be cancelled. If there is not sufficient size to execute the entire agency order at a better price or prices, whether the agency order will be executed against the Solicited Order at the proposed execution price depends on whether there is one or more Book Priority Public Customer Order(s) on the BOX Book at the time of execution. If no such Book Priority public customer Orders are on the BOX Book at the time of execution, the agency order will be executed against the Solicited Order at the proposed execution price. However, if there is one or more Book Priority Public Customer Orders on the Book, then BOX will calculate whether sufficient size exists to execute the agency order at its proposed price. If there is sufficient size available on the BOX Book to execute the entire agency order at the proposed price, the agency order will be executed against the BOX Book. If there is not sufficient size available on the BOX Book to execute the entire agency order at the proposed price, the agency order and the solicited order will be cancelled and

It will be a violation of an Option Participant's duty of best execution to its customer if it were to cancel a Facilitation Order to avoid execution of the customer order at a better price that may be available on BOX.[178] Additionally, Options Participants may not use the Solicitation Auction to circumvent the limitations in Rule 7140 regarding Participants trading as principal with their customer orders.[179]

The Commission believes that BOX Exchange's proposed display, execution, and priority rules are consistent with the Act. In particular, the Commission finds that the proposed rules are consistent with Section 6(b)(5) of the Act,[180] which, among other things, requires 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 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, and to not permit unfair discrimination between customers, issuers, or dealers. The Commission also finds that the proposed rules are consistent with Section 6(b)(8) of the Act,[181] which requires that the rules of an exchange not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Commission notes that the trading rules of BOX Exchange are substantially similar to the current BOX trading rules, which were filed with and approved by the Commission (or otherwise became effective) pursuant to Section 19(b) of the Act. Thus, the Commission is making its findings regarding BOX Exchange's trading rules for the reasons set forth in the Commission approval orders relating to the current BOX trading rules.

2. Section 11 of the Act

Section 11(a)(1) of the Act[182] prohibits a member of a national securities exchange from effecting transactions on that exchange for its own account, the account of an associated person, or an account over which it or its associated person exercises discretion (collectively, ''covered accounts''), unless an exception applies. The Exchange has represented that it has analyzed its rules proposed hereunder, and believes that they are consistent with Section 11(a) of the Act and rules thereunder. For the reasons set forth below, the Commission believes that BOX Option Participants entering orders into the Trading Host, excluding those transactions effected through the PIP process, will satisfy the conditions of Rule 11a2–2(T). The Commission further believes that BOX Option Participants effecting transactions through the PIP process will satisfy the requirements of Section 11(a)(1)(G) of the Act, provided that BOX Option Participants comply with the requirements set forth in Rule 11a1–1(T) thereunder.

a. Rule 11a2–2(T)

Rule 11a2–2(T) under the Act,[183] known as the ''effect versus execute'' rule, provides exchange members with an exemption from the Section 11(a)(1) prohibition. Rule 11a2–2(T) permits an exchange member, subject to certain conditions, to effect transactions for covered accounts by arranging for an unaffiliated member to execute the transactions on the exchange. To comply with Rule 11a2–2(T)'s conditions, a member: (1) May not be affiliated with the executing member; (2) must transmit the order from off the exchange floor; (3) may not participate in the execution of the transaction once it has been transmitted to the member performing the execution;[184] and (4) with respect to an account over which the member has investment discretion, neither the member nor its associated person may retain any compensation in connection with effecting the transaction except as provided in the Rule.

In a letter to the Commission,[185] BOX Exchange requested that the Commission concur with its conclusion that BOX Options Participants that enter orders into the Trading Host, excluding those transactions effected through the PIP process, satisfy the requirements of Rule 11a2–2(T). For the reasons set forth below, the Commission believes that BOX Option Participants entering orders into the Trading Host, excluding those transactions effected through the PIP process, will satisfy the conditions of Rule 11a2–2(T).

Rule 11a2–2(T)'s first condition is that the order be executed by an exchange member who is unaffiliated with the member initiating the order. The Commission has stated that the requirement is satisfied when automated exchange facilities, such as the Trading Host, are used, as long as the design of these systems ensures that members do not possess any special or unique trading advantages over non-members in handling their orders after transmitting them to the Exchange.[186] BOX Exchange has represented that the design of the trading platform ensures that no member has any special or unique trading advantage in the handling of its orders after transmitting its orders to BOX Exchange.[187] Based on the Exchange's representation, the Commission believes that the Trading Host satisfies this requirement.

Second, Rule 11a2–2(T) requires orders for covered accounts be transmitted from off the exchange floor. The Trading Host receives orders electronically through remote terminals or computer-to-computer interfaces. In the context of other automated trading systems, the Commission has found that the off-floor transmission requirement is met if a covered account order is transmitted from a remote location directly to an exchange's floor by

no executions will occur. *See* BOX Exchange Rule 7270(b)(2).

[178] *See* BOX Exchange IM–7270–1

[179] *See* BOX Exchange IM–7270–5. This may include, but is not limited to, Options Participants entering Solicitation Orders that are solicited from: (1) affiliated broker-dealers; or (2) broker-dealers with which the BOX Options Participant has an arrangement that allows the Options Participant to realize similar economic benefits from the solicited transaction as it would achieve by executing the customer order in whole or in part as principal. Further, any Solicited Orders entered by Options Participants to trade against Agency Orders may not be for the account of a BOX Market Maker that is assigned to the options class.

[180] 15 U.S.C. 78f(b)(5).

[181] 15 U.S.C. 78f(b)(8).

[182] 15 U.S.C. 78k(a)(1).

[183] 17 CFR 240.11a2–2(T).

[184] The member may, however, participate in clearing and settling the transaction. *See* Securities Exchange Act Release No. 14563 (March 14, 1978), 43 FR 11542 (March 17, 1978) (regarding the NYSE's Designated Order Turnaround System (''1978 Release'')).

[185] *See* letter from Lisa Fall, President, BOX Exchange, to Elizabeth Murphy, Secretary, Commission, dated March 30, 2012 (''Exchange 11(a) Request Letter'').

[186] In considering the operation of automated execution systems operated by an exchange, the Commission noted that while there is no independent executing exchange member, the execution of an order is automatic once it has been transmitted into each system. Because the design of these systems ensures that members do not possess any special or unique trading advantages in handling their orders after transmitting them to the exchange, the Commission has stated that executions obtained through these systems satisfy the independent execution requirement of Rule 11a2–2(T). *See* Securities Exchange Act Release No. 15533 (January 29, 1979), 44 FR 6084 (January 31, 1979) (regarding the American Stock Exchange (''Amex'') Post Execution Reporting System, the Amex Switching System, the Intermarket Trading System, the Multiple Dealer Trading Facility of the Cincinnati Stock Exchange, the PCX Communications and Execution System, and the Philadelphia Stock Exchange (''Phlx'') Automated Communications and Execution System (''1979 Release'')).

[187] *See* Exchange 11(a) Request Letter, *supra* note 185.

electronic means.[188] Since the Trading Host receives all orders electronically through remote terminals or computer-to-computer interfaces, the Commission believes that the trading platform satisfies the off-floor transmission requirement.

Third, Rule 11a2–2(T) requires that the member not participate in the execution of its order once it has been transmitted to the member performing the execution. BOX Exchange represented that at no time following the submission of an order is a member able to acquire control or influence over the result or timing of an order's execution.[189] According to BOX Exchange, the execution of a member's order is determined solely by what orders, bids, or offers are present in the Trading Host and where the order is ranked based on an established price-time priority matching algorithm at the time the BOX Options Participant submits the order and on the priority of those orders, bids and offers.[190] Accordingly, the Commission believes that a BOX Options Participant does not participate in the execution of an order submitted into the trading platform.

Fourth, in the case of a transaction effected for an account with respect to which the initiating member or an associated person thereof exercises investment discretion, neither the initiating member nor any associated person thereof may retain any compensation in connection with effecting the transaction, unless the person authorized to transact business for the account has expressly provided otherwise by written contract referring to Section 11(a) of the Act and Rule 11a2–2(T).[191] BOX Options Participants trading for covered accounts over which they exercise investment discretion must comply with this condition in order to rely on the rule's exemption.[192]

b. Section 11(a)(1)(G) and Rule 11a1–1(T)

Section 11(a)(1)(G) of the Act provides an additional exemption from the general prohibition set forth in Section 11(a)(1) for any transaction for a member's own account, provided that: (i) Such member is primarily engaged in certain underwriting, distribution, and other activities generally associated with broker-dealers and whose gross income is derived principally from such business and related activities; and (ii) the transaction is effected in compliance with the rules of the Commission, which, as a minimum, assure that the transaction is not inconsistent with the maintenance of fair and orderly markets and yields priority, parity, and precedence in execution to orders for the account of persons who are not members or associated with members of the exchange.[193] In addition, Rule 11a1–1(T) under the Act specifies that a transaction effected on a national securities exchange for the account of a member which meets the requirements of Section 11(a)(1)(G)(i) of the Act is deemed, in accordance with the requirements of Section 11(a)(1)(G)(ii), to be not inconsistent with the maintenance of fair and orderly markets and to yield priority, parity, and precedence in execution to orders for the account of non-members or persons associated with non-members of the exchange, if such transaction is effected in compliance with certain requirements.[194]

The rules relating to the PIP process of the Trading Host prohibit any orders for the accounts of non-Marker Maker BOX Options Participants to be executed prior to the execution of Public Customer Orders, both CPO and unrelated Customer Orders, and non-BOX Options Participant broker-dealer orders at the same price.[195] Because the rules will require BOX Options Participants that are not market makers[196] to yield priority in the PIP to all non-member orders, the Commission believes that the proposal with respect to transactions effected through the PIP process is consistent with the requirements in Section 11(a) of the Act and Rule 11a1–1(T) thereunder.[197] The Commission also reminds exchanges and their members, however, that, in addition to yielding priority to non-member orders at the same price, members must also meet the other requirements under Section 11(a)(1)(G) of the Act and Rule 11a1–1(T) thereunder (or satisfy the requirements of another exception) to effect transactions for their own accounts.

D. Other BOX Exchange Rules

1. BOX Options Participant Access

Membership on BOX Exchange will be available to any broker or dealer registered under Section 15 of the Act that meets the standards for membership set forth in the Rule 2000 Series of BOX Exchange's rules.[198]

---

[188] *See, e.g.,* Securities Exchange Act Release Nos. 59154 (December 23, 2008) 73 FR 80468 (December 31, 2008) (SR–BSE–2008–48) (order approving proposed rules of BX); 49068, *supra* note 6 (establishing, among other things, BOX as an options trading facility of BSE); 44983, *supra* note 130 (approving the PCX's use of the Archipelago Exchange as its equity trading facility); 29237 (May 24, 1991), 56 FR 24853 (May 31, 1991) (regarding NYSE's Off-Hours Trading Facility). *See* 1978 Release, *supra* note 184. *See* 1979 Release, *supra* note 186.

[189] *See* Exchange 11(a) Request Letter, *supra* note 185. The member may only cancel or modify the order, or modify the instructions for executing the order, but only from off the Exchange floor. The Commission has stated that the non-participation requirement is satisfied under such circumstances so long as such modifications or cancellations are also transmitted from off the floor. *See* 1978 Release, *supra* note 184 (stating that the ''non-participation requirement does not prevent initiating members from canceling of modifying orders (or the instructions pursuant to which the initiating member wishes orders to be executed) after the orders have been transmitted to the executing member, provided that any such instructions are also transmitted from off the floor'').

[190] *See* Exchange 11(a) Request Letter, *supra* note 185.

[191] 17 CFR 240.11a2–2(T)(a)(2)(iv). In addition, Rule 11a2–2(T)(d) requires a member or associated person authorized by written contract to retain compensation, in connection with effecting transactions for covered accounts over which such member or associated person thereof exercises investment discretion, to furnish at least annually to the person authorized to transact business for the account a statement setting forth the total amount of compensation retained by the member in connection with effecting transactions for the account during the period covered by the statement. *See* 17 CFR 240.11a2–2(T)(d). *See also* 1978 Release, *supra* note 184 (stating ''[t]he contractual and disclosure requirements are designed to assure that accounts electing to permit transaction-related compensation do so only after deciding that such arrangements are suitable to their interests'').

[192] *See* Exchange 11(a) Request Letter, *supra* note 185.

[193] *See* 15 U.S.C. 78k(a)(1)(G).

[194] Rule 11a1–1(T)(a)(1)–(3) provides that each of the following requirements must be met: (1) A member must disclose that a bid or offer for its account is for its account to any member with whom such bid or offer is placed or to whom it is communicated, and any member through whom that bid or offer is communicated must disclose to others participating in effecting the order that it is for the account of a member; (2) immediately before executing the order, a member (other than the specialist in such security) presenting any order for the account of a member on the exchange must clearly announce or otherwise indicate to the specialist and to other members then present for the trading in such security on the exchange that he is presenting an order for the account of a member; and (3) notwithstanding rules of priority, parity, and precedence otherwise applicable, any member presenting for execution a bid or offer for its own account or for the account of another member must grant priority to any bid or offer at the same price for the account of a person who is not, or is not associated with, a member, irrespective of the size of any such bid or offer or the time when entered. *See* 17 CFR 240.11a1–1(T)(a)(1)–(3).

[195] *See* BOX Rules, 7150(f)(4) and (g)(3)(i).

[196] Section 11(a)(1)(A) of the Act provides an exception to the general prohibition in Section 11(a) on an exchange member effecting transactions for its own account if such member is a dealer acting in the capacity of a market maker. *See* 15 U.S.C. 78k(a)(1)(A).

[197] *See also* Securities Exchange Act Release No. 49068, *supra* note 6.

[198] *See* BOX Exchange Rule 2020(a); Form 1 Application, Exhibit L. To become or continue as a BOX Options Participant, a firm must: (1) Have as the principal purpose of being a Participant the conduct of a securities business; (2) be a Clearing Participant or establish a clearing arrangement with a Clearing Participant; (3) meet the capital requirements of BOX Exchange or Rule 15c3–1 of the Act, whichever is greater; (4) demonstrate an ability to adhere to all applicable Exchange,

Access to the Trading Host will be available to persons that have applied and been approved by BOX Exchange as BOX Options Participants.[199] BOX Exchange will have two classes of BOX Options Participants: (1) OFPs, who can represent customer orders as agents and/or conduct proprietary trading; and (2) market makers. OFPs can transact business with public customers only if the OFPs are members of another registered national securities exchange or association.[200]

For a temporary 90-day period after the Commission's approval of BOX Exchange's Form 1 Application, an applicant that is an active member of FINRA or a registered national securities exchange and is a current or former BOX Options Participant of BOX trading facility will not be required to submit a full application for membership on the Exchange, but rather will only need to complete a short-form waive-in membership application form.[201] This waive-in process is similar to arrangements that were in place temporarily at other SROs.[202] All other applicants (and after the 90-day period has ended, those that could have waived in through the expedited process) may apply for membership on the Exchange by submitting a full membership application to the Exchange.[203] Applications for association with a BOX Options Participant shall be submitted to the Exchange on Form U–4 and such other forms as BOX Exchange may prescribe.[204]

A prospective BOX Options Participant must enter into a Participant Agreement, whereby it will, among other things, agree to abide by the Agreement, the Exchange Rules, and by all circulars, notices, directives or decisions adopted pursuant to or made in accordance with the Rules. Pursuant to BOX Exchange's rules, every applicant must have and maintain membership in another options exchange that is registered under the Act and that is not registered solely under Section 6(g) of the Act.[205]

The Exchange will receive and review all membership applications, and will provide to the applicant written notice of the Exchange's determination within 30 days after completion of its consideration of an application, specifying in the case of disapproval of an application the grounds thereof.[206] The Exchange also will qualify associated persons of BOX Options Participants.[207] Once an applicant becomes a BOX Options Participant or a person associated with a BOX Options Participant, it must continue to satisfy all of the qualifications to be an options participant set forth in the BOX Exchange rules.[208] When BOX Exchange has reason to believe that a BOX Options Participant or associated person fails to meet such qualifications, the Exchange may suspend or terminate such person's membership or association.[209]

The Commission finds that BOX Exchange's membership rules are consistent with Section 6 of the Act,[210] including Section 6(b)(2) of the Act [211] in particular, which requires that a national securities exchange have rules that provide that any registered broker or dealer or natural person associated with such broker or dealer may become a member and any person may become associated with an exchange member. The Commission notes that pursuant to Section 6(c) of the Act,[212] an exchange must deny membership to any person, other than a natural person, that is not a registered broker or dealer, any natural person that is not, or is not associated with, a registered broker or dealer, and registered broker-dealers that do not satisfy certain standards, such as financial responsibility or operational capacity. As a registered exchange, BOX Exchange must independently determine if an applicant satisfies the standards set forth in the Act, regardless of whether an applicant is a member of another SRO.[213]

2. Linkage

The Exchange plans to become a participant in the Plan Relating to Options Order Protection and Locked/Crossed Markets or any successor plan (''Linkage Plan'').[214] If admitted as a participant to the Plan, other plan participants would be able to send orders to the Trading Host in accordance with the terms of the plan as applied to the Exchange.

BOX Exchange rules include relevant definitions, establish the conditions pursuant to which members may enter orders in accordance with the Linkage Plan, impose obligations on the Exchange regarding how it must process incoming orders, establish a general standard that members and the Exchange should avoid trade-throughs, establish potential regulatory liability for members that engage in a pattern or practice of trading through other exchanges, and establish obligations with respect to locked and crossed markets.

The Commission believes that BOX Exchange has proposed rules that are designed to comply with the requirements of the Linkage Plan.[215] Further, before BOX Exchange can commence operations as an exchange, BOX Exchange must become a participant in the Linkage Plan.

3. Market Makers

a. Registration of Market Makers

A BOX Options Participant may register with BOX Exchange as a market maker by filing a written application with the Exchange, which will consider an applicant's market making ability and other factors it deems appropriate in determining whether to approve an applicant's registration.[216] To qualify for registration as a market maker, a BOX Options Participant must meet the requirements established in Rule 15c3–1(a)(6)(i) under the Act and the general requirements set forth in BOX Exchange Rule 8000.[217] All market makers will be designated as specialists on the Exchange for all purposes under the Act and rules thereunder.[218] BOX Exchange will not limit the number of qualifying entities that may become market makers.[219] The registration of a market

Commission, Options Clearing Corporation and Federal Reserve Board policies, rules and regulations, including those concerning record-keeping, reporting, finance and trading procedures; and (5) be able to satisfactorily demonstrate reasonably adequate systems capability and capacity. *See also* BOX Exchange Rules 2000, 2010, 2020 and 10000 Series.

[199] *See* BOX Exchange Rule 2010. *See also* Form 1 Application, Exhibit L.

[200] *See* BOX Exchange Rule 4000.

[201] *See* BOX Exchange Rules 2030. *See also* Form 1 Application, Exhibit L.

[202] *See, e.g.,* Nasdaq Rule 1013(a)(5)(C) (containing a similar expedited waive-in membership process for members of FINRA).

[203] *See* BOX Exchange Rule 2030.

[204] *See* BOX Exchange IM–2040–6.

[205] *See* BOX Exchange Rule 2010.

[206] *See* BOX Exchange Rule 2000(b).

[207] *Id. See also* BOX Exchange Rule 2030.

[208] *See* BOX Exchange Rule 2040.

[209] *See* BOX Exchange Rule 2040.

[210] 15 U.S.C. 78f.

[211] 15 U.S.C. 78f(b)(2).

[212] 15 U.S.C. 78f(c).

[213] *See, e.g.,* BATS Order, *supra* note 21, at 73 FR 49502; and Nasdaq Order, *supra* note 34, at 71 FR 3555.

[214] *See* Form 1 Application, Exhibit E, Response 6. *See also* Securities Exchange Act Release No. 60405 (July 30, 2009), 74 FR 39362 (August 6, 2009) (File No. 4–546) (order approving the national market system Plan Relating to Options Order Protection and Locked/Crossed Markets Submitted by the Chicago Board Options Exchange, Incorporated (''CBOE''), ISE, The NASDAQ Stock Market LLC, NASDAQ OMX BX, Inc., NASDAQ OMX PHLX, Inc., NYSE Amex LLC, and NYSE Arca, Inc.).

[215] *See* BOX Exchange Rule 15000 Series.

[216] *See* BOX Exchange Rule 8000(b) and (c).

[217] *See* BOX Exchange Rule 8010.

[218] *See* BOX Exchange Rule 8000(a).

[219] *See* BOX Exchange Rule 8000(e). However, BOX Exchange may limit access to the System

Continued

maker may be suspended or terminated by the Exchange upon a determination that such market maker failed to properly perform as a market maker, comply with BOX Exchange rules, or acted in a manner inconsistent with the best interest of fair and orderly markets.[220]

The Commission finds that BOX Exchange's proposed market maker qualifications requirements are consistent with the Act. In particular, BOX Exchange's rules provide an objective process by which a BOX Options Participant can become a market maker on the BOX and provide for appropriate oversight by the Exchange to monitor for continued compliance by market makers with the terms of their application for such status and the BOX Exchange Rules. The Commission notes that BOX Exchange's proposed market maker registration requirements are similar to those of other options exchanges.[221]

b. Market Maker Obligations

Pursuant to BOX Exchange rules, the transactions of a market maker in its market making capacity must constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market.[222] Among other things, a market maker must: (1) Maintain a two-sided market on a continuous basis for options classes to which it is appointed at least 60% of the time that the classes are open for trading; [223] (2) engage in dealings for its own account when there is a lack of price continuity, a temporary disparity between the supply of and demand for a particular option contract, or a temporary distortion of the price relationships between options contracts of the same class; (3) compete with other market makers; (4) update quotations in response to changed market conditions; (5) maintain active markets; and (6) make markets that will be honored for the number of contacts entered.[224] In addition, market makers must maintain minimum net capital in accordance with Commission and BOX Exchange rules.[225] Market makers also must maintain information barriers that are reasonably designed to prevent the misuse of material, non-public information.[226]

If BOX Exchange finds any substantial or continued failure by a market maker to engage in a course of dealings as specified in Exchange Rule 8040, then such market maker will be subject to disciplinary action, suspension, or revocation of registration in one or more of the securities in which the market maker is registered.[227]

Market makers receive certain benefits for carrying out their responsibilities.[228] For example, a broker-dealer or other lender may extend ''good faith'' credit to a member of a national securities exchange or registered broker-dealer to finance its activities as a market maker or specialist.[229] In addition, market makers are excepted from the prohibition in Section 11(a) of the Act.[230] The Commission believes that a market maker must have sufficient affirmative obligations, including the obligation to hold itself out as willing to buy and sell options for its own account on a regular or continuous basis, to justify this favorable treatment.[231]

The Commission further believes that the rules of all U.S. options markets need not provide the same standards for market maker participation, so long as they impose affirmative obligations that are consistent with the Act.[232] The Commission believes that BOX Exchange's market maker participation requirements impose sufficient affirmative obligations on the Exchange's market makers and, accordingly, that BOX Exchange's requirements are consistent with the Act. In particular, the Act does not mandate a particular market model for exchanges, and while market makers may become an important source of liquidity on BOX Exchange, they will likely not be the only source as BOX is designed to match buying and selling interest of all BOX Options Participants.

4. Discipline and Oversight of Members

As noted above, one prerequisite for Commission granting an exchange's application for registration is that a proposed exchange must be so organized and have the capacity to carry out the purposes of the Act. Specifically, an exchange must be able to enforce compliance by its members and persons associated with its members with federal securities laws and the rules of the exchange.[233]

BOX Exchange rules codify BOX Exchange's disciplinary jurisdiction over its members, thereby facilitating its ability to enforce its members' compliance with its rules and the federal securities laws.[234] BOX Exchange's rules permit it to sanction members for violations of its rules and violations of the federal securities laws by, among other things, expelling or suspending members; limiting members' activities, functions, or operations; fining or censuring members; suspending or barring a person from being associated with a member; or any other appropriate sanction.[235]

BOX Exchange's disciplinary and oversight functions will be administered in accordance with Rule 12000 Series, which governs disciplinary actions. BOX Exchange regulatory staff will, among other things, investigate potential securities laws violations and initiate charges pursuant to BOX Exchange rules.[236]

Upon a finding by BOX Exchange's regulatory staff (and approved by the CRO) of probable cause of a violation within the disciplinary jurisdiction of the Exchange and that further proceedings are warranted,[237] BOX

based on System constraints, capacity restrictions, or other factors relevant to protecting the integrity of the System, pending action required to address the issue of concern. To the extent that BOX Exchange places limitations on any Participant's access to the System, such limits shall be objectively determined and submitted to the Commission for approval pursuant to a rule change filed under Section 19(b) of the Act.

[220] *See* BOX Exchange Rule 8000(d).

[221] *See, e.g.,* Nasdaq Rules, Chapter VII, Sections 2 and 4; Chapter VI, Section 2 of the current BOX Rules; and ISE Rule 804.

[222] *See* BOX Exchange Rule 8040.

[223] *See* BOX Exchange Rule 8050(e). These obligations will apply to all of the Market Maker's appointed classes collectively, rather than on a class-by-class basis.

[224] *See* BOX Exchange Rule 8040.

[225] *See* BOX Exchange Rule 8080.

[226] *See* BOX Exchange Rule 8090.

[227] *See* BOX Exchange Rule 8040(f).

[228] *See, e.g.,* NOM Approval Order, *supra* note 122 (discussing the benefits and obligations of market makers).

[229] *See* 12 CFR 221.5 and 12 CFR 220.7; *see also* 17 CFR 240.15c3–1(a)(6) (capital requirements for market makers).

[230] 15 U.S.C. 78k(a).

[231] *See* NOM Approval Order, *supra* note 122, at 73 FR 14526.

[232] *See e.g.,* C2 Order, *supra* note 29 and NOM Approval Order, *supra* note 122.

[233] *See* 15 U.S.C. 78f(b)(1).

[234] *See* BOX Exchange Rule 12000 Series.

[235] *Id.*

[236] *See* BOX Exchange Rule 12000 Series. As noted above, BOX Exchange has entered into a RSA with FINRA under which FINRA will perform certain regulatory functions on behalf of BOX Exchange. FINRA may perform some or all of the functions specified in the Rule 12000 Series. *See also* BOX Exchange Rule 12150 and IM–12150–1. FINRA will: Assist BOX Exchange in conducting investigations of potential violations of BOX Exchange rules and/or federal securities laws related to activity on the Exchange; conduct examinations related to BOX Option Participants' conduct on BOX Exchange; assist BOX Exchange with disciplinary proceedings pursuant to BOX Exchange rules, including issuing charges and conducting hearings; and provide dispute resolution services to BOX Option Participants on behalf of BOX Exchange, including operation of the BOX Exchange's arbitration program. *See supra* notes 236 to 243 and accompanying text.

[237] *See* BOX Exchange Rule 12040. If there is probable cause for finding a violation, the Exchange regulatory staff will prepare a statement of charges including the allegations and specifying the provisions of the Act and/or Exchange rules, regulations or policies thereunder alleged to have been violated by the BOX Options Participant or

Exchange will conduct a hearing on disciplinary matters before a professional hearing officer [238] and two members of the Hearing Committee [239] (the ''Panel'').[240] The BOX Options Participant (or associated person) or the Exchange regulatory staff may petition for review of the decision of the Panel by the BOX Exchange Board.[241] The review will be conducted by the BOX Exchange Board or a committee thereof composed of at least three Directors of the BOX Exchange Board (whose decision must be ratified by a majority of the BOX Exchange Board) and such decision will be final.[242] In addition, the BOX Exchange Board on its own motion may order review of a disciplinary decision.[243]

Appeals from any termination or suspension with regard to access to the Exchange will be instituted under, and governed by, the provisions in the Rule 13000 Series of the Exchange Rules. BOX Exchange Rule Series 13000 applies to persons economically aggrieved by any of the following Exchange actions including, but not limited to: (a) Denial of an application to become a BOX Options Participant; (b) prohibiting a person from becoming associated with a BOX Options Participant; (c) limiting, suspending, or prohibiting a BOX Options Participant's activities, functions or operations on BOX Exchange; or (d) limiting or denial of access to services provided to a BOX Options Participant pursuant to BOX Exchange rules.[244]

Any person aggrieved by an action of the Exchange within the scope of the 13000 Rule Series may file a written application to be heard within thirty days [245] after such action has been taken.[246] Applications for hearing and review will be referred to the Hearing Committee, which will appoint a hearing panel of no less than three members of such committee.[247] The decision of the hearing panel shall be made in writing and sent to the parties to the proceedings.[248] The decision of the hearing panel made pursuant to the 13000 Rule Series becomes final thirty calendar days after issuance unless the applicant, the Chief Executive Officer of BOX Exchange or his designee, or the BOX Exchange Board on its own motion, petitions for review of the decision.[249] The BOX Exchange Board, or a committee of the BOX Exchange Board, will have sole discretion to grant or deny either request.[250] The review shall be conducted by the BOX Exchange Board or a committee of the BOX Exchange board composed of at least three directors.[251] The BOX Exchange Board or its designated committee may affirm, reverse or modify in whole or in part, the decision of the hearing panel.[252]

The Commission finds that BOX Exchange's proposed disciplinary and oversight rules and structure, as well as its proposed process for persons economically aggrieved by certain BOX Exchange actions, are consistent with the requirements of Sections 6(b)(6) and 6(b)(7) of the Act [253] in that they provide fair procedures for the disciplining of members and persons associated with members. The Commission further finds that the proposed BOX Exchange rules are designed to provide the Exchange with the ability to comply, and with the authority to enforce compliance by its members and persons associated with its members, with the provisions of the Act, the rules and regulations thereunder, and the rules of BOX Exchange.[254]

5. Listing Requirements

BOX Exchange does not intend to offer original listings. Instead, BOX Exchange will list and trade only equity and index options that are listed on other national securities exchanges and cleared by the Options Clearing Corporation.[255] The Commission finds that BOX Exchange's proposed initial and continued listing rules are consistent with the Act, including Section 6(b)(5), in that they are designed to protect investors and the public interest and to promote just and equitable principles of trade. The Commission notes that, before beginning operation, BOX Exchange will need to become a participant in the Plan for the Purpose of Developing and Implementing Procedures Designed to Facilitate the Listing and Trading of Standardized Options Submitted Pursuant to Section 11A(a)(3)(B) of the Act (''OLPP''). In addition, before beginning operation, BOX Exchange will need to become a participant in the Options Clearing Corporation.

associated person. The CRO must approve the statement of charges.

[238] *See* BOX Exchange Rule IM–12150–1. As noted above, BOX Exchange has entered into a RSA with FINRA to provide certain regulatory functions, including providing professional hearing officers. Under BOX Exchange Rule 12060(a), the professional hearing officer is designated as the Chairman of the Panel. Under BOX Exchange Rule 12060(e), the Panel Chairman has the sole responsibility to determine the time and place of all meetings of the Panel, and make all determinations with regard to procedural or evidentiary matters, as well as prescribe the time within which all documents, exhibits, briefs, stipulations, notices or other written materials must be filed where such is not specified in Exchange rules.

[239] *See* BOX Exchange Bylaws Section 6.08. The Hearing Committee is not a BOX Exchange Board committee but is a separate committee of BOX Exchange. Promptly after the annual meeting of the BOX Exchange owners, the Chairman of the BOX Exchange Board will appoint a Hearing Committee composed of such number of BOX Options Participants and individuals who are not BOX Options Participants, as determined by the Chairman, none of whom shall be Directors. The Hearing Committee or any panel thereof shall include at least one officer, director or employee of a BOX Options Participant. The Hearing Committee shall have exclusive jurisdiction to conduct hearings on disciplinary proceedings brought by the Exchange against any BOX Options Participant, or any person employed by or associated with any BOX Options Participant for any alleged violation of the Act, the rules and regulations thereunder, the BOX Exchange Bylaws or the rules, or the interpretations and stated policies of the BOX Exchange Board.

[240] *See* BOX Exchange Rule 12060. A Panel may make a determination without a hearing and may impose a penalty as to violations that the BOX Options Participant or associated person has admitted or has failed to answer or that otherwise do not appear to be in dispute. *See* BOX Exchange Rule 12080. A BOX Options Participant or associated person alleged to have committed a disciplinary violation may submit a written offer of settlement to the Panel, or CRO if a Panel is not yet been appointed, which the Panel or CRO may accept or reject. If the second offer of settlement is rejected (such decision is not subject to review), a hearing will proceed in accordance with BOX Exchange Rule 12060. *See* BOX Exchange Rule 12090.

[241] *See* BOX Exchange Rule 12100.

[242] *See* BOX Exchange Rule 12100.

[243] *Id.*

[244] *See* BOX Exchange Rule 13000. As noted above, BOX Exchange has entered into a RSA with FINRA under which FINRA will perform certain regulatory functions on behalf of BOX Exchange. FINRA may perform some or all of the functions specified in the Rule 13000 Series. *See supra* note 236. *See also* BOX Exchange Rule 13060.

[245] An applicant may file for an extension of time as allowed by the Chairman of the Hearing Committee within thirty days of the Exchange action. An application for an extension will be ruled upon by the Chairman of the Hearing Committee, and his ruling will be given in writing. Rulings on applications for extensions of time are not subject to appeal. *See* BOX Exchange Rule 13000.

[246] The application must include: (1) The action for which review is sought; (2) the specific reasons for the applicant's exception to such action; (3) the relief sought; and (4) whether the applicant intends to submit any documents, statements, arguments or other material in support of the application, with a description of any such materials. *See* BOX Exchange Rule 13010.

[247] *See* BOX Exchange Rule 13020.

[248] *See* BOX Exchange Rule 13030.

[249] *See* BOX Exchange Rule 13040(a).

[250] *Id.*

[251] *See* BOX Exchange Rule 13040(b).

[252] The decision of the BOX Exchange Board or its designated committee shall be in writing, shall be sent to the parties to the proceeding, and shall be final. *See* BOX Exchange Rule 13040(c).

[253] 15 U.S.C. 78f(b)(6) and (b)(7), respectively.

[254] *See* Section 6(b)(1) of the Act, 15 U.S.C. 78f(b)(1).

[255] BOX Exchange's listing rules for the underlying securities and indices of the options to be traded are substantially similar to the rules of another exchange. *See* BOX Exchange Rule 5020 and ISE Rule 502.

III. Exemption From Section 19(b) of the Act With Regard to FINRA Rules Incorporated by Reference

BOX Exchange proposes to incorporate by reference certain FINRA rules.[256] Thus, for certain BOX Exchange rules, BOX Options Participants will comply with a BOX Exchange rule by complying with the referenced FINRA rule.

In connection with the proposal to incorporate the FINRA rules by reference, BOX Exchange requested, pursuant to Rule 240.0–12 under the Act,[257] an exemption under Section 36 of the Act from the rule filing requirements of Section 19(b) of the Act for changes to the BOX Exchange rules that are effected solely by virtue of a change to a cross-referenced FINRA rule.[258] BOX Exchange proposes to incorporate by reference categories of rules, rather than individual rules within a category, that are not trading rules. BOX Exchange agrees to provide written notice to BOX Options Participants whenever FINRA proposes a change to a cross-referenced rule [259] and whenever any such proposed changes are approved by the Commission or otherwise become effective.[260]

Using the authority under Section 36 of the Act, the Commission previously exempted certain SROs from the requirement to file proposed rule changes under Section 19(b) of the Act.[261] Each exempt SRO agreed to be governed by the incorporated rules, as amended from time to time, but is not required to file a separate proposed rule change with the Commission each time the SRO whose rules are incorporated by reference seeks to modify such rules. In addition, each exempt SRO incorporated by reference only regulatory rules, for example, margin, suitability, and arbitration rules, and not trading rules, and incorporated by reference whole categories of rules. Each exempt SRO had reasonable procedures in place to provide written notice to its members each time a change is proposed to the incorporated rules of another SRO in order to provide such members with notice of a proposed rule change that affects the members' interests, so that the members will have an opportunity to comment.

The Commission is granting BOX Exchange's request for exemption, pursuant to Section 36 of the Act, from the rule filing requirements of Section 19(b) of the Act with respect to the rules that BOX Exchange proposes to incorporate by reference. The exemption is conditioned upon BOX Exchange providing written notice to BOX Options Participants whenever FINRA proposes to change an incorporated by reference rule. The Commission believes that the exemption is appropriate in the public interest and consistent, with the protection of investors because it will promote more efficient use of Commission and SROs resources by avoiding duplicative rule filings based on simultaneous changes to identical rule text sought by more than one SRO.

IV. Conclusion

It is ordered that the application of BOX Exchange for registration as a national securities exchange be, and it hereby is, granted.

It is furthered ordered that operation of BOX Exchange is conditioned on the satisfaction of the requirements below:

A. *Participation in National Market System Plans Relating to Options Trading.* BOX Exchange must join: (1) The Plan for the Reporting of Consolidated Options Last Sale Reports and Quotation Information (Options Price Reporting Authority); (2) the OLPP; (3) the Linkage Plan; and (4) the Plan of the Options Regulatory Surveillance Authority.

B. *Participation in Multiparty Rule 17d–2 Plans.* BOX Exchange must become a party to the multiparty Rule 17d–2 agreements concerning options sales practice regulation and market surveillance.

C. *Participation in the Options Clearing Corporation.* BOX Exchange must become an Options Clearing Corporation participant exchange.

D. *Participation in the Intermarket Surveillance Group.* BOX Exchange must join the Intermarket Surveillance Group.

E. *Effective Regulation.* BOX Exchange must have, and represent in a letter to the staff in the Commission's Office of Compliance Inspections and Examinations that it has, adequate procedures and programs in place to effectively regulate the BOX options trading facility.

F. *Trade Processing and Exchange Systems.* BOX Exchange must have, and represent in a letter to the staff in the Commission's Division of Trading and Markets that it has, adequate procedures and programs in place, as detailed in Commission Automation Policy Review guidelines, to effectively process trades and maintain the confidentiality, integrity, and availability of BOX Exchange's systems.[262]

It is further ordered, pursuant to Section 36 of the Act,[263] that BOX Exchange shall be exempted from the rule filing requirements of Section 19(b) of the Act with respect to the FINRA rules that BOX Exchange proposes to incorporate by reference, subject to the conditions specified in this Order.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2012–10620 Filed 5–2–12; 8:45 am]

BILLING CODE 8011–01–P

---

[256] Specifically, BOX Exchange proposes to incorporate by reference the following FINRA rules: Series 12000 (Code of Arbitration for Customer Disputes) and 13000 (Code of Arbitration Procedure for Industry Disputes), referenced in Exchange Rule 14000.

[257] 17 CFR 240.0–12.

[258] *See* letter from Lisa J. Fall, President, BOX Exchange, to Elizabeth M. Murphy, Secretary, Commission, dated March 30, 2012 (''Section 19(b) Exemption Request'').

[259] *See id.*

[260] BOX Exchange will provide such notice through a posting on the same Web site location where BOX Exchange posts its own rule filings pursuant to Rule 19b–4 under the Act, within the required time frame. The Web site posting will include a link to the location on the FINRA Web site where FINRA's proposed rule change is posted. *See id.*

[261] *See e.g.,* DirectEdge Exchanges Order and BATS Order, *supra* note 21, C2 Order, *supra* note 29, Nasdaq Order, *supra* note 34 and NOM Approval Order, supra note 122.

[262] On November 16, 1989, the Commission published its first Automation Review Policy (''ARP I''), in which the Commission created a voluntary framework for SROs to establish comprehensive planning and assessment programs to determine systems capacity and vulnerability. On May 9, 1991, the Commission published its second Automation Review Policy (''ARP II'') to clarify the types of review and reports expected from SROs. *See* Securities Exchange Act Release Nos. 27445 (November 16, 1989), 54 FR 48703 (November 24, 1989) and 29185 (May 9, 1991), 56 FR 22490 (May 15, 1991).

[263] 15 U.S.C. 78mm.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66872; File No. SR–FINRA–2012–001]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendments No. 1 and 2, To Amend FINRA Rule 4560 (Short-Interest Reporting)

April 27, 2012.

I. Introduction

On January 10, 2012, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4

[1] 15 U.S.C. 78s(b)(1).

thereunder,[2] a proposed rule change to amend FINRA Rule 4560. On January 20, 2012, FINRA filed Amendment No. 1 to the proposed rule change (''Amendment No. 1'').[3] The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on January 30, 2012.[4] The Commission received one comment letter, from the Securities Industry and Financial Markets Association (''SIFMA''), on the proposal.[5] On April 23, 2012, FINRA responded to the comments in the SIFMA Letter[6] and filed Amendment No. 2 to the proposed rule change (''Amendment No. 2'' and collectively with Amendment No. 1, the ''Amendments'').[7] The Commission is publishing this notice and order to solicit comments on Amendment No. 2 and to approve the proposed rule change, as modified by the Amendments, on an accelerated basis.

II. Description of the Proposal

FINRA has proposed to amend FINRA Rule 4560. FINRA Rule 4560 (the ''Rule'') requires each FINRA member to maintain a record of total short positions in all customer and proprietary firm accounts in all equity securities (other than Restricted Equity Securities as defined in Rule 6420) and regularly report such information to FINRA in the manner prescribed by FINRA. The Rule generally provides that the short positions to be recorded and reported are those resulting from ''short sales'' as that term is defined in Rule 200(a) of Regulation SHO.[8] FINRA has proposed to amend the Rule to clarify members' recording and reporting obligations and to delete several exceptions to the Rule.

First, FINRA has proposed to codify interpretive guidance previously issued by the Intermarket Surveillance Group (ISG) that instructed members to report ''gross'' short positions existing in each proprietary and customer account (rather than net positions across accounts).[9] Thus, the proposed rule change provides that members must report all gross short positions existing in each firm or customer account, including the account of a broker-dealer, that resulted from a ''short sale'' as that term is defined in Rule 200(a) of Regulation SHO, as well as where the sale transaction that caused the short position was marked ''long,'' consistent with SEC Regulation SHO, due to the firm's or the customer's net long position at the time of the transaction (*e.g.,* aggregation units).

Second, FINRA has proposed to clarify that members' short interest reports must reflect only those short positions that have settled or reached settlement date by the close of the reporting settlement date designated by FINRA. Therefore, short positions resulting from short sales that were effected but have not reached settlement date by the given designated reporting settlement date, should not be included in a member's short interest report for that reporting cycle. Of course, short interest positions resulting from short sales that reached the expected settlement date, but failed to settle (*i.e.,* ''fails''), must be included.

Third, FINRA has proposed to clarify that members must reflect company-related actions in their short-interest reports adjusted as of the ex-date of the corporate action (and if no ex-date is declared by a self-regulatory organization (''SRO''), then the payment date).[10] Therefore, for the purposes of short interest reporting, members must reflect corporate actions (*e.g.,* a reverse or forward split) that impact the total number of shares in the short position in their short interest report for a reporting cycle if the ex-date of the corporate action occurs by the reporting settlement date designated by FINRA for such cycle (even if payment of the distribution is not received until after the designated reporting settlement date).

Finally, consistent with discussions with the ISG, FINRA has proposed amendments to delete certain existing exceptions to the Rule.[11] The Rule provides five exceptions, including an exception for stabilizing activity, domestic arbitrage and international arbitrage. FINRA, in cooperation with the ISG Short Interest Working Group (''ISG Working Group''), determined that the transactions addressed in these three exceptions result in the type of short positions that would be of interest to regulators and the public, and therefore, determined that these exceptions no longer are appropriate.[12]

FINRA has stated that it believes that the proposed amendments will remove confusion regarding the operation of the Rule and help facilitate the availability to the public and regulators of accurate and complete short interest information.

FINRA has represented that it will announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 120 days following Commission approval. FINRA has also represented that the effective date will be no more than 365 days following Commission approval.

---

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 was a partial amendment that clarified the reference to a defined term in SEC Regulation SHO in the rule text and purpose section of the proposed rule change.

[4] *See* Securities Exchange Act Release No. 66220 (January 24, 2012), 77 FR 4599 (January 30, 2012).

[5] *See* letter from Melissa MacGregor, Managing Director and Associate General Counsel, SIFMA, to Elizabeth M. Murphy, Secretary, Commission, dated February 23, 2012 (''SIFMA Letter'').

[6] *See* letter from Racquel L. Russell, Assistant General Counsel, FINRA, to Elizabeth M. Murphy, Secretary, Commission, dated April 23, 2012 (''Response Letter'').

[7] Amendment No. 2 was a partial amendment that deleted the proposed requirement concerning the adjustment of corporate actions for short interest reporting purposes. The text of the proposed rule change and FINRA's Response Letter are available on FINRA's Web site at *http://www.finra.org,* at the principal offices of FINRA, on the Commission's Web site at *http://www.sec.gov,* and at the Commission's Public Reference Room.

[8] Rule 200 of SEC Regulation SHO provides that ''short sale'' means ''any sale of a security which the seller does not own or any sale which is consummated by the delivery of a security borrowed by, or for the account of, the seller.'' *See* Rule 200(a) of SEC Regulation SHO, 17 CFR 242.200. SEC Rule 200 further provides, among other things, that a person is deemed to own a security if: (a) The person or his agent has title to it; or (b) The person has purchased, or has entered into an unconditional contract, binding on both parties thereto, to purchase it, but has not yet received it; or (c) The person owns a security convertible into or exchangeable for it and has tendered such security for conversion or exchange; or (d) The person has an option to purchase or acquire it and has exercised such option; or (e) The person has rights or warrants to subscribe to it and has exercised such rights or warrants; or (f) The person holds a security futures contract to purchase it and has received notice that the position will be physically settled and is irrevocably bound to receive the underlying security. *See* Rule 200(b) of SEC Regulation SHO.

[9] *See* Intermarket Surveillance Group, Consolidated Reporting of Short Interest Positions, ISG Regulatory Memorandum 95–01 (March 6, 1995).

[10] The ex-date is the date on or after which a security is traded without a specific dividend or distribution. The ex-date also is the date that DTCC uses to determine who is entitled to the distribution. The payable date is the date that the dividend is sent to the record owner of the security. *See e.g., Regulatory Notice* 00–54 (August 2000).

[11] FINRA has worked closely with other SRO members of the ISG, a group that includes representatives of every U.S. SRO, to address problems that reach across marketplaces. Each ISG member adopted consistent short-interest reporting rules to enhance surveillance capabilities, augment market transparency, enable investors to make more informed decisions, and provide greater disclosure for regulatory purposes.

[12] FINRA and the ISG Working Group determined that the remaining two exceptions continue to be appropriate. Specifically, the exception for sales for an account in which the person has an interest, owns the security and intends to deliver it as soon as is possible (which FINRA is retaining) is intended to address circumstances where there may be a brief delay in delivery but the sale is a long sale, *i.e.,* exercise of a right, option, or warrant. In addition, the over-allotment exception (which FINRA also is retaining) addresses the narrow circumstance where the underwriter has not received shares and results in a short position for a very brief duration.

III. Summary of Comments and FINRA's Response

In the SIFMA Letter, the commenter generally supports the proposal but raised concerns with one aspect of the proposal. In the SIFMA Letter, the commenter also recommends other changes to the existing short interest reporting requirements. First, the commenter supports (1) the reporting of short positions based on gross short positions in all customer and proprietary accounts, (2) the deletion of certain existing exceptions to short interest reporting for stabilizing activity, domestic arbitrage and international arbitrage, and (3) the reporting of short positions that have settled or reached settlement date by the close of the reporting settlement date designated by FINRA. The commenter, however, opposes the proposed requirement that short interest reports reflect corporate actions adjusted as of the ex-date of the corporate action (and if no ex-date is declared by an SRO, then the payment date of a corporate action). The commenter argues that such requirement is inconsistent with other proposed requirements, is inconsistent with how firms maintain their stock records and how firms' systems capture short interest position information, and would require extensive programming at significant cost.

In the Response Letter, FINRA stated that it would amend the proposed rule change to delete the adjustment of corporate actions aspect of the proposal to provide FINRA additional time to gather further information on the issue and formulate a regulatory approach. FINRA also stated that it would separately amend Rule 4560 at a future date to propose a uniform requirement regarding the adjustment of corporate actions for short interest reporting purposes.

Additionally, in the SIFMA Letter, the commenter recommends changes to the existing short interest reporting requirements, including narrowing the exception from the reporting requirements for ''owned'' securities. FINRA declined to amend the proposal to make the requested changes suggested by SIFMA. In the Response Letter, FINRA stated that the additional comments raised by SIFMA relate to existing requirements of the Rule and not the current proposal. FINRA noted that SIFMA's recommendations are not germane to the consideration of the merits of the proposal or relevant to whether the proposal is consistent with the Exchange Act.

IV. Discussion and Commission's Findings

After careful review of the proposed rule change, the comments received and FINRA's Response Letter and the Amendments, the Commission finds that the proposed rule change, as modified by the Amendments, is consistent with the requirements of the Act, and the rules and regulations thereunder that are applicable to a national securities association.[13] In particular, the Commission believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. More specifically, the Commission believes that the proposed rule change to amend FINRA Rule 4560 will promote consistency and accuracy in the calculation and reporting of short interest positions by members. The Commission believes that FINRA has adequately responded to the concerns the SIFMA Letter. In response to SIFMA's comments concerning the adjustment of corporate actions for short interest reporting purposes, FINRA amended its proposal to delete this aspect of the proposal in order to allow additional time to gather further information. In addition, FINRA has suitably explained its reasons for declining to amend the proposed rule change by making the additional changes recommended by SIFMA.

V. Accelerated Approval

The Commission finds good cause, pursuant to Section 19(b)(2) of the Act[14] for approving the proposed rule change, as modified by the Amendments, prior to the 30th day after publication of Amendment No. 2 in the **Federal Register**. In response to certain concerns raised by SIFMA, FINRA proposed in Amendment No. 2 to delete the proposed requirement that short interest reports reflect corporate actions adjusted as of the ex-date of the corporate action (and if no ex-date is declared by a self-regulatory organization, then the payment date of a corporate action). FINRA proposed Amendment No. 2 to allow FINRA additional time to gather further information on the issue of adjustment of corporate actions for short interest reporting purposes. Accordingly, the Commission finds that good cause exists to approve the proposal, as modified by the Amendments, on an accelerated basis.

VI. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether Amendment No. 2 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 email to *rule-comments@sec.gov*. Please include File Number SR–FINRA–2012–001 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2012–001. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2012–001 and

[13] In approving the proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 15 U.S.C. 78s(b)(2).

should be submitted on or before May 24, 2012.

VII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[15] that the proposed rule change (File No. SR–FINRA–2012–001), as modified by the Amendments, be and hereby is approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–10642 Filed 5–2–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66873; File No. SR–EDGX–2012–15]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to New EDGX Rule Regarding Telemarketing

April 27, 2012.

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 April 16, 2012, EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') 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 the Exchange. 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 add Rule 3.26, Telemarketing,[3] to its rulebook to codify provisions that are substantially similar to Federal Trade Commission (''FTC'') rules that prohibit deceptive and other abusive telemarketing acts or practices. The text of the proposed rule change is available on the Exchange's Web site at *www.directedge.com,* at the Exchange's principal office, on the Commission's Web site at *www.sec.gov,* and at the Public Reference Room of the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to add Rule 3.26, *Telemarketing,* to its rulebook to codify provisions that are substantially similar to FTC rules that prohibit deceptive and other abusive telemarketing acts or practices. Rule 3.26 will require Members to, among other things, maintain do-not-call lists, limit the hours of telephone solicitations, and not use deceptive and abusive acts and practices in connection with telemarketing. The Commission directed EDGX to enact these telemarketing rules in accordance with the Telemarketing Consumer Fraud and Abuse Prevention Act of 1994 (''Prevention Act'').[4] The Prevention Act requires the Commission to promulgate, or direct any national securities exchange or registered securities association to promulgate, rules substantially similar to the FTC rules [5] to prohibit deceptive and other abusive telemarketing acts or practices, unless the Commission determines either that the rules are not necessary or appropriate for the protection of investors or the maintenance of orderly markets, or that existing federal securities laws or Commission rules already provide for such protection.[6]

In 1997, the Commission determined that telemarketing rules promulgated and expected to be promulgated by self-regulatory organizations, together with the other rules of the self-regulatory organizations, the federal securities laws and the Commission's rules thereunder, satisfied the requirements of the Prevention Act because, at the time, the applicable provisions of those laws and rules were substantially similar to the FTC's telemarketing rules.[7] Since 1997, the FTC has amended its telemarketing rules in light of changing telemarketing practices and technology.[8]

As mentioned above, the Prevention Act requires the Commission to promulgate, or direct any national securities exchange or registered securities association to promulgate, rules substantially similar to the FTC rules to prohibit deceptive and other abusive telemarketing acts or practices.[9] In May 2011, Commission staff directed EDGX to conduct a review of its telemarketing rule and propose rule amendments that provide protections that are at least as strong as those provided by the FTC's telemarketing rules.[10] Commission staff had concerns ''that the [Exchange] rules overall have not kept pace with the FTC's rules, and thus may no longer meet the standards of the [Prevention] Act.'' [11]

The proposed rule change, as directed by the Commission staff, adopts provisions in Rule 3.26 that are substantially similar to the FTC's current rules that prohibit deceptive and other abusive telemarketing acts or practices as described below.[12]

Telemarketing Restrictions

The proposed rule change codifies the telemarketing restrictions in Rule 3.26(a) to provide that no Member or

[15] 15 U.S.C. 78s(b)(2).

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The proposed rule change is substantially similar in all material respects to Financial Industry Regulatory Authority, Inc. (''FINRA'') Rule 3230 (Telemarketing), which the Commission recently approved. *See* Securities Exchange Act Release No. 66279 (Jan. 30, 2012), 77 FR 5611 (Feb. 3, 2012) (SR–FINRA–2011–059) (approval order of proposed rule change to adopt telemarketing rule).

[4] 15 U.S.C. 6101–6108.

[5] 16 CFR 310.1–.9. The FTC adopted these rules under the Prevention Act in 1995. *See* Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995).

[6] 15 U.S.C. 6102.

[7] *See Telemarketing and Consumer Fraud and Abuse Prevention Act; Determination that No Additional Rulemaking Required,* Securities Exchange Act Release No. 38480 (Apr. 7, 1997), 62 FR 18666 (Apr. 16, 1997). The Commission also determined that some provisions of the FTC's telemarketing rules related to areas already extensively regulated by existing securities laws or activities not applicable to securities transactions *See id.*

[8] *See, e.g.,* Federal Trade Commission, *Telemarketing Sales Rule,* 73 FR 51164 (Aug. 29, 2008) (amendments to the *Telemarketing Sales Rule* relating to prerecorded messages and call abandonments); and Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) (amendments to the *Telemarketing Sales Rule* establishing requirements for sellers and telemarketers to participate in the national do-not-call registry).

[9] *See supra* note 6.

[10] *See* Letter from Robert W. Cook, Director, Division of Trading and Markets, Securities and Exchange Commission, to William O'Brien, Chief Executive Officer, Direct Edge Holdings LLC, dated May 12, 2011.

[11] *Id.*

[12] The proposed rule change is also substantially similar to FINRA Rule 3230. *See supra* note 3.

associated person of a Member [13] may make an outbound telephone call [14] to:

(1) Any person's residence at any time other than between 8 a.m. and 9 p.m. local time at the called person's locations;

(2) any person that previously has stated that he or she does not wish to receive any outbound telephone calls made by or on behalf of the Member; or

(3) any person who has registered his or her telephone number on the FTC's national do-not-call registry.

The proposed rule change is substantially similar to the FTC's provisions regarding abusive telemarketing acts or practices.[15] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[16]

Caller Disclosures

The proposed rule change codifies in Rule 3.26(b) that no Member or associated person of a Member shall make an outbound telephone call to any person without disclosing truthfully, promptly and in a clear and conspicuous manner to the called person the following information: (i) The identity of the caller and the Member; (ii) the telephone number or address at which the caller may be contacted; and (iii) that the purpose of the call is to solicit the purchase of securities or related services. The proposed rule change also provides that the telephone number that a caller provides to a person as the number at which the caller may be contacted may not be a 900 number or any other number for which charges exceed local or long-distance transmission charges.[17]

Exceptions

The proposed rule change adds Rule 3.26(c) to provide that the prohibition in paragraph (a)(1) [18] does not apply to outbound telephone calls by a Member or an associated person of a Member if:

(1) The Member has received that person's express prior written consent;

(2) the Member has an established business relationship [19] with the person; or

(3) The person is a broker or dealer.

Member's Firm-Specific Do-Not-Call List

The proposed rule change adds Rule 3.26(d) to provide that each Member must make and maintain a centralized list of persons who have informed the Member or any of its associated persons that they do not wish to receive outbound telephone calls. The proposed term ''outbound telephone call'' is defined substantially similar to the FTC's definition of that term.[20]

Proposed Rule 3.26(d)(2) adopts procedures that Members must institute to comply with Rule 3.26(a) and (b) prior to engaging in telemarketing. These procedures must meet the following minimum standards:

(1) Member must have a written policy for maintaining their firm-specific do-not-call lists.

(2) Personnel engaged in any aspect of telemarketing must be informed and trained in the existence and use of the Member's firm-specific do-not-call list.

(3) If a Member receives a request from a person not to receive calls from that Member, the Member must record the request and place the person's name, if provided, and telephone number on its firm-specific do-not-call list at the time the request is made.[21]

(4) Members or associated persons of Members making an outbound telephone call must make the caller disclosures set forth in Rule 3.26(b).

(5) In the absence of a specific request by the person to the contrary, a person's do-not-call request will apply to the Member making the call, and will not apply to affiliated entities unless the consumer reasonably would expect them to be included given the identification of the call and the product being advertised.

(6) A Member making outbound telephone calls must maintain a record of a person's request not to receive further calls.

Inclusion of this requirement to adopt these procedures will not create any new obligations on Members, as they are already subject to identical provisions under Federal Communications Commission (''FCC'') telemarketing regulations.[22]

---

[13] An ''associated person of a Member'' is any partner, officer, director, or branch manager of a Member (or person occupying a similar status or performing similar functions), any person directly or indirectly controlling, controlled by, or under common control with such Member, or any employee of such Member, except that any person associated with a Member whose functions are solely clerical or ministerial shall not be included in the meaning of such term. *See* Rule 1.5(q).

[14] An ''outbound telephone call'' is a telephone call initiated by a telemarketer to induce the purchase of goods or services or to solicit a charitable contribution from a donor. A ''telemarketer'' is any person who, in connection with telemarketing, initiates or receives telephone calls to or from a customer or donor. A ''customer'' is any person who is or may be required to pay for goods or services through telemarketing. A ''donor'' means any person solicited to make a charitable contribution. A ''person'' is any individual, group, unincorporated association, limited or general partnership, corporation, or other business entity. ''Telemarketing'' means consisting of or relating to a plan, program, or campaign involving at least one outbound telephone call, for example cold-calling. The term does not include the solicitation of sales through the mailing of written marketing materials, when the person making the solicitation does not solicit customers by telephone but only receives calls initiated by customers in response to the marketing materials and during those calls takes orders only without further solicitation. For purposes of the previous sentence, the term ''further solicitation'' does not include providing the customer with information about, or attempting to sell, anything promoted in the same marketing materials that prompted the customer's call. A ''charitable contribution'' means any donation or gift of money or any other thing of value, for example a transfer to a pooled income fund. *See* proposed Rule 3.26(n)(3), (11), (16), (17), (20), and (21); *see also* FINRA Rule 3230(m)(11), (14), (16), (17), and (20); and 16 CFR 310.2(f), (l), (n), (v), (w), (cc), and (dd).

[15] *See* 16 CFR 310.4(b)(1)(iii)(A) and (B) and (c); *see also* FINRA Rule 3230(a). *See* proposed Rule 3.26(n)(16) and (21) and *supra* note 14.

[16] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4628; and Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995) at 43855.

[17] *See* proposed Rule 3.26(b); *see also* FINRA Rule 3230(d)(4). The proposed rule change is substantially similar to the Federal Communications Commission's regulations regarding call disclosures. *See* 47 CFR 64.1200(d)(4).

[18] The Exchange believes that even if a Member satisfies the exception in paragraph (c), the Member should still make the caller disclosures required by paragraph (b) to the called person to ensure that the called person receives sufficient information regarding the purpose of the call.

[19] An ''established business relationship'' is a relationship between a Member and a person if (a) the person has made a financial transaction or has a security position, a money balance, or account activity with the Member or at a clearing firm that provides clearing services to the Member within the 18 months immediately preceding the date of an outbound telephone call; (b) the Member is the broker-dealer of record for an account of the person within the 18 months immediately preceding the date of an outbound telephone call; or (c) the person has contacted the Member to inquire about a product or service offered by the Member within the three months immediately preceding the date of an outbound telephone call. A person's established business relationship with a Member does not extend to the Member's affiliated entities unless the person would reasonably expect them to be included. Similarly, a person's established business relationship with a Member's affiliate does not extend to the Member unless the person would reasonably expect the Member to be included. The term ''account activity'' includes, but is not limited to, purchases, sales, interest credits or debits, charges or credits, dividend payments, transfer activity, securities receipts or deliveries, and/or journal entries relating to securities or funds in the possession or control of the Member. The term ''broker-dealer of record'' refers to the broker or dealer identified on a customer's account application for accounts held directly at a mutual fund or variable insurance product issuer. *See* proposed Rule 3.26(n)(1), (4), and (12); *see also* 16 CFR 310.2(o) and FINRA Rule 3230(m)(1), (4), and (12).

[20] *See* 16 CFR 310.4(b)(1)(iii)(A) and *supra* note 14; *see also* FINRA Rule 3230(a)(2).

[21] Members must honor a person's do-not-call request within a reasonable time from the date the request is made, which may not exceed 30 days from the date of the request. If these requests are recorded or maintained by a party other than the Member on whose behalf the outbound telephone call is made, the Member on whose behalf the outbound telephone call is made will still be liable for any failures to honor the do-not-call request.

[22] *See* 47 CFR 64.1200(d); *see also* FINRA Rule 3230(d).

Do-Not-Call Safe Harbors

Proposed Rule 3.26(e) provides for certain exceptions to the telemarketing restriction set forth in proposed Rule 3.26(a)(3), which prohibits outbound telephone calls to persons on the FTC's national do-not-call registry. First, proposed Rule 3.26(e)(1) provides that a Member or associated person of a Member making outbound telephone calls will not be liable for violating proposed Rule 3.26(a)(3) if:

(1) The Member has an established business relationship with the called person; however, a person's request to be placed on the Member's firm-specific do-not-call list terminates the established business relationship exception to the national do-not-call registry provision for that Member even if the person continues to do business with the Member;

(2) The Member has obtained the person's prior express written consent, which must be clearly evidenced by a signed, written agreement (which may be obtained electronically under the E–Sign Act [23]) between the person and the Member that states that the person agrees to be contacted by the Member and includes the telephone number to which the calls may be placed; or

(3) The Member or associated person of a Member making the call has a personal relationship [24] with the called person.

The proposed rule change is substantially similar to the FTC's provision regarding an exception to the prohibition on making outbound telephone calls to persons on the FTC's do-not-call registry.[25] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[26]

Second, proposed Rule 3.26(e)(2) provides that a Member or associated person of a Member making outbound telephone calls will not be liable for violating proposed Rule 3.26(a)(3) if the Member or associated person of a Member demonstrates that the violation is the result of an error and that as part of the Member's routine business practice:

(1) The Member has established and implemented written procedures to comply with Rule 3.26(a) and (b);

(2) The Member has trained its personnel, and any entity assisting in its compliance, in the procedures established pursuant to the preceding clause;

(3) The Member has maintained and recorded a list of telephone numbers that it may not contact in compliance with Rule 3.26(d); and

(4) The Member uses a process to prevent outbound telephone calls to any telephone number on the Member's firm-specific do-not-call list or the national do-not-call registry, employing a version of the national do-not-call registry obtained from the FTC no more than 31 days prior to the date any call is made, and maintains records documenting this process.

The proposed rule change is substantially similar to the FTC's safe harbor to the prohibition on making outbound telephone calls to persons on a firm-specific do-not-call list or on the FTC's national do-not-call registry.[27] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[28]

Wireless Communications

Proposed Rule 3.26(f) clarifies that the provisions set forth in Rule 3.26 are applicable to Members and associated persons of Members making outbound telephone calls to wireless telephone numbers.[29]

Outsourcing Telemarketing

Proposed Rule 3.26(g) states that if a Member uses another entity to perform telemarketing services on its behalf, the Member remains responsible for ensuring compliance with Rule 3.26. The proposed rule change also provides that an entity or person to which a Member outsources its telemarketing services must be appropriately registered or licensed, where required.[30]

Billing Information

Proposed Rule 3.26(h) provides that, for any telemarketing transaction, no Member or associated person of a Member may submit billing information [31] for payment without the express informed consent of the customer. Proposed Rule 3.26(h) requires that each Member or associated person of a Member must obtain the express informed consent of the person to be charged and to be charged using the identified account.

If the telemarketing transaction involves preacquired account information [32] and a free-to-pay conversion [33] feature, the Member or associated person of a Member must:

(1) Obtain from the customer, at a minimum, the last four digits of the account number to be charged;

(2) Obtain from the customer an express agreement to be charged and to be charged using the identified account number; and

(3) Make and maintain an audio recording of the entire telemarketing transaction.

For any other telemarketing transaction involving preacquired account information, the Member or associated person of a Member must:

(1) Identify the account to be charged with sufficient specificity for the customer to understand what account will be charged; and

(2) Obtain from the customer an express agreement to be charged and to be charged using the identified account number.

The proposed rule change is substantially similar to the FTC's provision regarding the submission of billing information.[34] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[35]

Caller Identification Information

Proposed Rule 3.26(i) provides that Members that engage in telemarketing must transmit caller identification information [36] and are explicitly prohibited from blocking caller identification information. The

[23] 15 U.S.C. 7001 *et seq.*

[24] The term ''personal relationship'' means any family member, friend, or acquaintance of the person making an outbound telephone call. *See* proposed Rule 3.26(n)(18); *see also* FINRA Rule 3230(m)(18).

[25] *See* 16 CFR 310.4(b)(1)(iii)(B); *see also* FINRA Rule 3230(b).

[26] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4628; Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995) at 43854.

[27] *See* 16 CFR 310.4(b)(3); *see also* FINRA Rule 3230(c).

[28] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4628; and Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995) at 43855.

[29] *See also* FINRA Rule 3230(e).

[30] *See also* FINRA Rule 3230(f).

[31] The term ''billing information'' means any data that enables any person to access a customer's or donor's account, such as a credit or debit card number, a brokerage, checking, or savings account number, or a mortgage loan account number. *See* proposed Rule 3.26(n)(3).

[32] The term ''preacquired account information'' means any information that enables a Member or associated person of a Member to cause a charge to be placed against a customer's or donor's account without obtaining the account number directly from the customer or donor during the telemarketing transaction pursuant to which the account will be charged. *See* proposed Rule 3.26(n)(19).

[33] The term ''free-to-pay conversion'' means, in an offer or agreement to sell or provide any goods or services, a provision under which a customer receives a product or service for free for an initial period and will incur an obligation to pay for the product or service if he or she does not take affirmative action to cancel before the end of that period. *See* proposed Rule 3.26(n)(13).

[34] *See* 16 CFR 310.4(a)(7); *see also* FINRA Rule 3230(i).

[35] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4616.

[36] Caller identification information includes the telephone number and, when made available by the Member's telephone carrier, the name of the Member.

telephone number provided must permit any person to make a do-not-call request during normal business hours. These provisions are similar to the caller identification provision in the FTC rules.[37] Inclusion of these caller identification provisions in this proposed rule change will not create any new obligations on Members, as they are already subject to identical provisions under FCC telemarketing regulations.[38]

Unencrypted Consumer Account Numbers

Proposed Rule 3.26(j) prohibits a Member or associated person of a Member from disclosing or receiving, for consideration, unencrypted consumer account numbers for use in telemarketing. The proposed rule change is substantially similar to the FTC's provision regarding unencrypted consumer account numbers.[39] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[40] Additionally, the proposed rule change defines ''unencrypted'' as not only complete, visible account numbers, whether provided in lists or singly, but also encrypted information with a key to its decryption. The proposed definition is substantially similar to the view taken by the FTC.[41]

Abandoned Calls

Proposed Rule 3.26(k) prohibits a Member or associated person of a Member from abandoning[42] any outbound telephone call. The abandoned calls prohibition is subject to a ''safe harbor'' under proposed Rule 3.26(k)(2) that requires a Member or associated person of a Member:

(1) To employ technology that ensures abandonment of no more than three percent of all calls answered by a person, measured over the duration of a single calling campaign, if less than 30 days, or separately over each successive 30-day period or portion thereof that the campaign continues;

(2) For each outbound telephone call placed, to allow the telephone to ring for at least 15 seconds or four rings before disconnecting an unanswered call;

(3) Whenever a Member or associated person of a Member is not available to speak with the person answering the outbound telephone call within two seconds after the person's completed greeting, promptly to play a prerecorded message stating the name and telephone number of the Member or associated person of a Member on whose behalf the call was placed; and

(4) To maintain records documenting compliance with the ''safe harbor.''

The proposed rule change is substantially similar to the FTC's provisions regarding abandoned calls.[43] The FTC provided a discussion of the provisions when they are adopted pursuant to the Prevention Act.[44]

Pre-recorded Messages

Proposed Rule 3.26(l) prohibits a Member or associated person of a Member from initiating any outbound telephone call that delivers a prerecorded message without a person's express written agreement[45] to receive such calls. The proposed rule change also requires that all prerecorded outbound telephone calls provide specified opt-out mechanisms so that a person can opt out of future calls. The prohibition does not apply to a prerecorded message permitted for compliance with the ''safe harbor'' for abandoned calls under proposed Rule 3.26(k)(2). The proposed rule change is substantially similar to the FTC's provisions regarding prerecorded messages.[46] The FTC provided a discussion of the provisions when they were adopted pursuant to the Prevention Act.[47]

Credit Card Laundering

Proposed Rule 3.26(m) prohibits credit card laundering, the practice of depositing into the credit card system[48] a sales draft that is not the result of a credit card transaction between the cardholder[49] and the Member. Except as expressly permitted, the proposed rule change prohibits a Member or associated person of a Member from:

(1) Presenting to or depositing into the credit card system for payment, a credit card sales draft[50] generated by a telemarketing transaction that is not the result of a telemarketing credit card transaction between the cardholder and the Member;

(2) Employing, soliciting, or otherwise causing a merchant,[51] or an employee, representative or agent of the merchant to present to or to deposit into the credit card system for payment, a credit card sales draft generated by a telemarketing transaction that is not the result of a telemarketing credit card transaction between the cardholder and the Member; or

(3) Obtaining access to the credit card system through the use of a business relationship or an affiliation with a merchant, when such access is not authorized by the merchant agreement[52] or the applicable credit card system.

The proposed rule change is substantially similar to the FTC's provision regarding credit card laundering.[53] The FTC provided a discussion of the provisions when they

---

[37] *See* 16 CFR 310.4(a)(8); *see also* FINRA Rule 3230(g).

[38] *See* 47 CFR 64.1601(e).

[39] *See* 16 CFR 310.4(a)(6); *see also* FINRA Rule 3230(h).

[40] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4615.

[41] *See id.* at 4616.

[42] An outbound telephone call is ''abandoned'' if the called person answers it and the call is not connected to a Member or associated person of a Member within two seconds of the called person's completed greeting.

[43] *See* 16 CFR 310.4(b)(1)(iv) and (b)(4); *see also* FINRA Rule 3230(j).

[44] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4641.

[45] The express written agreement must: (a) Have been obtained only after a clear and conspicuous disclosure that the purpose of the agreement is to authorize the Member to place prerecorded calls to such person; (b) have been obtained without requiring, directly or indirectly, that the agreement be executed as a condition of purchasing any good or service; (c) evidence the willingness of the called person to receive calls that deliver prerecorded messages by or on behalf of the Member; and (d) include the person's telephone number and signature (which may be obtained electronically under the E-Sign Act).

[46] *See* 16 CFR 310.4(b)(1)(v); *see also* FINRA Rule 3230(k).

[47] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 73 FR 51164 (Aug. 29, 2008) at 51165.

[48] The term ''credit card system'' means any method or procedure used to process credit card transactions involving credit cards issued or licensed by the operator of that system. The term ''credit card'' means any card, plate, coupon book, or other credit device existing for the purpose of obtaining money, property, labor, or services on credit. The term ''credit'' means the right granted by a creditor to a debtor to defer payment of debt or to incur debt and defer its payment. *See* proposed Rule 3.26(n)(7), (8), and (10).

[49] The term ''cardholder'' means a person to whom a credit card is issued or who is authorized to use a credit card on behalf of or in addition to the person to whom the credit card is issued. *See* proposed Rule 3.26(n)(6).

[50] The term ''credit card sales draft'' means any record or evidence of a credit card transaction. *See* proposed Rule 3.26(n)(9).

[51] The term ''merchant'' means a person who is authorized under a written contract with an acquirer to honor or accept credit cards, or to transmit or process for payment credit card payments, for the purchase of goods or services or a charitable contribution. The term ''acquirer'' means a business organization, financial institution, or an agent of a business organization or financial institution that has authority from an organization that operates or licenses a credit card system to authorize merchants to accept, transmit, or process payment by credit card through the credit card system for money, goods or services, or anything else of value. *See* proposed Rule 3.26(n)(2) and (14).

[52] The term ''merchant agreement'' means a written contract between a merchant and an acquirer to honor or accept credit cards, or to transmit or process for payment credit card payments, for the purchase of goods or services or a charitable contribution. *See* proposed Rule 3.26(n)(15).

[53] *See* 16 CFR 310.3(c); *see also* FINRA Rule 3230(l).

were adopted pursuant to the Prevention Act.[54]

Definitions

Proposed Rule 3.26(n) adopts the following definitions, which are substantially similar to the FTC's definitions of these terms: ''Acquirer,'' ''billing information,'' ''caller identification service,'' ''cardholder,'' ''charitable contribution,'' ''credit,'' ''credit card,'' ''credit card sales draft,'' ''credit card system,'' ''customer,'' ''donor,'' ''established business relationship,'' ''free-to-pay conversion,'' ''merchant,'' ''merchant agreement,'' ''outbound telephone call,'' ''person,'' ''preacquired account information,'' ''telemarketer,'' and ''telemarketing.'' [55] The FTC provided a discussion of each definition when they were adopted pursuant to the Prevention Act.[56]

State and Federal Laws

Proposed Rule 3.26, Interpretation and Policy .01 [57] reminds Members and associated persons of Members that engage in telemarketing that they also are subject to the requirements of relevant state and federal laws and rules, including the Prevention Act, the Telephone Consumer Protection Act of 1991,[58] and the rules of the FCC relating to telemarketing practices and the rights of telephone consumers.[59]

Announcement in Regulatory Circular

The Exchange will announce the implementation date of the proposed rule change in a Regulatory Notice to be published no later than 90 days following the effective date. The implementation date will be no later than 180 days following the effective date.

[54] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995) at 43852.

[55] *See* proposed Rule 3.26(n)(2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (19), (20), and (21); and 16 CFR 310.2(a), (c), (d), (e), (f), (h), (i), (j), (k), (l), (n), (o), (p), (s), (t), (v), (w), (x), (cc), and (dd); *see also* FINRA Rule 3230(m)(2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (19), and (20). The proposed rule change also adopts definitions of ''account activity,'' ''broker-dealer of record,'' and ''personal relationship'' that are substantially similar FINRA's definitions of these terms. *See* proposed Rule 3.26(n)(1), (4), and (18) and FINRA Rule 3230(m)(1), (4), and (18); *see also* 47 CFR 64.1200(f)(14) (FCC's definition of ''personal relationship'').

[56] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995) at 43843; and Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4587.

[57] *See also* FINRA Rule 3230, Supplementary Material .01, *Compliance with Other Requirements.*

[58] *See* 47 U.S.C. 227.

[59] *See* 47 CFR 64.1200.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[60] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [61] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest.

In particular, the proposed rule change will prevent fraudulent and manipulative acts and protect investors and the public interest by continuing to prohibit Members from engaging in deceptive and other abusive telemarketing acts or practices. Additionally, the proposed rule change removes impediments to and perfects the mechanism for a free and open market and a national market system, because it provides consistency among telemarketing rules of national securities exchanges and FINRA, therefore making it easier for investors to comply with these rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

II. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change is filed for immediate effectiveness pursuant to Section 19(b)(3)(A) of Act [62] and Rule 19b–4(f)(6) [63] thereunder. The Exchange designates that the proposed rule change effects a change 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) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. Additionally, the Exchange has given the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change. The proposed rule change is substantially similar in all material respects to FTC rules and FINRA Rule 3230, which the Commission recently approved.[64]

For the foregoing reasons, this rule filing qualifies as a ''non-controversial'' rule change under Rule 19b–4(f)(6), which renders the proposed rule change effective upon filing with the Commission. The Exchange has requested that the Commission waive the 30-day operative delay period after which a proposed rule change under Rule 19b–4(f)(6) becomes effective. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver will afford Exchange members the benefit of the proposal—the prohibition of deceptive and other abusive telemarketing acts or practices—without unnecessary delay. Such waiver will also allow the Exchange to comply with the Commission's directive and implement uniform telemarketing rules across self-regulatory organizations, creating consistency among these rules for investors, as soon as possible. For these reasons, the Commission designates the proposed rule change as operative under upon filing.[65]

At any time within 60 days of the filing of this proposed rule change, the Commission summarily may temporarily suspend 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.

III. 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:

[60] 15 U.S.C. 78f(b).

[61] 15 U.S.C. 78f(b)(5).

[62] 15 U.S.C. 78s(b)(3)(A).

[63] 17 CFR 240.19b–4(f)(6).

[64] *See supra* note 3.

[65] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 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 Email to *rule-comments@sec.gov.* Please include File No. SR–EDGX–2012–15 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGX–2012–15. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGX–2012–15 and should be submitted by May 24, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[66]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–10643 Filed 5–2–12; 8:45 am]

BILLING CODE 8011–01–P

[66] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66874; File No. SR–EDGA–2012–16]

Self-Regulatory Organizations; EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to New EDGA Rule Regarding Telemarketing

April 27, 2012.

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 April 16, 2012, EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') 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 the Exchange. 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 add Rule 3.26, Telemarketing,[3] to its rulebook to codify provisions that are substantially similar to Federal Trade Commission (''FTC'') rules that prohibit deceptive and other abusive telemarketing acts or practices. The text of the proposed rule change is available on the Exchange's Web site at *www.directedge.com,* at the Exchange's principal office, on the Commission's Web site at *www.sec.gov,* and at the Public Reference Room of the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The proposed rule change is substantially similar in all material respects to Financial Industry Regulatory Authority, Inc. (''FINRA'') Rule 3230 (Telemarketing), which the Commission recently approved. *See* Securities Exchange Act Release No. 66279 (Jan. 30, 2012), 77 FR 5611 (Feb. 3, 2012) (SR–FINRA–2011–059) (approval order of proposed rule change to adopt telemarketing rule).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to add Rule 3.26, *Telemarketing,* to its rulebook to codify provisions that are substantially similar to FTC rules that prohibit deceptive and other abusive telemarketing acts or practices. Rule 3.26 will require Members to, among other things, maintain do-not-call lists, limit the hours of telephone solicitations, and not use deceptive and abusive acts and practices in connection with telemarketing. The Commission directed EDGA to enact these telemarketing rules in accordance with the Telemarketing Consumer Fraud and Abuse Prevention Act of 1994 (''Prevention Act'').[4] The Prevention Act requires the Commission to promulgate, or direct any national securities exchange or registered securities association to promulgate, rules substantially similar to the FTC rules [5] to prohibit deceptive and other abusive telemarketing acts or practices, unless the Commission determines either that the rules are not necessary or appropriate for the protection of investors or the maintenance of orderly markets, or that existing federal securities laws or Commission rules already provide for such protection.[6]

In 1997, the Commission determined that telemarketing rules promulgated and expected to be promulgated by self-regulatory organizations, together with the other rules of the self-regulatory organizations, the federal securities laws and the Commission's rules thereunder, satisfied the requirements of the Prevention Act because, at the time, the applicable provisions of those laws and rules were substantially similar to the FTC's telemarketing rules.[7] Since 1997, the FTC has amended its telemarketing rules in light of changing telemarketing practices and technology.[8]

[4] 15 U.S.C. 6101–6108.

[5] 16 CFR 310.1–.9. The FTC adopted these rules under the Prevention Act in 1995. *See* Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995).

[6] 15 U.S.C. 6102.

[7] *See Telemarketing and Consumer Fraud and Abuse Prevention Act; Determination that No Additional Rulemaking Required,* Securities Exchange Act Release No. 38480 (Apr. 7, 1997), 62 FR 18666 (Apr. 16, 1997). The Commission also determined that some provisions of the FTC's telemarketing rules related to areas already extensively regulated by existing securities laws or activities not applicable to securities transactions *See id.*

[8] *See, e.g.,* Federal Trade Commission, *Telemarketing Sales Rule,* 73 FR 51164 (Aug. 29, 2008) (amendments to the *Telemarketing Sales Rule*

As mentioned above, the Prevention Act requires the Commission to promulgate, or direct any national securities exchange or registered securities association to promulgate, rules substantially similar to the FTC rules to prohibit deceptive and other abusive telemarketing acts or practices.[9] In May 2011, Commission staff directed EDGA to conduct a review of its telemarketing rule and propose rule amendments that provide protections that are at least as strong as those provided by the FTC's telemarketing rules.[10] Commission staff had concerns ''that the [Exchange] rules overall have not kept pace with the FTC's rules, and thus may no longer meet the standards of the [Prevention] Act.'' [11]

The proposed rule change, as directed by the Commission staff, adopts provisions in Rule 3.26 that are substantially similar to the FTC's current rules that prohibit deceptive and other abusive telemarketing acts or practices as described below.[12]

Telemarketing Restrictions

The proposed rule change codifies the telemarketing restrictions in Rule 3.26(a) to provide that no Member or associated person of a Member [13] may make an outbound telephone call [14] to:

(1) Any person's residence at any time other than between 8 a.m. and 9 p.m. local time at the called person's locations;

(2) Any person that previously has stated that he or she does not wish to receive any outbound telephone calls made by or on behalf of the Member; or

(3) Any person who has registered his or her telephone number on the FTC's national do-not-call registry.

The proposed rule change is substantially similar to the FTC's provisions regarding abusive telemarketing acts or practices.[15] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[16]

Caller Disclosures

The proposed rule change codifies in Rule 3.26(b) that no Member or associated person of a Member shall make an outbound telephone call to any person without disclosing truthfully, promptly and in a clear and conspicuous manner to the called person the following information: (i) The identity of the caller and the Member; (ii) the telephone number or address at which the caller may be contacted; and (iii) that the purpose of the call is to solicit the purchase of securities or related services. The proposed rule change also provides that the telephone number that a caller provides to a person as the number at which the caller may be contacted may not be a 900 number or any other number for which charges exceed local or long-distance transmission charges.[17]

Exceptions

The proposed rule change adds Rule 3.26(c) to provide that the prohibition in paragraph (a)(1) [18] does not apply to outbound telephone calls by a Member or an associated person of a Member if:

(1) The Member has received that person's express prior written consent;

(2) The Member has an established business relationship [19] with the person; or

(3) The person is a broker or dealer.

Member's Firm-Specific Do-Not-Call List

The proposed rule change adds Rule 3.26(d) to provide that each Member must make and maintain a centralized list of persons who have informed the Member or any of its associated persons that they do not wish to receive outbound telephone calls. The proposed term ''outbound telephone call'' is defined substantially similar to the FTC's definition of that term.[20]

Proposed Rule 3.26(d)(2) adopts procedures that Members must institute to comply with Rule 3.26(a) and (b) prior to engaging in telemarketing. These procedures must meet the following minimum standards:

---

relating to prerecorded messages and call abandonments); and Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) (amendments to the *Telemarketing Sales Rule* establishing requirements for sellers and telemarketers to participate in the national do-not-call registry).

[9] *See supra* note 6.

[10] *See* Letter from Robert W. Cook, Director, Division of Trading and Markets, Securities and Exchange Commission, to William O'Brien, Chief Executive Officer, Direct Edge Holdings LLC, dated May 12, 2011.

[11] *Id.*

[12] The proposed rule change is also substantially similar to FINRA Rule 3230. *See supra* note 3.

[13] An ''associated person of a Member'' is any partner, officer, director, or branch manager of a Member (or person occupying a similar status or performing similar functions), any person directly or indirectly controlling, controlled by, or under common control with such Member, or any employee of such Member, except that any person associated with a Member whose functions are solely clerical or ministerial shall not be included in the meaning of such term. *See* Rule 1.5(q).

[14] An ''outbound telephone call'' is a telephone call initiated by a telemarketer to induce the purchase of goods or services or to solicit a charitable contribution from a donor. A ''telemarketer'' is any person who, in connection with telemarketing, initiates or receives telephone calls to or from a customer or donor. A ''customer'' is any person who is or may be required to pay for goods or services through telemarketing. A ''donor'' means any person solicited to make a charitable contribution. A ''person'' is any individual, group, unincorporated association, limited or general partnership, corporation, or other business entity. ''Telemarketing'' means consisting of or relating to a plan, program, or campaign involving at least one outbound telephone call, for example cold-calling. The term does not include the solicitation of sales through the mailing of written marketing materials, when the person making the solicitation does not solicit customers by telephone but only receives calls initiated by customers in response to the marketing materials and during those calls takes orders only without further solicitation. For purposes of the previous sentence, the term ''further solicitation'' does not include providing the customer with information about, or attempting to sell, anything promoted in the same marketing materials that prompted the customer's call. A ''charitable contribution'' means any donation or gift of money or any other thing of value, for example a transfer to a pooled income fund. *See* proposed Rule 3.26(n)(3), (11), (16), (17), (20), and (21); *see also* FINRA Rule 3230(m)(11), (14), (16), (17), and (20); and 16 CFR 310.2(f), (l), (n), (v), (w), (cc), and (dd).

[15] *See* 16 CFR 310.4(b)(1)(iii)(A) and (B) and (c); *see also* FINRA Rule 3230(a). *See* proposed Rule 3.26(n)(16) and (21) and *supra* note 14.

[16] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4628; and Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995) at 43855.

[17] *See* proposed Rule 3.26(b); *see also* FINRA Rule 3230(d)(4). The proposed rule change is substantially similar to the Federal Communications Commission's regulations regarding call disclosures. *See* 47 CFR 64.1200(d)(4).

[18] The Exchange believes that even if a Member satisfies the exception in paragraph (c), the Member should still make the caller disclosures required by paragraph (b) to the called person to ensure that the called person receives sufficient information regarding the purpose of the call.

[19] An ''established business relationship'' is a relationship between a Member and a person if (a) The person has made a financial transaction or has a security position, a money balance, or account activity with the Member or at a clearing firm that provides clearing services to the Member within the 18 months immediately preceding the date of an outbound telephone call; (b) the Member is the broker-dealer of record for an account of the person within the 18 months immediately preceding the date of an outbound telephone call; or (c) the person has contacted the Member to inquire about a product or service offered by the Member within the three months immediately preceding the date of an outbound telephone call. A person's established business relationship with a Member does not extend to the Member's affiliated entities unless the person would reasonably expect them to be included. Similarly, a person's established business relationship with a Member's affiliate does not extend to the Member unless the person would reasonably expect the Member to be included. The term ''account activity'' includes, but is not limited to, purchases, sales, interest credits or debits, charges or credits, dividend payments, transfer activity, securities receipts or deliveries, and/or journal entries relating to securities or funds in the possession or control of the Member. The term ''broker-dealer of record'' refers to the broker or dealer identified on a customer's account application for accounts held directly at a mutual fund or variable insurance product issuer. *See* proposed Rule 3.26(n)(1), (4), and (12); *see also* 16 CFR 310.2(o) and FINRA Rule 3230(m)(1), (4), and (12).

[20] *See* 16 CFR 310.4(b)(1)(iii)(A) and *supra* note 14; *see also* FINRA Rule 3230(a)(2).

(1) Member must have a written policy for maintaining their firm-specific do-not-call lists.

(2) Personnel engaged in any aspect of telemarketing must be informed and trained in the existence and use of the Member's firm-specific do-not-call list.

(3) If a Member receives a request from a person not to receive calls from that Member, the Member must record the request and place the person's name, if provided, and telephone number on its firm-specific do-not-call list at the time the request is made.[21]

(4) Members or associated persons of Members making an outbound telephone call must make the caller disclosures set forth in Rule 3.26(b).

(5) In the absence of a specific request by the person to the contrary, a person's do-not-call request will apply to the Member making the call, and will not apply to affiliated entities unless the consumer reasonably would expect them to be included given the identification of the call and the product being advertised.

(6) A Member making outbound telephone calls must maintain a record of a person's request not to receive further calls.

Inclusion of this requirement to adopt these procedures will not create any new obligations on Members, as they are already subject to identical provisions under Federal Communications Commission (''FCC'') telemarketing regulations.[22]

Do-Not-Call Safe Harbors

Proposed Rule 3.26(e) provides for certain exceptions to the telemarketing restriction set forth in proposed Rule 3.26(a)(3), which prohibits outbound telephone calls to persons on the FTC's national do-not-call registry. First, proposed Rule 3.26(e)(1) provides that a Member or associated person of a Member making outbound telephone calls will not be liable for violating proposed Rule 3.26(a)(3) if:

(1) The Member has an established business relationship with the called person; however, a person's request to be placed on the Member's firm-specific do-not-call list terminates the established business relationship exception to the national do-not-call registry provision for that Member even if the person continues to do business with the Member;

(2) The Member has obtained the person's prior express written consent, which must be clearly evidenced by a signed, written agreement (which may be obtained electronically under the E–Sign Act[23]) between the person and the Member that states that the person agrees to be contacted by the Member and includes the telephone number to which the calls may be placed; or

(3) The Member or associated person of a Member making the call has a personal relationship[24] with the called person.

The proposed rule change is substantially similar to the FTC's provision regarding an exception to the prohibition on making outbound telephone calls to persons on the FTC's do-not-call registry.[25] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[26]

Second, proposed Rule 3.26(e)(2) provides that a Member or associated person of a Member making outbound telephone calls will not be liable for violating proposed Rule 3.26(a)(3) if the Member or associated person of a Member demonstrates that the violation is the result of an error and that as part of the Member's routine business practice:

(1) The Member has established and implemented written procedures to comply with Rule 3.26(a) and (b);

(2) The Member has trained its personnel, and any entity assisting in its compliance, in the procedures established pursuant to the preceding clause;

(3) The Member has maintained and recorded a list of telephone numbers that it may not contact in compliance with Rule 3.26(d); and

(4) The Member uses a process to prevent outbound telephone calls to any telephone number on the Member's firm-specific do-not-call list or the national do-not-call registry, employing a version of the national do-not-call registry obtained from the FTC no more than 31 days prior to the date any call is made, and maintains records documenting this process.

The proposed rule change is substantially similar to the FTC's safe harbor to the prohibition on making outbound telephone calls to persons on a firm-specific do-not-call list or on the FTC's national do-not-call registry.[27] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[28]

Wireless Communications

Proposed Rule 3.26(f) clarifies that the provisions set forth in Rule 3.26 are applicable to Members and associated persons of Members making outbound telephone calls to wireless telephone numbers.[29]

Outsourcing Telemarketing

Proposed Rule 3.26(g) states that if a Member uses another entity to perform telemarketing services on its behalf, the Member remains responsible for ensuring compliance with Rule 3.26. The proposed rule change also provides that an entity or person to which a Member outsources its telemarketing services must be appropriately registered or licensed, where required.[30]

Billing Information

Proposed Rule 3.26(h) provides that, for any telemarketing transaction, no Member or associated person of a Member may submit billing information[31] for payment without the express informed consent of the customer. Proposed Rule 3.26(h) requires that each Member or associated person of a Member must obtain the express informed consent of the person to be charged and to be charged using the identified account.

If the telemarketing transaction involves preacquired account information[32] and a free-to-pay conversion[33] feature, the Member or associated person of a Member must:

---

[21] Members must honor a person's do-not-call request within a reasonable time from the date the request is made, which may not exceed 30 days from the date of the request. If these requests are recorded or maintained by a party other than the Member on whose behalf the outbound telephone call is made, the Member on whose behalf the outbound telephone call is made will still be liable for any failures to honor the do-not-call request.

[22] *See* 47 CFR 64.1200(d); *see also* FINRA Rule 3230(d).

[23] 15 U.S.C. 7001 *et seq.*

[24] The term ''personal relationship'' means any family member, friend, or acquaintance of the person making an outbound telephone call. *See* proposed Rule 3.26(n)(18); *see also* FINRA Rule 3230(m)(18).

[25] *See* 16 CFR 310.4(b)(1)(iii)(B); *see also* FINRA Rule 3230(b).

[26] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4628; Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995) at 43854.

[27] *See* 16 CFR 310.4(b)(3); *see also* FINRA Rule 3230(c).

[28] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4628; and Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995) at 43855.

[29] *See also* FINRA Rule 3230(e).

[30] *See also* FINRA Rule 3230(f).

[31] The term ''billing information'' means any data that enables any person to access a customer's or donor's account, such as a credit or debit card number, a brokerage, checking, or savings account number, or a mortgage loan account number. *See* proposed Rule 3.26(n)(3).

[32] The term ''preacquired account information'' means any information that enables a Member or associated person of a Member to cause a charge to be placed against a customer's or donor's account without obtaining the account number directly from the customer or donor during the telemarketing transaction pursuant to which the account will be charged. *See* proposed Rule 3.26(n)(19).

[33] The term ''free-to-pay conversion'' means, in an offer or agreement to sell or provide any goods or

(1) Obtain from the customer, at a minimum, the last four digits of the account number to be charged;

(2) Obtain from the customer an express agreement to be charged and to be charged using the identified account number; and

(3) Make and maintain an audio recording of the entire telemarketing transaction.

For any other telemarketing transaction involving preacquired account information, the Member or associated person of a Member must:

(1) Identify the account to be charged with sufficient specificity for the customer to understand what account will be charged; and

(2) Obtain from the customer an express agreement to be charged and to be charged using the identified account number.

The proposed rule change is substantially similar to the FTC's provision regarding the submission of billing information.[34] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[35]

Caller Identification Information

Proposed Rule 3.26(i) provides that Members that engage in telemarketing must transmit caller identification information[36] and are explicitly prohibited from blocking caller identification information. The telephone number provided must permit any person to make a do-not-call request during normal business hours. These provisions are similar to the caller identification provision in the FTC rules.[37] Inclusion of these caller identification provisions in this proposed rule change will not create any new obligations on Members, as they are already subject to identical provisions under FCC telemarketing regulations.[38]

Unencrypted Consumer Account Numbers

Proposed Rule 3.26(j) prohibits a Member or associated person of a Member from disclosing or receiving, for consideration, unencrypted consumer account numbers for use in telemarketing. The proposed rule change is substantially similar to the FTC's provision regarding unencrypted consumer account numbers.[39] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[40] Additionally, the proposed rule change defines ''unencrypted'' as not only complete, visible account numbers, whether provided in lists or singly, but also encrypted information with a key to its decryption. The proposed definition is substantially similar to the view taken by the FTC.[41]

Abandoned Calls

Proposed Rule 3.26(k) prohibits a Member or associated person of a Member from abandoning[42] any outbound telephone call. The abandoned calls prohibition is subject to a ''safe harbor'' under proposed Rule 3.26(k)(2) that requires a Member or associated person of a Member:

(1) To employ technology that ensures abandonment of no more than three percent of all calls answered by a person, measured over the duration of a single calling campaign, if less than 30 days, or separately over each successive 30-day period or portion thereof that the campaign continues;

(2) For each outbound telephone call placed, to allow the telephone to ring for at least 15 seconds or four rings before disconnecting an unanswered call;

(3) Whenever a Member or associated person of a Member is not available to speak with the person answering the outbound telephone call within two seconds after the person's completed greeting, promptly to play a prerecorded message stating the name and telephone number of the Member or associated person of a Member on whose behalf the call was placed; and

(4) To maintain records documenting compliance with the ''safe harbor.''

The proposed rule change is substantially similar to the FTC's provisions regarding abandoned calls.[43] The FTC provided a discussion of the provisions when they are adopted pursuant to the Prevention Act.[44]

Prerecorded Messages

Proposed Rule 3.26(l) prohibits a Member or associated person of a Member from initiating any outbound telephone call that delivers a prerecorded message without a person's express written agreement[45] to receive such calls. The proposed rule change also requires that all prerecorded outbound telephone calls provide specified opt-out mechanisms so that a person can opt out of future calls. The prohibition does not apply to a prerecorded message permitted for compliance with the ''safe harbor'' for abandoned calls under proposed Rule 3.26(k)(2). The proposed rule change is substantially similar to the FTC's provisions regarding prerecorded messages.[46] The FTC provided a discussion of the provisions when they were adopted pursuant to the Prevention Act.[47]

Credit Card Laundering

Proposed Rule 3.26(m) prohibits credit card laundering, the practice of depositing into the credit card system[48] a sales draft that is not the result of a credit card transaction between the cardholder[49] and the Member. Except as expressly permitted, the proposed rule change prohibits a Member or associated person of a Member from:

(1) Presenting to or depositing into the credit card system for payment, a credit

services, a provision under which a customer receives a product or service for free for an initial period and will incur an obligation to pay for the product or service if he or she does not take affirmative action to cancel before the end of that period. *See* proposed Rule 3.26(n)(13).

[34] *See* 16 CFR 310.4(a)(7); *see also* FINRA Rule 3230(i).

[35] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4616.

[36] Caller identification information includes the telephone number and, when made available by the Member's telephone carrier, the name of the Member.

[37] *See* 16 CFR 310.4(a)(8); *see also* FINRA Rule 3230(g).

[38] *See* 47 CFR 64.1601(e).

[39] *See* 16 CFR 310.4(a)(6); *see also* FINRA Rule 3230(h).

[40] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4615.

[41] *See id.* at 4616.

[42] An outbound telephone call is ''abandoned'' if the called person answers it and the call is not connected to a Member or associated person of a Member within two seconds of the called person's completed greeting.

[43] *See* 16 CFR 310.4(b)(1)(iv) and (b)(4); *see also* FINRA Rule 3230(j).

[44] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4641.

[45] The express written agreement must: (a) Have been obtained only after a clear and conspicuous disclosure that the purpose of the agreement is to authorize the Member to place prerecorded calls to such person; (b) have been obtained without requiring, directly or indirectly, that the agreement be executed as a condition of purchasing any good or service; (c) evidence the willingness of the called person to receive calls that deliver prerecorded messages by or on behalf of the Member; and (d) include the person's telephone number and signature (which may be obtained electronically under the E–Sign Act).

[46] *See* 16 CFR 310.4(b)(1)(v); *see also* FINRA Rule 3230(k).

[47] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 73 FR 51164 (Aug. 29, 2008) at 51165.

[48] The term ''credit card system'' means any method or procedure used to process credit card transactions involving credit cards issued or licensed by the operator of that system. The term ''credit card'' means any card, plate, coupon book, or other credit device existing for the purpose of obtaining money, property, labor, or services on credit. The term ''credit'' means the right granted by a creditor to a debtor to defer payment of debt or to incur debt and defer its payment. *See* proposed Rule 3.26(n)(7), (8), and (10).

[49] The term ''cardholder'' means a person to whom a credit card is issued or who is authorized to use a credit card on behalf of or in addition to the person to whom the credit card is issued. *See* proposed Rule 3.26(n)(6).

card sales draft [50] generated by a telemarketing transaction that is not the result of a telemarketing credit card transaction between the cardholder and the Member;

(2) Employing, soliciting, or otherwise causing a merchant,[51] or an employee, representative or agent of the merchant to present to or to deposit into the credit card system for payment, a credit card sales draft generated by a telemarketing transaction that is not the result of a telemarketing credit card transaction between the cardholder and the Member; or

(3) Obtaining access to the credit card system through the use of a business relationship or an affiliation with a merchant, when such access is not authorized by the merchant agreement [52] or the applicable credit card system.

The proposed rule change is substantially similar to the FTC's provision regarding credit card laundering.[53] The FTC provided a discussion of the provisions when they were adopted pursuant to the Prevention Act.[54]

Definitions

Proposed Rule 3.26(n) adopts the following definitions, which are substantially similar to the FTC's definitions of these terms: ''acquirer,'' ''billing information,'' ''caller identification service,'' ''cardholder,'' ''charitable contribution,'' ''credit,'' ''credit card,'' ''credit card sales draft,'' ''credit card system,'' ''customer,'' ''donor,'' ''established business relationship,'' ''free-to-pay conversion,'' ''merchant,'' ''merchant agreement,'' ''outbound telephone call,'' ''person,'' ''preacquired account information,'' ''telemarketer,'' and ''telemarketing.'' [55] The FTC provided a discussion of each definition when they were adopted pursuant to the Prevention Act.[56]

State and Federal Laws

Proposed Rule 3.26, Interpretation and Policy .01 [57] reminds Members and associated persons of Members that engage in telemarketing that they also are subject to the requirements of relevant state and federal laws and rules, including the Prevention Act, the Telephone Consumer Protection Act of 1991,[58] and the rules of the FCC relating to telemarketing practices and the rights of telephone consumers.[59]

Announcement in Regulatory Circular

The Exchange will announce the implementation date of the proposed rule change in a Regulatory Notice to be published no later than 90 days following the effective date. The implementation date will be no later than 180 days following the effective date.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[60] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [61] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest.

In particular, the proposed rule change will prevent fraudulent and manipulative acts and protect investors and the public interest by continuing to prohibit Members from engaging in deceptive and other abusive telemarketing acts or practices. Additionally, the proposed rule change removes impediments to and perfects the mechanism for a free and open market and a national market system, because it provides consistency among telemarketing rules of national securities exchanges and FINRA, therefore making it easier for investors to comply with these rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change is filed for immediate effectiveness pursuant to Section 19(b)(3)(A) of Act [62] and Rule 19b–4(f)(6) [63] thereunder. The Exchange designates that the proposed rule change effects a change 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) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. Additionally, the Exchange has given the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change. The proposed rule change is substantially similar in all material respects to FTC rules and FINRA Rule 3230, which the Commission recently approved.[64]

For the foregoing reasons, this rule filing qualifies as a ''non-controversial'' rule change under Rule 19b–4(f)(6), which renders the proposed rule change effective upon filing with the

[50] The term ''credit card sales draft'' means any record or evidence of a credit card transaction. *See* proposed Rule 3.26(n)(9).

[51] The term ''merchant'' means a person who is authorized under a written contract with an acquirer to honor or accept credit cards, or to transmit or process for payment credit card payments, for the purchase of goods or services or a charitable contribution. The term ''acquirer'' means a business organization, financial institution, or an agent of a business organization or financial institution that has authority from an organization that operates or licenses a credit card system to authorize merchants to accept, transmit, or process payment by credit card through the credit card system for money, goods or services, or anything else of value. *See* proposed Rule 3.26(n)(2) and (14).

[52] The term ''merchant agreement'' means a written contract between a merchant and an acquirer to honor or accept credit cards, or to transmit or process for payment credit card payments, for the purchase of goods or services or a charitable contribution. *See* proposed Rule 3.26(n)(15).

[53] *See* 16 CFR 310.3(c); *see also* FINRA Rule 3230(l).

[54] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995) at 43852.

[55] *See* proposed Rule 3.26(n)(2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (19), (20), and (21); and 16 CFR 310.2(a), (c), (d), (e), (f), (h), (i), (j), (k), (l), (n), (o), (p), (s), (t), (v), (w), (x), (cc), and (dd); *see also* FINRA Rule 3230(m)(2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (19), and (20). The proposed rule change also adopts definitions of ''account activity,'' ''broker-dealer of record,'' and ''personal relationship'' that are substantially similar FINRA's definitions of these terms. *See* proposed Rule 3.26(n)(1), (4), and (18) and FINRA Rule 3230(m)(1), (4), and (18); *see also* 47 CFR 64.1200(f)(14) (FCC's definition of ''personal relationship'').

[56] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (Aug. 23, 1995) at 43843; and Federal Trade Commission, *Telemarketing Sales Rule,* 68 FR 4580 (Jan. 29, 2003) at 4587.

[57] *See also* FINRA Rule 3230, Supplementary Material .01, *Compliance with Other Requirements.*

[58] *See* 47 U.S.C. 227.

[59] *See* 47 CFR 64.1200.

[60] 15 U.S.C. 78f(b).

[61] 15 U.S.C. 78f(b)(5).

[62] 15 U.S.C. 78s(b)(3)(A).

[63] 17 CFR 240.19b–4(f)(6).

[64] *See supra* note 3.

Commission. The Exchange has requested that the Commission waive the 30-day operative delay period after which a proposed rule change under Rule 19b–4(f)(6) becomes effective. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver will afford Exchange members the benefit of the proposal—the prohibition of deceptive and other abusive telemarketing acts or practices—without unnecessary delay. Such waiver will also allow the Exchange to comply with the Commission's directive and implement uniform telemarketing rules across self-regulatory organizations, creating consistency among these rules for investors, as soon as possible. For these reasons, the Commission designates the proposed rule change as operative under upon filing.[65]

At any time within 60 days of the filing of this proposed rule change, the Commission summarily may temporarily suspend 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 Email to *rule-comments@sec.gov*. Please include File No. SR–EDGA–2012–16 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGA–2012–16. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGA–2012–16 and should be submitted by May 24, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[66]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–10644 Filed 5–2–12; 8:45 am]

BILLING CODE 8011–01–P

[65] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[66] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 7867]

Culturally Significant Objects Imported for Exhibition Determinations: ''Lygia Clark''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be imported from abroad for temporary study and inclusion in the exhibition ''Lygia Clark,'' within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Museum of Modern Art, New York, New York, from on or about May 4, 2014 until on or about August 25, 2014, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Paul W. Manning, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: (202) 632-6473). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: April 25, 2012.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2012–10680 Filed 5–2–12; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 7869]

Notice of Availability of the Environmental Assessment and Request for Comments on Environmental Issues, and the National Interest Determination for the Vantage Pipeline Project

Vantage US LP has applied to the Department of State (DOS) for a Presidential Permit to construct and operate facilities at the border for a proposed pipeline carrying ethane from North Dakota to Canada. The DOS has released an Environmental Assessment (EA) that discusses the potential environmental impacts of the proposed Vantage Pipeline Project. This EA will be used by the DOS in its decision-making process to determine whether the project would serve the national interest and whether the applicant should receive a Presidential Permit. This notice announces the opening of the public comment process the DOS will use to gather input from the public on the proposed project. Your input will help the DOS determine the next steps in the environmental review of this project and whether the project would serve the national interest. The DOS is requesting comments on: (1) The EA, and (2) whether the Vantage Pipeline Project serves the national interest. Please note that the public comment period will close on June 2, 2012.

Summary of the Proposed Project

The proposed Vantage Pipeline Project would be an underground high vapor pressure pipeline that would carry liquid ethane from Tioga, North Dakota to Alberta, Canada. In the United States, Vantage proposes to construct and operate 79.8 miles of 10-inch-diameter ethane pipeline in Williams and Divide Counties, North Dakota. Aboveground, the project would include the installation of mainline valves at seven locations along the pipeline and the use of various ancillary facilities (*e.g.,* access roads, yards).

The Vantage Pipeline would export ethane to Canada that is extracted from North Dakota-produced natural gas and compressed to a liquid form at an existing natural gas facility in North Dakota. The ethane that would be transported in the Vantage Pipeline is a flammable liquid that is non-corrosive, odorless, and colorless. It has similar characteristics to natural gas, the fuel that is used in furnaces to heat homes. Ethane is currently used as a petrochemical feedstock and is ultimately converted to plastics, anti-freeze, rubber, detergents, solvents, and like products. Vantage anticipates that the ethane transported through the proposed pipeline would be used for these purposes by the Alberta petrochemical industry. The Canadian National Energy Board approved the Canadian portion of the pipeline system on January 19, 2012.

The Presidential Permit Process

The Secretary of State is designated and empowered under Executive Order 13337 to receive all applications for Presidential permits for the construction, connection, operation, or maintenance at the borders of the United States, of facilities for the exportation or importation of petroleum, petroleum products, coal, or other liquid or solid fuels to or from a foreign country. As a part of the review of an application for a Presidential Permit, the Secretary of State must determine whether or not the project would be in the national interest. The determination of national interest involves consideration of many factors, which can include energy security, environmental, cultural, economic and foreign policy impacts. The EA that is the subject of this notification is considered in the national interest determination.

The Environmental Review Process

Consistent with the National Environmental Policy Act (NEPA) of 1969, as amended, regulations developed by the Council on Environmental Quality (40 CFR 1500), and DOS regulations for implementing NEPA (22 CFR 161), the DOS is undertaking an environmental review of the proposed pipeline in the United States. DOS now has issued an EA for the proposed Vantage Pipeline Project.

In the EA, the DOS discusses impacts that could occur as a result of the construction and operation and maintenance of pipeline facilities of natural gas liquids and also evaluates reasonable alternatives to the proposed project. The potential environmental impacts of the Project are based on currently available information.

In addition, the DOS is carrying out the Section 106 review process under Section 101(d)(6)(b) of the National Historic Preservation Act of 1966 through which it consults with any Indian tribe that attaches religious or cultural significance to historic properties that may be affected by construction of the Vantage Pipeline.

The EA is available to the public from the Web site *http://vantagepipeline.state.gov/* and by mail. Following the 30-day public comment period, and after taking into account any comments received during that period, the DOS will decide whether to issue a Finding of No Significant Impact (FONSI) or proceed with further environmental review through an Environmental Impact Statement (EIS). To ensure that your comments are considered, please carefully follow the instructions detailed in the Public Participation section below.

Public Participation

You are encouraged to become involved in this process and provide your comments or concerns about the proposed project. As noted above, we are requesting comments on two aspects of the Vantage Pipeline Project. First, we request comments on the EA that focus on the potential environmental impacts of the project, reasonable alternatives, and measures to avoid or lessen environmental impacts. The EA is available on the DOS Web site for the project at *http://vantagepipeline.state.gov/.*

Second, we are requesting comments on whether this project is in the national interest. The determination of national interest involves consideration of many factors, which can include energy security, environmental, cultural, and economic impacts.

To ensure that we have the opportunity to consider your comments, please make sure that comments on one or both of these issues described above are postmarked by June 2, 2012.

For your convenience, there are two methods that you can use to submit your comments. In all instances please reference the project (i.e., Vantage) with your submission. We encourage electronic filing of comments.

(1) You may mail your comments to the following address: State Department Vantage Comments, 2020 Pennsylvania Avenue NW., Box #501, Washington, DC 20006.

(2) You may enter your comments directly on the DOS Web site at: *http://vantagepipeline.state.gov/.*

Environmental Mailing List

The DOS sends information related to this environmental review to individuals, organizations, and government entities interested in and/or potentially affected by the proposed project and maintains an environmental mailing list for this purpose. The environmental mailing list includes: Federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners who are potential right-of-way grantors, whose property may be used temporarily for project purposes, and anyone who submits comments on the project. The DOS will update the environmental mailing list as the analysis proceeds. If you would like to be included on the mailing list, please submit your address by accessing the DOS Web site at *http://vantagepipeline.state.gov/.*

Additional Information

The EA and related documents to be considered by the DOS in connection with this application, including environmental information and associated maps, are downloadable at: *http://www.vantagepipeline.state.gov.* The Vantage Pipeline Project toll free number is 1–877–918–6818 (United States).

Dated: Issued in Washington, DC on May 1, 2012.

George N. Sibley,

Director, Office of Environmental Policy, Bureau of Oceans and International Environmental and Scientific Affairs, U.S. Department of State.

[FR Doc. 2012–10812 Filed 5–2–12; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Avenida Rio Salado/Broadway Road

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review of actions by FHWA and other Federal Agencies.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to the extension and reconstruction of Broadway Road between 67th Avenue and 7th Street within the city of Phoenix, Maricopa County, Arizona. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before October 30, 2012. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Mr. Tom Deitering, Area Engineer, Federal Highway Administration, 4000 N. Central Avenue, Suite 1500, Phoenix, Arizona 85012–3500; telephone: (602) 379-3646, fax: (602) 382-8998, email: *Thomas.Deitering@dot.gov.*

The FHWA Arizona Division Office's normal business hours are 8 a.m. to 5 p.m. (Mountain Standard Time).

You may also contact: Mr. Ken Davis, Senior Engineering Manager, Federal Highway Administration, 4000 N. Central Avenue, Suite 1500, Phoenix, Arizona 85012–3500; telephone: (602) 379-3646, fax: (602) 382-8998, email: *Ken.Davis@dot.gov.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA and other Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the following project in the State of Arizona: Avenida Rio Salado/Broadway Road. The improvements include extending Broadway Road by constructing a new 6-lane roadway between 67th and 43rd avenues, widening the existing Broadway Road to 6-lanes between 43rd and 17th avenues, and improving the Broadway Road intersections at 15th, 7th, and Central avenues and 7th Street. The project will require approximately 102.63 acres of additional right of way and would not result in residential or commercial displacements. Some properties will require reconfiguration to remain functional under the changed roadway conditions.

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Avenida Rio Salado/Broadway Road Final Environmental Assessment and Section 4(f) Evaluation (Final EA) for the project, approved on January 5, 2012, in the FHWA Finding of No Significant Impact (FONSI) issued on January 5, 2012, and in other documents in the FHWA administrative record. The FONSI, Final EA, and other documents in the FHWA administrative record file are available by contacting the FHWA or the Arizona Department of Transportation at the addresses provided above. The FONSI and Final EA including the Public Hearing Summary are available online at: *http://avenidariosalado.com/environmental_assessment.php.* This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536], Marine Mammal Protection Act [16 U.S.C. 1361], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–11]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601–4604]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)–300(j)(6)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; Flood Disaster Protection Act [42 U.S.C. 4001–4128].

8. *Water:* Clean Water Act 33 U.S.C. 1251–1387.

9. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: April 25, 2012.

Karla S. Petty,

Division Administrator, Phoenix, Arizona.

[FR Doc. 2012–10574 Filed 5–2–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2012–0005]

Surface Transportation Project Delivery Pilot Program; Caltrans Audit Report

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final report.

SUMMARY: Section 6005 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) established the Surface Transportation Project Delivery Pilot Program, codified at 23 U.S.C. 327. To ensure compliance by each State participating in the Pilot Program, 23 U.S.C. 327(g) mandates semiannual audits during each of the first 2 years of State participation. This final report presents the findings from the sixth FHWA audit of the California Department of Transportation (Caltrans) under the pilot program.

FOR FURTHER INFORMATION CONTACT: Ms. Ruth Rentch, Office of Project Development and Environmental Review, (202) 366–2034, *Ruth.Rentch@dot.gov,* or Mr. Michael Harkins, Office of the Chief Counsel, (202) 366–4928, *Michael.Harkins@dot.gov,* Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

This document, the notice and request for comment, and all comments received may be viewed online through the Federal eRulemaking portal at: *http://www.regulations.gov.* Electronic submission and retrieval help and guidelines are available on the Web site. It is available 24 hours each day, 366 days this year. Please follow the instructions. An electronic copy of this notice may be downloaded from the Office of the Federal Register's home page at *http://www.archives.gov* and the Government Printing Office's Web site at *http://www.access.gpo.gov.*

Background

Section 6005 of SAFETEA–LU (codified at 23 U.S.C. 327) established a pilot program to allow up to five States to assume the Secretary of Transportation's responsibilities for environmental review, consultation, or other actions under any Federal environmental law pertaining to the review or approval of highway projects. In order to be selected for the pilot program, a State must submit an application to the Secretary.

On June 29, 2007, Caltrans and FHWA entered into a Memorandum of Understanding (MOU) that established the assignments to and assumptions of responsibility to Caltrans. Under the MOU, Caltrans assumed the majority of FHWA's responsibilities under the National Environmental Policy Act, as well as the FHWA's responsibilities under other Federal environmental laws for most highway projects in California.

To ensure compliance by each State participating in the Pilot Program, 23 U.S.C. 327(g) requires the Secretary to conduct semiannual audits during each of the first 2 years of State participation; and annual audits during each subsequent year of State participation. The results of each audit must be presented in the form of an audit report and be made available for public comment. The FHWA solicited comments on the sixth audit report in a **Federal Register** Notice published on February 22, 2012, at 77 FR 10599. The FHWA received one comment from Caltrans. This notice provides the final draft of the sixth FHWA audit report for Caltrans under the pilot program.

Authority: Section 6005 of Pub. L. 109–59; 23 U.S.C. 315 and 327; 49 CFR 1.48.

Issued on: April 26, 2012.

Victor M. Mendez,

Administrator.

[FR Doc. 2012–10616 Filed 5–2–12; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2010–0060]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated March 12, 2012, the Norfolk Southern Railway (NS) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations. FRA assigned the petition to Docket Number FRA–2010–0060.

Pursuant to the requirements of 49 CFR Section 236.1035 (Field testing requirements), NS has submitted the Interoperable Electronic Train Management System (I–ETMS) Positive Train Control (PTC) test waiver request, Version 1.1, dated March 12, 2012, along with associated required documents for request of relief from select parts of Subparts A–G. In conjunction with those requests, per 49 CFR Section 236.1035, the NS test waiver includes requests for relief from regulations other than those contained in Subparts A–G.

I–ETMS is a vital overlay system as defined in 49 CFR Part 236, Subpart I, Section 236.1015(e)(2) and fully described in the NS I–ETMS PTC Development Plan (FRA–2010–0060–0002) found in Appendix A, and for which FRA Type Approval FRA–TA–2011–02 was issued on August 26, 2011.

The I–ETMS system is designed to support different railroads and their individual methods of operation and is intended to be implementable across a broad spectrum of railroads without significant modification. This design approach supports interoperability across railroads as I–ETMS-equipped locomotives apply consistent warning and enforcement functionality regardless of trackage ownership.

NS seeks a waiver of compliance from certain sections of 49 CFR, including Parts 216, Special Notice and Emergency Order Procedures: Railroad Track, Locomotive and Equipment; 217, Railroad Operating Rules; 218, Railroad Operating Practices; 229, Railroad Locomotive Safety Standards; 233, Signal Systems Reporting Requirements; 235, Instructions Governing Applications for Approval of a Discontinuance or Material Modification of a Signal System or Relief from the Requirements of Part 236; and 240, Qualification and Certification of Locomotive Engineers. NS also seeks a waiver of compliance from 49 CFR Section 211.51 (Tests) to allow them to test I–ETMS, on nonrevenue trains, on the Charleston District from Charleston, SC, milepost (MP) SC 7.0, to Andrews Yard, Columbia, SC, MP SC 128.9; and on the Columbia District from Andrews Yard, Columbia, SC, MP R 108.5, to Charolette Junction, MP R0.0.

The following are the waiver requests and their justifications:

Section 216.13, Special Notice for Repairs—Locomotive

Waiver is requested for I–ETMS-equipped locomotives to the extent that non-operation of I–ETMS equipment installed on board, whether through malfunction or deactivation, shall not be construed as an unsafe condition requiring special notice for repairs. Waiver is also sought for non-I–ETMS-equipped locomotives operating in I–ETMS territory to the extent that the absence of I–ETMS equipment on board shall not be construed as an unsafe condition requiring special notice for repairs.

Justification: With or without I–ETMS equipment operating on board the controlling locomotive, a train remains subject to existing operating rules. I–ETMS tests require flexibility in installing, removing, turning on, and turning off the equipment.

Section 217.9, Program of Operational Tests and Inspections; Recordkeeping

Waiver is requested, exempting operation of I–ETMS equipment and procedures from the requirements for operational tests and inspections, and associated recordkeeping.

Justification: During the I–ETMS test phase, procedures for using I–ETMS equipment and functions will be refined and modified. Until such procedures are defined in the PTC Safety Plan (PTCSP), or associated documentation, they cannot be addressed in NS operating rules. I–ETMS is expected to have minimal impact on existing operating

rules due to its nature of overlay to existing methods of operation.

Section 217.11, Program of Instruction on Operating Rules; Recordkeeping; Electronic Recordkeeping

Waiver is requested, exempting I–ETMS testing and its equipment and procedures from the requirements for instruction and recordkeeping.

Justification: During the I–ETMS test phase, procedures for using I–ETMS equipment and functions will be refined and modified. Until such procedures are defined in the PTCSP, or associated documentation, they cannot be addressed in NS operating rules. I–ETMS is expected to have minimal impact on existing operating rules due to its nature of overlay to existing methods of operation.

Part 218, Subpart D, Prohibition Against Tampering With Safety Devices

Waiver is requested, exempting onboard I–ETMS equipment from the requirements of Sections 218.51, 218.53, 218.55, 218.57, 218.59, and 218.61 to the extent that I–ETMS equipment on board a locomotive shall not be considered a ''safety device'' subject to the provisions of this subpart at any time during the test and demonstration phase.

Justification: I–ETMS tests and demonstrations require flexibility in installing, removing, turning on, and turning off the onboard equipment. NS also needs the flexibility to permanently disable or remove I–ETMS equipment in the event that a revenue service system is not implemented.

Section 229.7, Prohibited Acts

Waiver is requested such for both I–ETMS equipped and non-I–ETMS equipped locomotives operating in the I–ETMS test territory during the test period.

Justification: Non-operation of I–ETMS equipment installed on board a locomotive, whether through malfunction or deactivation, shall not be construed as an unsafe condition subject to this section. Additionally, in the absence of I–ETMS equipment onboard, non-I–ETMS-equipped locomotives operating in I–ETMS territory shall not be construed as an unsafe condition subject to this regulation. The I–ETMS test program requires flexibility in installing, removing, turning on, and turning off the onboard equipment. NS also requires the flexibility to permanently disable or remove I–ETMS equipment in the event that a production system is not implemented. The train remains subject to the safety provisions of the existing method of operation whether or not I–ETMS equipment on board a locomotive is functioning.

Section 229.135, Event Recorders

Waiver is requested to the extent that I–ETMS equipment on board a locomotive shall not be considered an ''event recorder'' subject to the provisions of this section during the test phase.

Justification: I–ETMS equipment by design will operate intermittently during the test phase. The data accumulated by the onboard I–ETMS equipment will be used to develop and refine I–ETMS functions. Such data can be expected to contain anomalies that do not reflect true operating conditions but, by analysis, will contribute to achieving necessary objectives in the I–ETMS design.

Section 233.9, Reports

Waiver is requested, exempting I–ETMS operations in the test phase from the reporting requirements of this section.

Justification: NS recognizes that a revenue service I–ETMS system is subject to the provisions of this section; however, imposition of these requirements during the test and demonstration phase would be an unnecessary paperwork burden. PTC testing should not affect the final inventory of the NS signal system, which will be included in the signal system 5-year report.

Section 235.5, Changes Requiring Filing of Application

Waiver is requested, exempting I–ETMS from the requirements of this section during the test phase.

Justification: I–ETMS tests require flexibility in installing, removing, modifying, turning on, and turning off the I–ETMS equipment. NS also requires the flexibility to permanently disable or remove I–EMS equipment in the event that a revenue service system is not implemented.

Section 240.127, Criteria for Examining Skill Performance

Waiver is requested exempting I–ETMS from the testing requirements for qualification and certification of locomotive engineers during the test phase.

Justification: Criteria and procedures for engineer performance evaluation, as related to I–ETMS, do not yet exist; they will be identified and defined during the I–ETMS test phase and included in the PTCSP.

Section 240.129, Criteria for Monitoring Operational Performance of Certified Engineers

Waiver is requested, exempting I–ETMS from the performance monitoring procedures during the I–ETMS test phase.

Justification: Criteria and procedures for I–ETMS monitoring the performance of engineers using I–ETMS do not yet exist; they will be identified and defined during the I–ETMS test phase and included in the PTCSP.

In addition, NS is requesting a waiver of compliance from certain portions of 49 CFR Part 236, Rules, Standards, and Instructions Governing the Installation, Inspection, Maintenance, and Repair of Signal and Train Control Systems, Devices, and Appliances; for information only and of which FRA is not receiving comments. Those sections are:

- 236.11, Adjustment, repair, or replacement of component.
- 236.15, Timetable instructions.
- 236.23, Aspects and indications.
- 236.76, Tagging of wires and interference of wires or tags with signal apparatus.
- 236.101, Purpose of inspection and tests; removal from service of relay or device failing to meet test requirements.
- 236.109, Time releases, timing relays and timing devices.
- 236.110, Results of tests.
- 236.501, Forestalling device and speed control.
- 236.552, Insulation resistance; requirement.
- 236.566, Locomotive of each train operating in train stop, train control or cab signal territory; equipped.
- 236.567, Restrictions imposed when device fails and/or is cut out en route.
- 236.586, Daily or after trip test.
- 236.587, Departure test.
- 236.588, Periodic test.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they

should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* (202) 493-2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by June 18, 2012 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

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

Issued in Washington, DC, on April 26, 2012.

Ron Hynes,

Acting Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2012–10703 Filed 5–2–12; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2010–0028]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated February 16, 2012, CSX Transportation, Inc. (CSX) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 236. FRA assigned the petition to Docket Number FRA–2010–0028.

Pursuant to the requirements of 49 CFR Section 236.1035, Field testing requirements, CSX has submitted the Interoperable Electronic Train Management System® (I–ETMS) Positive Train Control (PTC) Test Waiver Request, Version 1.0, dated February 16, 2012, along with associated required documents for request of relief from select parts of Subparts A–G. In conjunction with those requests, CSX test waiver includes requests for relief from regulations other than that contained in Subparts A–G.

I–ETMS is a vital overlay system as defined in 49 CFR part 236, subpart I, Section 236.1015(e)(2) and fully described in the CSX I–ETMS PTC Development Plan found in Appendix A, and for which FRA Type Approval, FRA–TA–2011–02, was issued on August 26, 2011.

The I–ETMS system is designed to support different railroads and their individual methods of operation, and is intended to be implementable across a broad spectrum of railroads without significant modification. This design approach supports interoperability across railroads, as I–ETMS equipped locomotives apply consistent warning and enforcement functionality regardless of trackage ownership.

CSX seeks a waiver of compliance from certain parts of 49 CFR (Parts 216, *Special Notice and Emergency Order Procedures: Railroad Track, Locomotive and Equipment;* Part 217, *Railroad Operating Rules; Part 218, Railroad Operating Practices;* Part 229, *Railroad Locomotive Safety Standards;* Part 233, *Signal Systems Reporting Requirements;* Part 235, *Instructions Governing Applications for Approval of a Discontinuance or Material Modification of a Signal System or Relief from the Requirements of Part 236;* and Part 240, *Qualification and Certification of Locomotive Engineers*), under Section 211.51 (Tests), to allow them to test I–ETMS on nonrevenue trains on the Aberdeen Subdivision (between Raleigh and Hamlet, NC) from Southern Junction (Milepost (MP) South 156.8) to Marston (MP South 241.6), and on the Wilmington Subdivision (between Hamlet and Wilmington, NC) from NE East Junction (MP Southeast 254.1) to end of main track (MP Southeast 354.0).

The following sections include the waiver request and justification:

- Section 216.13, Special notice for repairs—locomotive. A waiver is requested for I–ETMS-equipped locomotives to the extent that non-operation of I–ETMS equipment installed on board, whether through malfunction or deactivation, shall not be construed as an unsafe condition requiring special notice for repairs. A waiver is also sought for non-I–ETMS-equipped locomotives operating in I–ETMS territory to the extent that the absence of I–ETMS equipment on board shall not be construed as an unsafe condition requiring special notice for repairs.

Justification: With or without I–ETMS equipment operating on board the controlling locomotive, a train remains subject to existing operating rules. I–ETMS tests require flexibility in installing, removing, turning on, and turning off the equipment.

- Section 217.9, Program of operational tests and inspections—recordkeeping. A waiver is requested exempting operation of I–ETMS equipment and procedures from the requirements for operational tests and inspections, and associated recordkeeping.

Justification: During the I–ETMS test phase, procedures for using I–ETMS equipment and functions will be refined and modified. Until such procedures are defined in the PTC Safety Plan (PTCSP) and associated documentation, they cannot be addressed in CSX Operating Rules. I–ETMS is expected to have minimal impact on existing operating rules due to its nature of overlay to existing methods of operation.

- Section 217.11, Program of instruction on operating rules; recordkeeping; electronic recordkeeping. A waiver is requested exempting I–ETMS testing and its equipment and procedures from the requirements for instruction and recordkeeping.

Justification: During the I–ETMS test phase, procedures for using I–ETMS equipment and functions will be refined and modified. Until such procedures are defined in the PTCSP and associated documentation, they cannot be addressed in CSX Operating Rules. I–ETMS is expected to have minimal impact on existing operating rules due to its nature of overlay to existing methods of operation.

- Part 218, Subpart D—*Prohibition Against Tampering With Safety Devices.* A waiver is requested exempting onboard I–ETMS equipment from the requirements of Sections 218.51, 218.53, 218.55, 218.57, 218.59, and 218.61 to the extent that I–ETMS equipment on board a locomotive shall not be considered a ''safety device'' subject to the provisions of this subpart at any time during the test and demonstration phase.

Justification: I–ETMS tests and demonstrations require flexibility in

installing, removing, turning on, and turning off the onboard equipment.

• Section 229.7, Prohibited acts. A waiver is requested for both I–ETMS-equipped and non-I–ETMS-equipped locomotives operating in the I–ETMS test territory during the test period.

Justification: Non-operation of I–ETMS equipment installed on board a locomotive, whether through malfunction or deactivation, shall not be construed as an unsafe condition subject to this section. Additionally, in the absence of I–ETMS equipment on board, non-I–ETMS-equipped locomotives operating in I–ETMS territory shall not be construed as an unsafe condition subject to this regulation. The I–ETMS test program requires flexibility in installing, removing, turning on, and turning off the onboard equipment. Whether I–ETMS equipment on board a locomotive is functioning, the train remains subject to the safety provisions of the existing method of operation.

• Section 229.135, Event recorders. A waiver is requested to the extent that I–ETMS equipment on board a locomotive shall not be considered an ''event recorder,'' subject to the provisions of this section, during the test phase.

Justification: I–ETMS equipment by design will operate intermittently during the test phase. The data accumulated by the onboard I–ETMS equipment will be used to develop and refine I–ETMS functions. Such data can be expected to contain anomalies that do not reflect true operating conditions but, by analysis, will contribute to achieving necessary objectives in the I–ETMS design.

• Section 233.9, Annual reports. A waiver is requested exempting I–ETMS operations in the test phase from the reporting requirements of this section.

Justification: CSX recognizes that a revenue service I–ETMS system is subject to the provisions of this section; however, imposition of these requirements during the test and demonstration phase would be an unnecessary paperwork burden. PTC testing should not affect the final inventory of the CSX signal system, which will be included in the Signal System Five-Year Report.

• Section 235.5, Changes requiring filing of application. A waiver is requested exempting I–ETMS from the requirements of this section during the test phase.

Justification: I–ETMS tests require flexibility in installing, removing, modifying, turning on, and turning off the I–ETMS equipment.

• Section 240.127, Criteria for examining skill performance. A waiver is requested exempting I–ETMS from the testing requirements for qualification and certification of locomotive engineers during the test phase.

Justification: Criteria and procedures for engineer performance evaluation as related to I–ETMS do not yet exist; they will be identified and defined during the I–ETMS test phase and included in the PTCSP.

• Section 240.129, Criteria for monitoring operational performance of certified engineers. A waiver is requested exempting I–ETMS from the performance monitoring procedures during the I–ETMS test phase.

Justification: Criteria and procedures for I–ETMS monitoring the performance of engineers using I–ETMS do not yet exist; they will be identified and defined during the I–ETMS test phase and included in the PTCSP.

In addition, CSX is requesting a waiver of compliance from certain sections of 49 CFR Part 236 (Rules, Standards, and Instructions Governing the Installation, Inspection, Maintenance, and Repair of Signal and Train Control Systems, Devices, and Appliances) for information only, and on which FRA is not receiving comments. Those sections are: 236.11, Adjustment, repair, or replacement of component; 236.15, Timetable instructions; 236.23, Aspects and indications; 236.76, Tagging of wires and interference of wires or tags with signal apparatus; 236.101, Purpose of inspection and tests; removal from service of relay or device failing to meet test requirements; 236.109, Time releases, timing relays and timing devices; 236.110, Results of tests; 236.501, Forestalling device and speed control; 236.552, Insulation resistance; requirement; 236.566, Locomotive of each train operating in train stop, train control or cab signal territory; equipped; 236.567, Restrictions imposed when device fails and/or is cut out en route; 236.586, Daily or after trip test; 236.587, Departure test; and 236.588, Periodic test.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

• *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.

• *Fax:* 202–493–2251.

• *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.

• *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by June 18, 2012 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

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

Issued in Washington, DC, on April 26, 2012.

Ron Hynes,

Acting Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2012–10706 Filed 5–2–12; 8:45 am]

BILLING CODE 4910–06–P

FEDERAL REGISTER

Vol. 77 Thursday,
No. 86 May 3, 2012

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 430, 431, 435, *et al.*
Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Setting Requirements for Community First Choice; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 430, 431, 435, 436, 440, 441, and 447

[CMS–2249–P2]

RIN 0938–AO53

Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Setting Requirements for Community First Choice

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise Medicaid regulations to define and describe State plan home and community-based services (HCBS) under the Social Security Act (the Act) as added by the Deficit Reduction Act of 2005 and amended by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act [1]). This proposed rule offers States new flexibility in providing necessary and appropriate services to elderly and disabled populations and reflects CMS' commitment to the general principles of the President's Executive Order released January 18, 2011, entitled ''Improving Regulation and Regulatory Review.'' In particular, this rule does not require the eligibility link between HCBS and institutional care that exists under the Medicaid HCBS waiver program. This regulation would describe Medicaid coverage of the optional State plan benefit to furnish home and community-based services and receive Federal matching funds. As a result, States will be better able to design and tailor Medicaid services to accommodate individual needs. This may result in improved patient outcomes and satisfaction, while enabling States to effectively manage their Medicaid resources.

This proposed rule would also amend Medicaid regulations consistent with the requirements of the Affordable Care Act, which amended the Act to provide authority for a 5-year duration for certain demonstration projects or waivers under the Act, at the discretion of the Secretary, when they involve individuals dually eligible for Medicaid and Medicare benefits.

In addition, this proposed rule would provide an additional limited exception to the general requirement that payment for services under a State plan must be made directly to the individual practitioner providing a service when the Medicaid program is the primary source of reimbursement for a class of individual practitioners. This exception would allow payments to be made to other parties to benefit the providers by ensuring health and welfare, and training. We are including the payment reassignment provisions in this HCBS proposed rule because State's Medicaid programs often operate as the primary or only payer for the class of practitioners that includes HCBS service providers.

Finally, this proposed rule would also amend Medicaid regulations to provide home and community-based setting requirements of the Affordable Care Act for the Community First Choice State plan option.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m., e.d.t., on June 4, 2012.

ADDRESSES: In commenting, please refer to file code CMS–2249–P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2249–P2, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2249–P2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Kathy Poisal, (410) 786–5940.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

[1] Affordable Care Act: Patient Protection and Affordable Care Act of 2010, Public Law 111–148 as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152.

Table of Contents

I. Executive Summary
II. Background
A. Expanded Access to Home and Community-Based Services for the Elderly and Disabled Under Section 1915(i) of the Act: History of Section 1915(i) of the Act
B. Overview of the State Plan Home and Community-Based Services (HCBS) Benefit To Provide HCBS for the Elderly and Individuals With Disabilities
1. Services
2. Eligibility
3. Number Served
4. Independent Evaluation
5. Adjustment Authority
6. Independent Assessment
7. Person-Centered Service Plan
8. Self-Direction
9. Quality Assurance
10. Conflict of Interest
11. Eligibility Redeterminations; Appeals
12. Option for Presumptive Eligibility for Assessment
13. Individual's Representative
14. Nonapplication
15. No Effect on Waiver Authority
16. Continuation of Federal Financial Participation (FFP) for Institutional Level of Care for Individuals Receiving Services as of the Effective Date of the State Plan HCBS Amendment
17. State Option To Provide HCBS to Individuals Eligible for Services Under a Waiver
18. Establishment of Optional Eligibility Group To Provide Full Medicaid Benefits to Individuals Receiving State Plan HCBS
19. State Option To Offer HCBS to Specific, Targeted Populations
20. Five-Year Approval for Targeted Section 1915(i) HCBS Benefits and Renewal Requirements
21. Phase-In of Services and Eligibility
C. Effective Date
D. The State Plan HCBS Benefit in the Context of the Medicaid Program as a Whole
E. Other Background
F. Section 2601 of the Affordable Care Act: 5-Year Period for Demonstration Projects
G. Prohibition Against Reassignment of Provider Claims
H. Definition of Home and Community-Based Settings for the 1915(k) Community First Choice State Plan Option
III. Provisions of the Proposed Rule
A. State Organization and General Administration (Part 431)
B. Eligibility in the States, District of Columbia, the Northern Mariana Islands, and American Samoa (Part 435) and Eligibility in Guam, Puerto Rico and the Virgin Islands (Part 436)
C. Services: General Provisions (Part 440)
D. Services: Requirements and Limits Applicable to Specific Services (Part 441)
E. Basis and Purpose (§ 441.650)
F. State Plan Requirements (§ 441.653)
G. Eligibility for Home and Community-Based Services Under Section 1915(i)(1) of the Act (§ 441.656)
H. Needs-Based Criteria and Evaluation (§ 441.659)
I. Independent Assessment (§ 441.662)
J. Service Plan (§ 441.665)
K. Provider Qualifications (§ 441.668)
L. Definition of Individual's Representative (§ 441.671)
M. Self-Directed Services (§ 441.674)
N. State Plan HCBS Administration: State Responsibilities and Quality Improvement (§ 441.677)
P. Section 2601 of the Affordable Care Act: 5-Year Period for Demonstration Projects: Waiver Requirements (§ 430.25)
Q. Prohibition Against Reassignment of Provider Claims (§ 447.10)
R. Section 2401 of the Affordable Care Act: Community First Choice State Plan Option: Home and Community-Based Setting Requirements (§ 441.530)
IV. Response to Comments
V. Collection of Information Requirements
VI. Regulatory Impact Analysis
VII. Regulatory Flexibility Act Analysis
VIII. Unfunded Mandates Reform Act Analysis
IX. Federalism Analysis
Regulation Text

Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding terms in alphabetical order below.

ADA Americans with Disabilities Act of 1990 (Pub. L. 110–325)
ADLs Activities of daily living
AHRQ Agency for Healthcare Research and Quality
ANPRM Advance Notice of Proposed Rulemaking
CFC Community First Choice (1915(k) State plan Option)
CHIPRA Children's Health Insurance Program Reauthorization of 2009 (Pub. L. 111–3)
CMS Centers for Medicare & Medicaid Services
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
EPSDT Early and Periodic Screening, Diagnosis and Treatment
FBR Federal benefit rate
FFP Federal financial participation
FPL Federal poverty line
FY Federal fiscal year
HCBS Home and Community-Based Services
HHS Department of Health and Human Services
IADLs Instrumental activities of daily living
ICF/MR Intermediate care facility for the mentally retarded
LOC Level of care
NF Nursing facility
OBRA'81 Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35)
OT Occupational therapy
PT Physical therapy
RFA Regulatory Flexibility Act
SPA State Plan Amendments
SSI Supplemental Security Income
SSI/FBR Supplemental Security Income Federal Benefit Rate
UPL Upper payment limit

I. Executive Summary

A. Purpose

This proposed rule would amend the Medicaid regulations to define and describe State plan home and community-based services (HCBS). This regulation outlines the optional State plan benefit to furnish home and community-based State plan services and draw Federal matching funds. As a result, States will be able to design and tailor Medicaid services to better accommodate individual needs. This may result in improved patient outcomes and satisfaction, while enabling States to effectively manage their Medicaid resources.

This proposed rule would also amend Medicaid regulations consistent with the requirements of section 2601 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), which added section 1915(h)(2) to the Act to provide authority for a 5-year duration for certain demonstration projects or waivers under sections 1115, 1915(b), (c), or (d) of the Act, at the discretion of the Secretary, when they involve individuals who are dually eligible for both Medicaid and Medicare benefits.

In addition, this proposed rule would provide an additional limited exception to the general requirement that payment for services under a State plan must be made directly to the individual practitioner providing a service when the Medicaid program is the primary source of reimbursement for a class of individual practitioners. This exception would allow payments to be made to other parties to benefit the providers by ensuring workforce stability, health and welfare, and trainings, and provide added flexibility to the State. We are including the payment reassignment provision in the HCBS proposed rule because States' Medicaid programs often operate as the primary or only payer for the class of practitioners that includes HCBS service providers.

This proposed rule would also amend Medicaid regulations to provide home and community-based setting requirements related to section 2401 of the Affordable Care Act for the section 1915(k) Community First Choice State plan option.

B. Summary of the Major Provisions

1. Section 1915(i) State Plan Home Community-Based Services

The Deficit Reduction Act (DRA) added a new provision to the Medicaid statute entitled ''Expanded Access to Home and Community-Based Services

for the Elderly and Disabled.'' This provision allows States to provide HCBS (as an optional program) under their State Medicaid plans. This option allows States to receive Federal financial participation for services that were previously eligible for Federal funds only under waiver or demonstration projects. This provision was further amended by the Affordable Care Act. The statute now provides additional options for States to design and implement HCBS under the Medicaid State Plan. In April 4, 2008, we published a proposed rule to amend Medicaid regulations to implement HCBS under the DRA. That proposed rule was not finalized, and with the passage of section 2402 of the Affordable Care Act, some previously proposed regulations would no longer be in compliance with the current law under section 1915(i) of the Act. In addition, several new provisions were added. Specifically, the Affordable Care Act amended the statute by adding a new optional categorical eligibility group for individuals to provide full Medicaid benefits to certain individuals who will be receiving HCBS. It also authorized States to elect not to comply with section 1902(a)(10)(B) of the Act pertaining to comparability of Medicaid services. After closely analyzing the Affordable Care Act provisions, we concluded that a new proposed rule was necessary. This proposed rule retains a large portion of the policies contained within the April 4, 2008 proposed rule, and updates some of our previous proposals to reflect comments that we received on the April 4, 2008 proposed rule as well as the statutory changes that were made by the Affordable Care Act.

2. Section 2601 of the Affordable Care Act: 5-Year Period for Certain Demonstration Projects and Waivers

This proposed rule also provides for a 5-year approval or renewal period, subject to the discretion of the Secretary, for certain Medicaid waivers. Specifically, this time period would apply for demonstration and waiver programs through which a State serves individuals who are dually eligible for both Medicare and Medicaid benefits.

3. Provider Payment Reassignments

Section 1902(a)(32) of the Act provides that State plans can allow payments to be made only to certain individuals or entities. Specifically, payment may only be made to an individual practitioner who provided the service. The statute provides several specific exceptions to the general principle of direct payment to the individual practitioner.

Over the years, some States have requested that we consider adopting additional exceptions to the direct payment principle to permit withholding from the payment due to the individual practitioner for amounts paid by the State directly to third parties for health and welfare benefits, training costs and other benefits customary for employees. These amounts would not be retained by the State, but would be remitted to third parties on behalf of the practitioner for the stated purpose.

While the statute does not expressly provide for additional exceptions to the direct payment principle, we believe the circumstances at issue were not contemplated under the statute. Therefore, we are proposing that the direct payment principle should not apply because we think its application would contravene the fundamental purpose of this provision. The apparent purpose of the direct payment principle was to prohibit factoring arrangements, and not to preclude a Medicaid program that is functioning as the practitioner's primary source of revenue from fulfilling the basic responsibilities that are associated with that role. Therefore, we are proposing an additional exception to describe payments that we do not see as within the intended scope of the statutory direct payment requirement, that would allow the State to claim as a provider payment amounts that are not directly paid to the provider, but are withheld and remitted to a third party on behalf of the provider for health and welfare benefit contributions, training costs, and other benefits customary for employees.

4. Section 2401 of the Affordable Care Act: Community First Choice State Plan Option: Home and Community-Based Setting Requirements

Section 1915(k)(1)(A)(ii) of the Act provides that home and community-based attendant services and supports must be provided in a home and community-based setting. The statute specifies that home and community-based settings do not include a nursing facility, institution for mental diseases, or an intermediate care facility for the mentally retarded.[2] We propose to adopt this statutory language in our regulations. Additionally, to provide greater clarity, we are proposing language to establish that home and community-based settings must exhibit specific qualities to be eligible sites for delivery of home and community-based services.

After consideration of comments received in response to the Community First Choice (CFC) proposed rule published on February 25, 2011, we decided to revise the setting provision and publish our proposed definition as a new proposed rule to allow for additional public comment before finalizing. Since CFC and section 1915(i) both pertain to home and community-based services, we have aligned this CFC proposed language with the section 1915(i) proposed home and community-based setting requirements also included in this rule. We find the public comment process to be valuable in our attempt to develop the best policy on this issue for Medicaid beneficiaries. Therefore, we plan to fully consider all comments received, and align decision making and language pertaining to home and community-based setting requirements across CFC, section 1915(i) State plan HCBS, as well as section 1915(c) HCBS waivers.

C. Summary of Costs and Benefits

Provision description	Total costs	Total benefits
1915(i) State Plan Home Community-Based Services.	We estimate that, adjusted for a phase-in period during which States gradually elect to offer the State plan HCBS benefit, in fiscal year (FY) 2012 the estimated Federal cost would be $80 million, and the estimated State cost would be $60 million.	We anticipate that States will make varying use of the State plan HCBS benefit provisions to provide needed long-term care services for Medicaid beneficiaries. These services will be provided in the home or alternative living arrangements in the community, which is of benefit to the beneficiary, and is less costly than institutional care.

[2] Although we recognize that the language used here is outdated, and that ''intellectual disability'' is the appropriate way to discuss this type of disability, the Social Security Act still refers to these types of facilities in this manner.

Provision description	Total costs	Total benefits
Section 2601 of the Affordable Care Act: 5-Year Period for Demonstration Projects (Waivers).	No impact on Federal or State Medicaid funding. This rule is voluntary on the part of States.	As this provision elongates the time period under which States may operate certain waiver programs without renewal, it will help States to minimize administrative and renewal requirements in order to better focus on program implementation and quality oversight.
Provider Payment Reassignments ...	We do not anticipate any impact on Federal Medicaid funding. This rule is voluntary on the part of States.	This rule proposes additional operational flexibilities for States to ensure a strong provider workforce. There is also no impact on individual practitioners, even though the proposed rule would allow States to deduct or withhold portions of such payments under the specific circumstances described in the proposed rule. State budgets will not likely be significantly affected because the operational flexibilities in the proposed rule would only facilitate the transfer of funds between participating entities, rather than the addition or subtraction of new funds.
Section 2401 of the Affordable Care Act: Community First Choice State Plan Option: Home and Community-Based Setting Requirements.	We do not believe there is an impact on Federal or State Medicaid funding as the purpose of the rule is merely to define home and community-based settings in which CFC services may be provided.	This rule will provide States with necessary guidance to support compliance with the requirement that CFC services are provided in a home or community based-setting. This rule also provides beneficiary protections to support an individual's choice to receive home and community-based services in a manner that allows for integration with the greater community.

II. Background

A. Expanded Access to Home and Community-Based Services for the Elderly and Disabled Under Section 1915(i) of the Social Security Act: History of Section 1915(i) of the Act

Section 6086 of the Deficit Reduction Act of 2005 (Pub. L. 109–171, enacted February 8, 2006) (DRA) entitled ''Expanded Access to Home and Community-Based Services for the Elderly and Disabled,'' added section 1915(i) to the Social Security Act (the Act) to allow States, at their option, to provide home and community-based services (HCBS) under their State Medicaid plans. This option allows States to receive Federal financial participation (FFP) for services that were previously only eligible for FFP under waivers or demonstration projects, such as those authorized under sections 1915(c) and 1115 of the Act. Section 1915(i) of the Act was later amended by sections 2402(b) through (g) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted March 23, 2010) (Affordable Care Act) to provide additional options for States to design and implement HCBS under the Medicaid State Plan.

In the April 4, 2008 **Federal Register** (73 FR 18676), we published a proposed rule to amend Medicaid regulations to implement HCBS under section 1915(i) of the Act. This rule was never finalized, and with the passage of the Affordable Care Act some of the proposed regulations would no longer be in compliance with the statute, as several new provisions were added to the statute. Therefore, we concluded that a new proposed rule and a new period of public comment were necessary. This proposed rule retains a large portion of the policies contained within the April 4, 2008 proposed rule. However, we have updated some of our proposals to reflect the statutory changes that were made by the Affordable Care Act.

B. Overview of the State Plan Home and Community-Based Services (HCBS) Benefit To Provide HCBS for the Elderly and Individuals With Disabilities

The following overview describes the provisions of section 1915(i) of the Act as established by the DRA and amended by the Affordable Care Act.

In the following discussion and the proposed regulation, we refer to particular home and community-based service(s) offered under section 1915(i) of the Act as ''State plan HCBS'' or simply ''HCBS''.[3] We refer to the ''State plan HCBS benefit'' when describing the collective requirements of section 1915(i) of the Act that apply to States electing to provide one, or several, of the authorized HCBS. We choose to use the term ''benefit'' rather than ''program'' to describe section 1915(i) of the Act to avoid possible confusion with section 1915(c) HCBS waiver programs. The State plan HCBS benefit shares many features with section 1915(c) waiver programs, but it is a State plan benefit, although one with very unique features not common to traditional State plan services.

Under section 1915(i) of the Act, States can provide HCBS to individuals who require less than institutional level of care (LOC) and who would, therefore, not be eligible for HCBS under section 1915(c) waivers, in addition to serving individuals who have needs that would meet entry requirements for an institution. As it is a State plan benefit, section 1915(i) of the Act also does not require cost neutrality compared to institutional services. Section 1915(i) of the Act differs from section 1915(c) waivers in other ways. As with other State plan services, the benefits must be provided Statewide, and States must not limit the number of eligible people served.

1. Services

Section 1915(i)(1) of the Act grants States the option to provide, under the State plan, the services and supports listed in section 1915(c)(4)(B) of the Act governing HCBS waivers. The services specifically listed in section 1915(c)(4)(B) of the Act are as follows:

- Case management.
- Homemaker/home health aide.
- Personal care.
- Adult day health.
- Habilitation.
- Respite care.
- Other services requested by the State as the Secretary may approve.

[3] Note that the abbreviation HCBS does not distinguish between singular and plural. Where this could be confusing, we spell out home and community-based service(s).

In addition, the following services may be provided for individuals with chronic mental illness:

- Day treatment.
- Other partial hospitalization services.
- Psychosocial rehabilitation services.
- Clinic services (whether or not furnished in a facility).

The HCBS may not include payment for room and board (see additional discussion in section II.E.3. of this proposed rule).

Section 1915(c)(4)(B) of the Act also permits States to request, and the Secretary to approve, coverage of other services not specifically designated in the list of specific services in the subparagraph. This authority was not included under section 1915(i) when it was created in the DRA. However, section 2402(c) of the Affordable Care Act amended section 1915(i)(1) of the Act to permit States to request, and the Secretary to approve, coverage for such other services in a 1915(i) benefit.

We interpret the statute as authorizing States to cover in their 1915(i) benefit both the services specifically identified in section 1915(c)(4)(B) of the Act, and any other services States request to include and which the Secretary approves. Therefore, we would expect States to define State plan HCBS with sufficient specificity so that we can determine whether the nature and scope of the service clearly relates to those listed in section 1915(c)(4)(B) of the Act. These services are described in § 440.180 of this proposed rule. However, we would not require the same standard for ''other services'' under section 1915(i) State plan HCBS that we would apply under section 1915(c) of the Act. Since section 1915(i) of the Act does not require an individual to meet the criteria for institutional LOC, there is no authority to apply the standard that the ''other services'' defined and provided through State plan HCBS be necessary to prevent institutionalization. We note that for all services, including those in the ''other services'' category, States must include a specific and complete description of the scope of the service, and not include open-ended statements.

We propose to review and approve these ''other services'' not specifically listed in section 1915(c)(4)(A) of the Act based upon the applicability to and consistency with the support needs as indicated in the needs-based criteria that a State defines for the HCBS benefit, and with assurance that the service will not duplicate other services available to individuals through the State's Medicaid State plan. Additionally, these services must be offered in a manner that would comply with section 1902(a)(23) of the Act regarding free choice of providers, and that permits individuals to receive services in the most integrated setting possible and consistent with the best interests of the beneficiaries and the requirements of the Americans with Disabilities Act (ADA). Section 1915(i) does not incorporate waiver authority or other exceptions from these legal requirements. Therefore, the services offered cannot have the impact of limiting the pool of qualified providers from which individuals would receive services, or have the impact of requiring/only allowing individuals to receive services from the same entity from which they purchase or who provide their housing. For example, we would not allow States to establish residential HCBS in provider-owned and/or operated settings only, when they do not have comparable HCBS available to individuals residing in their own homes.

2. Eligibility

Eligibility for this option is based upon several different factors that are either specified by the statute or that a State may define. These include financial eligibility, the establishment of needs-based criteria, and the State option to target the benefit and to offer benefits differing in type, amount, duration or scope to specific populations. Due to the complex interaction between these provisions, the following section is divided into subsections that address eligibility for the benefits. These include:

- Eligibility Overview.
- Income Eligibility.
- Needs-Based Criteria Overview.
- Option to Disregard Comparability.
- Establishing Needs-Based Criteria.

a. Section 1915(i) of the Act: Eligibility Overview

Section 1915(i) of the Act explicitly provides that State plan HCBS may be provided without determining that, but for the provision of these services, individuals would require the LOC provided in a hospital, a nursing facility (NF), or an intermediate care facility for the mentally retarded [4] (ICF/MR) as is required in section 1915(c) HCBS waivers. While HCBS services provided through section 1915(c) waivers must be ''cost-neutral'' as compared to institutional services, no cost neutrality requirement applies to the section 1915(i) State plan HCBS benefit. States are not required to produce comparative cost estimates of institutional care and the State plan HCBS benefit. This significant distinction allows States to offer HCBS to individuals whose needs are substantial, but not severe enough to qualify them for institutional or waiver services, and to individuals for whom there is not an offset for cost savings in NFs, ICFs/MR, or hospitals.

One particular result of this distinction is that, through the section 1915(i) benefit, States have the ability to provide a full array of HCBS to adults with mental health and substance use disorders. The benefit also creates an opportunity to provide HCBS to other individuals with significant needs who do not qualify for an institutional LOC, such as some individuals with Autism Spectrum Disorder, diabetes, acquired immune deficiency syndrome, or Alzheimer's disease. In many cases, without the provision of HCBS, these conditions may deteriorate to the point where the individuals become eligible for more costly facility-based care.

State plan HCBS are intended to enable individuals to receive needed services in their own homes, or in alternative living arrangements in what is collectively termed the ''community'' in this context. (See additional discussion in section II.E.2. of this proposed rule regarding institutions not considered to be in the community, and in which State plan HCBS will not be available.)

b. Income Eligibility

Section 1915(i)(1) of the Act requires that in order to receive State plan HCBS, individuals must be eligible for Medicaid under an eligibility group covered under the State's Medicaid plan. In determining whether either of the relevant income requirements (discussed) is met, the regular rules for determining income eligibility for the individual's eligibility group apply, including any less restrictive income rules used by the State for that group under section 1902(r)(2) of the Act. Section 1915(i)(3) of the Act permits States to not apply the requirements of section 1902(a)(10)(C)(i)(III) of the Act relating to income and resource rules in the community for the medically needy. Under this authority States are permitted to use institutional eligibility rules in determining eligibility for the medically needy. The nonapplication requirements are described in section II.B.14 of the preamble. This eligibility criterion was not changed by the Affordable Care Act.

[4] Although we recognize that the language used here is outdated, and that ''intellectual disability'' is the appropriate way to discuss this type of disability, the Social Security Act still refers to these types of facilities in this manner.

Section 2402(b) of the Affordable Care Act added a new option at section 1915(i)(6) of the Act, to allow States to provide section 1915(i) services to certain individuals who meet the needs-based criteria, who would be eligible for HCBS under section 1915(c), (d) or (e) waivers or a section 1115 waiver approved for the State, and who have income up to 300 percent of the Supplemental Security Income Federal Benefit Rate (SSI/FBR).

Section 2402(d) of the Affordable Care Act also amended section 1902(a)(10)(A)(ii) of the Act by adding a new optional categorically needy eligibility group specified at section 1902(a)(10)(A)(ii)(XXII) of the Act to provide full Medicaid benefits to certain individuals who will be receiving section 1915(i) services. This eligibility group has two parts, and States can cover individuals under either or both parts of the group. Under this group, States can elect to cover individuals who are not otherwise eligible for Medicaid who meet the needs-based criteria of the section 1915(i) benefit, have income up to 150 percent of the Federal poverty line (FPL) with no resource test and who will receive section 1915(i) services, or individuals with income up to 300 percent of the SSI/FBR, who would be eligible under an existing section 1915(c), (d) or (e)[5] waiver or section 1115 waiver approved for the State and who will receive section 1915(i) services. These individuals do not have to be receiving services under an existing section 1915(c), (d) or (e) waiver or section 1115 waiver; the individual just has to be determined eligible for the waiver.

c. Needs-Based Criteria Overview

In contrast to the institutional LOC requirement for eligibility in HCBS waivers, section 1915(i)(1)(A) of the Act requires States to impose needs-based criteria for eligibility for the State plan HCBS benefit. Institutional level of care criteria must be more stringent than the needs-based criteria for the State plan HCBS benefit. Additionally, the State may establish needs-based criteria for each specific State plan home and community-based service that an individual would receive.

Thus, under section 1915(i) of the Act, States determine eligibility for State plan HCBS based on the following:

- Individuals eligible for medical assistance under the State plan whose income is below 150 percent of FPL, as determined by the State under the methodology applicable to the group, including any less restrictive income rules in place through section 1902(r)(2) of the Act.
- At the State option, individuals eligible under the new optional categorical needy group 1902(a)(10)(A)(ii)(XXII) of the Act. This includes:

++ Individuals with income below 300 percent of the SSI/FBR who are eligible for HCBS through a waiver approved for the State under sections 1115, 1915(c), 1915(d), or 1915(e) of the Act and will receive section 1915(i) services.

++ Individuals who are not otherwise eligible for medical assistance who have income below 150 percent and who will receive section 1915(i) services. There will be no resource test for this group.

- The individual resides in the home or community.
- The individual meets the needs-based criteria established by the State.
- The individual meets any targeting criteria in accordance with CMS requirements that the State elects to establish.

For more information about the optional eligibility category for individuals who receive services through the State plan HCBS benefit, please see section II.B.18. of this proposed rule.

The needs-based criteria for coverage of individual services provided within a State's section 1915(i) benefit are subject to the same requirements as the needs-based eligibility criteria for the benefit, and may not limit or target any service based on age, nature or type of disability, disease, condition, or residential setting, but could include risk factors or take into account service history. However, section 1915(i)(7) of the Act provides States with the option to target eligibility for the benefit to specific populations.

d. Option To Disregard Comparability

Effective October 1, 2010, section 2402(f) of the Affordable Care Act, amended section 1915(i)(3) of the Act to permit States to elect not to comply with the requirement of section 1902(a)(10)(B) of the Act relating to comparability of services. A waiver of comparability is a key feature of section 1915(c) HCBS waivers, permitting a State to target the HCBS benefit to certain populations by defining which groups will be eligible for waiver services, and by having separate waivers for different groups. With this change, States may exercise the authority to target the section 1915(i) benefit similarly, but are not required to do so. A State must establish needs-based criteria for eligibility for and receipt of State plan HCBS regardless of whether it elects the option to not comply with the comparability requirement. For additional information regarding the option for targeting in the benefit, please see the discussion at (section II.B.19 of the proposed rule).

e. Establishing Needs-Based Criteria

The heading of section 1915(i) of the Act describes the State plan HCBS benefit as ''for Elderly and Disabled Individuals.'' However, section 1915(i) of the Act does not include definitions of the terms ''elderly'' or ''disabled'' in setting forth eligibility criteria, and instead requires eligibility to be based on need and on eligibility for medical assistance under a State plan group. Thus, we believe that the use of these terms in the statute is descriptive. Individuals who are eligible for medical assistance under a group covered in the State's plan and who meet the needs-based eligibility criteria for State plan HCBS will be likely to have needs stemming either from a disability or from being elderly. We note that section 1902(b)(1) of the Act prohibits the Secretary from approving any plan for medical assistance that imposes an age requirement of more than 65 years as a condition of eligibility.

The statute does not define ''needs-based.'' We are proposing to define the nature of needs-based criteria to distinguish them from targeting criteria, which are permitted under the statute as a State option and are distinct from the needs-based criteria. We propose to provide States with the flexibility to define the specific needs-based criteria they will establish.

We believe that the statute distinguishes needs-based criteria from other possible descriptors of an individual's medical condition or diagnosis. We interpret needs-based criteria as describing the individual's particular need for support, regardless of the conditions and diagnoses that may cause the need. However, as discussed in section II.B.19. of this proposed rule, States may also disregard comparability requirements contained in section 1902(a)(10)(B) of the Act, and thus, target the section 1915(i) benefit (or multiple benefits) to individuals with specific diagnoses and conditions. We interpret the statute to mean that, when a State elects to disregard comparability in order to target the benefit to individuals with specific diagnoses, those individuals must meet both the targeting criteria, as well as the State's needs-based criteria.

[5] 1915(d) and (e) waivers are State options to provide HCBS to the elderly and to individuals with disabilities, respectively. Currently, no State elects to provide services under either of these authorities.

Section 1915(i)(1)(B) of the Act additionally requires that the needs-based criteria for determining whether an individual requires the LOC provided in a hospital, NF, or ICF/MR or under a waiver of the State plan be more stringent than the needs-based eligibility criteria for the State plan HCBS benefit. Institutional/waiver LOC criteria in some States do not include needs-based criteria. Since the two must be comparable, we interpret this to mean that States without a needs-based component to their institutional LOC evaluation must establish needs-based criteria for those services, as well as for the State plan HCBS benefit. We also believe that States electing to implement a section 1915(i) benefit must include a needs-based evaluation component of the institutional/waiver LOC determination process so that stringency of those criteria can be compared to stringency of eligibility criteria for the State plan HCBS benefit.

''Stringency'' is not defined in the statute. The requirement is simply that there be a differential between the threshold of need for the State plan HCBS benefit as compared to the threshold of need for institutional services. The required difference in criteria will be relative, specific to each State's unique institutional levels of care, and can be constructed in several ways. Because we have received many questions on the stringency requirements of the statute we will illustrate some of the possible options. We want to be clear, however, that the requirement of section 1915(i) of the Act is simply that the needs-based criteria for institutions and for the State plan HCBS benefit be set so that the latter are lower at the time the benefit is implemented. There is no requirement that institutional criteria be higher, lower, or unchanged from their level prior to implementing the State plan HCBS benefit. The only test is that the result of all the needs-based criteria must be that some individuals will be served under the State plan HCBS benefit who are not eligible to be served by Medicaid institutional services. If institutional LOC criteria are changed in implementing the benefit, States may provide protections for individuals who lose eligibility due to the application of those new criteria (see section II.B.16. of this proposed rule).

There are issues for States to consider other than section 1915(i) of the Act that will influence decisions on levels of care and needs-based criteria, that are far beyond the scope of this document, for example, statutory requirements for maintenance of effort (MOE) in effect at the time of this proposed rule, requirements of the Americans with Disabilities Act and the *Olmstead* decision, and funding constraints [6]. In this proposed rule, we focus on the choices a State may make in setting up a State plan HCBS benefit in ways that are consistent with requirements of section 1915(i) of the Act. As an illustration, this proposed regulation would permit a State to define the needs-based criteria for a new HCBS benefit at a lower level than the State's existing institutional levels of care, and leave the institutional criteria unchanged (if they already include needs-based criteria). This would satisfy the requirement that the institutional criteria be more stringent than the State plan HCBS benefit, meet a goal to service individuals who have not previously had access to HCBS because they have not yet reached the level of need for admission to an institution, without making any change to existing services. This proposed regulation would also permit States to take other approaches. A State could raise one or more institutional levels of care, and provide HCBS under the State plan benefit for some or all of the individuals who would have not yet reached the level of need for admission to an institution. The State could choose (or not) to also include in the benefit individuals below the former institutional level of care. This scenario would also satisfy the stringency requirement, but would be more complex and would require analysis of some of the other relevant issues mentioned above.

We note that section 1915(i) of the Act does not modify the statutory coverage provisions governing institutional benefits. States must be cautious not to establish more stringent needs-based criteria for hospitals, NFs or ICFs/MR that would reduce access to services mandated elsewhere in title XIX, since those other provisions of the statute were not amended. For example, the NF benefit is defined in section 1919(a)(1) of the Act as an institution that is primarily engaged in providing to residents skilled nursing care, rehabilitation services, and ''[o]n a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities.'' To the extent an individual has a medical need for such health-related care and services which are only available in an institutional setting because that needed home or community-based health-related care and services are not available, the NF institutional benefit must remain available to all Medicaid eligible individuals described in section 1919(a)(1)(C) of the Act.

We interpret the reference to hospitals in section 1915(i)(1)(B) of the Act to mean facilities certified by Medicaid as hospitals that are providing long-term care services. General acute care Medicaid hospital services are not subject to LOC determinations by the State.

We interpret the reference in section 1915(i)(1)(B) of the Act ''under any waiver of such plan'' to apply to section 1915(c), 1915(d) and 1915(e) waivers, as well as those section 1115 waivers that include HCBS, as specified in section 1915(i)(6)(a) of the Act. Sections 1915(c), (d) and (e) [7] of the Act will have more stringent minimum criteria than the State plan HCBS benefit, as the waivers are required to use LOC assessments equivalent to one or more of the institutional levels of care. If a State has an approved section 1115 demonstration with multiple levels of care for institutional and/or HCBS, we interpret this requirement to apply to the least stringent institutional LOC criteria within that demonstration that would likely be the comparison for purposes of section 1915(i) of the Act.

In summary, the needs-based eligibility criteria for the State plan HCBS benefit must have the effect of allowing some individuals who do not meet the needs-based criteria for institutionalized care to access HCBS through the section 1915(i) benefit, but may also allow access to individuals who meet the institutional needs-based eligibility criteria. States may also enroll individuals in both a section 1915(i) benefit, and a section 1915(c) waiver, as discussed earlier in this rule.

3. Number Served

Section 1915(i)(1)(C) of the Act, as amended by section 2402(e) of the

[6] Under section 2001(b) of the Affordable Care Act, States are not permitted to establish eligibility standards, methodologies, or procedures that are more restrictive than those in place on the date of the Affordable Care Act's enactment (March 23, 2010). For adults, this requirement lasts until the Secretary determines that a health insurance exchange is fully operational in the State; for children under the age of 19, the requirement lasts until September 30, 2019.

Because the application of LOC requirements for institutions and HCBS waivers may have an impact on Medicaid eligibility for some individuals, we encourage States interested in using the State plan HCBS to contact CMS for technical assistance in meeting these statutory requirements.

[7] Although the statute references waivers under Section 1915(d) and (e), no State currently operates a waiver under either authority. In the event that a State elects to include a (d) or (e) waiver, these requirements would apply.

Affordable Care Act, does not permit States to limit the number of eligible individuals receiving services and to establish waiting lists. Instead, the benefit requires a State to provide to the Secretary a projection of the number of individuals expected to receive services. If this projection is exceeded, section 1915(i)(1)(D)(ii) of the Act permits the State to constrict its needs-based eligibility thresholds for State plan HCBS (see the discussion on Adjustment Authority in I.B.5. of this proposed rule).

Section 1915(i)(1)(C) of the Act requires that the State submit projections, in the form and manner, and upon the frequency as the Secretary specifies, of the number of individuals to be provided HCBS. We propose to follow the practice used in HCBS waivers to calculate the number served as unduplicated persons receiving services during a 12-month period. We further propose to specify that, during the application process, States would project the total number of individuals to be served by the benefit during the initial year. We further propose to specify that States with an approved State plan HCBS benefit annually submit both the projected number of individuals to be served and the actual number of individuals served in the previous year. We refer to individuals served under the benefit and included in the annual number served as having been enrolled in the benefit. The statute refers to ''enrollment'' in section 1915(i)(1)(D)(ii) of the Act concerning ''Adjustment Authority.'' Because there are a number of steps involved in an individual initiating service under the State plan HCBS benefit, ''enrollment'' is a useful term to indicate individuals for whom those steps have been completed, services have been authorized or provided, and who will be accounted for in the annual number served under the benefit. If the State exceeds its enrollment estimate, the State would report the number of individuals actually served in the required annual report to the Secretary, and revise the estimate for succeeding years.

4. Independent Evaluation

Section 1915(i)(1)(D) of the Act sets forth a requirement for an individual evaluation of need for each person seeking coverage of the State plan HCBS benefit. The statute here uses the term ''assessment,'' while sections 1915(i)(1)(E) and (H) of the Act refer to the initial eligibility determination as the ''independent evaluation.'' We would use the latter term for consistency. ''Independent evaluation,'' as understood in light of section 1915(i)(1)(H) of the Act, means free from conflict of interest on the part of the evaluator. The independent evaluation is separate from, but related to, the independent assessment (as discussed below).

The independent evaluation applies the needs-based HCBS eligibility criteria (established by the State according to section 1915(i)(1)(A) of the Act), to an applicant for the State plan HCBS benefit. Section 1915(i)(1)(D) of the Act establishes that determining whether an individual meets the needs-based eligibility criteria specified in sections 1915(i)(1)(A) and (B) of the Act requires an individualized and independent evaluation of each person's support needs and capabilities. We interpret ''needs and capabilities'' to mean a balanced approach that considers both needs and strengths. However, the words ''capability'' and ''ability'' are historically connected with a deficit-oriented approach to assessment, which is the opposite of the statute's person-centered approach. Therefore, we would refer to needs and strengths in this discussion and in the regulation.

Section 1915(i)(1)(D) of the Act indicates that the independent evaluation ''may take into account'' the inability of the individual to perform two or more activities of daily living (ADLs), (which the statute defines by reference to section 7702B(c)(2)(B) of the Internal Revenue Code of 1986), or the need for significant assistance to perform these activities. The State may also assess other risk factors it determines to be appropriate in determining eligibility for, and receipt of, HCBS. The statute does not limit the factors a State may take into account in the evaluation. For example, difficulty with instrumental activities of daily living (IADLs) or the need for cueing in order to perform a task could be considered. A State could choose to use a person-centered functional assessment tool or strategy to fulfill this requirement.

5. Adjustment Authority

Section 1915(i)(1)(D)(ii) of the Act permits the State to adjust the needs-based criteria described in section 1915(i)(1)(B) of the Act in the event that enrollment exceeds the annual maximum number of individuals that the State has projected it would serve within parameters as noted above. The purpose of an adjustment would be to revise the State's needs-based criteria to reduce the number of individuals who would be eligible for the HCBS benefit. To preserve the requirement of section 1915(i)(1)(B) of the Act that more stringent needs-based criteria be in place for institutionalized care, the adjusted eligibility criteria must still be less stringent than those applicable to institutional levels of care in the State plan institutional benefit, and thus, in any HCBS waivers that require participants to meet an institutional LOC. If the State chooses to make this adjustment, it must provide at least 60 days written notice to the Secretary and to the public, stating the revisions it proposes.

While the adjustment authority is granted to States without having to obtain prior approval from the Secretary, we believe that the statute requires the State to amend the State plan to reflect the adjusted criteria. We believe that the State's adjustment authority does not prevent the Secretary from disapproving a State plan amendment (SPA) that fails to comply with the statute and regulations. This provision of the law must be interpreted in light of existing Medicaid requirements not waived by section 1915(i) of the Act. We have, therefore, incorporated within the proposed regulation those relevant requirements in addition to the statutory provisions within section 1915(i)(1)(D)(ii) of the Act. Section 441.559(c) provides the greatest degree of authority for adjustment possible within the constraints of other requirements. The Secretary will evaluate the State's adjusted criteria for compliance with the provisions of this subparagraph and all requirements of subpart K. A State may implement the adjusted criteria as early as 60 days after notifying all required parties. Section 430.16 provides the Secretary 90 days to approve or disapprove a State plan amendment, or request additional information. If the State implements the modified criteria prior to the Secretary's final determination with respect to the State plan amendment, the State would be at risk for any actions it takes that are later disapproved.

After needs-based criteria are adjusted under this authority, the statute requires that individuals served under the previous State plan HCBS needs-based criteria would continue to receive HCBS. As amended by section 2402(e) of the Affordable Care Act, section 1915(i)(1)(D)(ii)(II) of the Act provides that an individual who is receiving HCBS before the effective date for modified needs-based criteria, (based on the most recent version of the criteria in effect before the modification), must be deemed by the State to continue to be eligible for State plan HCBS until the individual no longer meets the needs-based criteria, and targeting criteria if

applicable, under which they were originally provided the benefit. Any changes to the institutional LOC criteria under this section are subject to the same requirements as described in 1915(i)(5) (see section II.B.16. of this proposed rule).

However, we would remind States of the maintenance of efforts requirements discussed in section II.B.2. of this proposed rule.

We note that the required processes for individual notification and appeals, contained within part 431, subpart E, remain in effect whenever a State modifies its needs-based criteria. Furthermore, section 1915(i)(5) of the Act provides protections for individuals who are receiving services in waivers or institutional settings prior to the modification of the LOC requirements, as discussed below.

It is important to note that the adjustment authority is a State option; there is nothing in the law that requires a State to constrict its needs-based criteria if enrollment exceeds projections.

6. Independent Assessment

Section 1915(i)(1)(E) of the Act describes the relationship of several required functions. Section 1915(i)(1)(E)(i) of the Act refers to the independent evaluation of eligibility in section 1915(i)(1)(A) and (B) of the Act, emphasizing the independence requirement. Section 1915(i)(1)(E)(ii) of the Act introduces the requirement of an independent assessment following the independent evaluation. Thus, there are two steps to the process: the eligibility determination, which requires the application of the needs-based criteria and any additional targeting criteria the State elects to require; and the assessment for individuals who were determined to be eligible under the first step, to determine specific needed services and supports. The assessment also applies the needs-based criteria for each service (if the State has adopted such criteria). Like the eligibility evaluation, the independent assessment is based on the individual's needs and strengths. The Act requires that both physical and mental needs and strengths are assessed. These requirements describe a person-centered assessment including behavioral health, which will take into account the individual's total support needs as well as the need for the HCBS to be offered. Section 1915(i)(1)(E)(ii) of the Act requires that States use the assessment to: Determine the necessary level of services and supports to be provided; prevent the provision of unnecessary or inappropriate care; and establish a written individualized service plan.

To achieve the three purposes of the assessment listed above, the assessor must be independent; that is, free from conflict of interest with regard to providers, to the individual and related parties, and to budgetary concerns. Therefore, we are proposing specific requirements for independence of the assessor in accordance with section 1915(i)(1)(H)(ii) of the Act, and we would apply these also to the evaluator and the person involved with developing the person-centered service plan, where the effects of conflict of interest would be equally deleterious. These considerations of independence inform the discussion below under section 1915(i)(1)(H)(ii) of the Act regarding conflict of interest standards.

Section 1915(i)(1)(F) of the Act provides detailed requirements for the independent assessment:

- A face-to-face evaluation of the individual by an assessor trained in the assessment and evaluation of persons whose physical or behavioral health conditions trigger a potential need for HCBS. To fulfill this statutory requirement, we would propose that the State must develop standards and determine the qualifications necessary for agencies and individuals who will perform independent assessments and be involved with developing the plans of care. Additionally, we recognize that many States are developing infrastructure and policies to support the use of telemedicine and other ways to provide distance-care to individuals in order to increase access to services in rural areas or other locations with a shortage of providers. To support these activities, we propose that the ''face-to-face'' assessment can include any session(s) performed through telemedicine or other information technology medium if the following conditions apply:

++ The health care professional(s) performing the assessment meet the provider qualifications defined by the State, including any additional qualifications or training requirements for the operation of required information technology;

++ The individual receives appropriate support during the assessment, including the use of any necessary on-site support-staff; and

++ The individual is provided the opportunity to request an in-person assessment in lieu of one performed via telemedicine.

- An objective evaluation of the individual's inability to perform two or more ADLs, or the need for significant assistance to perform the activities is required. We do not interpret ''objective'' to refer to the independence required of the assessor as discussed above, but to refer to an additional requirement for reliance on some level of valid measurement appropriate to the ADLs in order to ensure that the assessments were applied uniformly across individuals in the section 1915(i) benefit. For example, an occupational therapy (OT) or physical therapy (PT) evaluation or a trauma screening could be required, the results of which would be utilized by the assessor. We note that the trained assessor is not necessarily responsible for performing the objective evaluation, but should make sure that the objective evaluation is performed by qualified individuals. We do not propose methods to achieve this requirement, as the nature of the HCBS to be provided and the needs-based criteria for the State plan HCBS benefit will determine the appropriate means of evaluating ADLs.

Section 1915(i)(1)(F) of the Act defines ADLs in terms of section 7702B(c)(2)(B) of the Internal Revenue Code of 1986, which includes the following: bathing, dressing, toileting, transferring, eating, and continence. This section of the Internal Revenue Code does not define the terms ''inability'' or ''significant assistance.'' While States have some flexibility to define these factors, we interpret ''inability'' to mean need for total support to perform an ADL, and ''significant assistance'' to mean assistance from another individual or from assistive technology necessary for the successful performance of the task.

An objective evaluation of inability to perform two or more ADLs is a required element of the assessment but only a suggested element of the eligibility evaluation. We conclude that partial or complete inability to perform two or more ADLs is not a statutory prerequisite to receive State plan HCBS, but is a required element of the assessment in order to inform the development of the service plan required by section 1915(i)(1)(G) of the Act. Because States may define very diverse needs-based criteria and HCBS service definitions, we do not believe it is possible to be more specific in regulation about the criteria for assessment. However, we would note that a functional assessment tool could be used to measure objectively an individual's needs to establish eligibility as well as to develop an appropriate service plan.

We note that we are currently engaged in an initiative to develop universal core elements to be included in an assessment, through work being done

under the Balancing Incentives Payment Program, created under section 10202 of the Affordable Care Act. For consistency across Medicaid programs, we therefore, intend to move toward States including any finalized universal core elements developed from this work in carrying out independent assessments under 1915(i), as well as under 1915(k) Community First Choice, and in performing other HCBS assessments as determined by CMS.

• Consultation with any responsible persons appropriate to the individual and the needed supports, including family, spouse, guardian, or healthcare and support providers. We do not believe the examples listed in the statute to be prescriptive or limiting. The assessor must give the individual and, if applicable, the individual's authorized representative, the opportunity to identify appropriate persons who should be consulted during this process. The role of the assessor is to facilitate free communication from persons relevant to the support needs of the individual, while protecting privacy, and promoting the wishes and best interests of the individual. In necessary circumstances, the consultations are not required to be performed in person or at the same time and place as the face-to-face evaluation, so long as any ancillary contacts are with persons the individual has identified, are divulged and discussed with the individual/representative, and documented. For example, telephone communications with parties not available for an in-person meeting would be permitted.

• An examination of the individual's relevant history, medical records, and care and support needs.

• Knowledge of best practices and research on effective strategies that result in improved health and quality of life outcomes, and knowledge of the adult and child public service systems. At section 1915(i)(1)(F)(v) of the Act, the statute requires that the examination of the individual's history, medical records, and care and support needs be guided by this knowledge, and we would propose that this evidence-based approach should apply to the entire process for assessment and service plan development in a comprehensive, coordinated manner. Since the individualized service plan must be based upon the independent assessment, these requirements for the assessment should be used to inform and strengthen the service plan and, subsequently, the services provided to the individual.

• If the State offers the option of self-direction and the individual so elects, the assessment should include gathering the information required to establish self-direction of services. We do not propose to require States to conduct a separate or additional assessment process for self-direction.

As long as States comply with all provisions related to conducting the independent eligibility evaluation, independent assessment, and developing the person-centered service plan, States have flexibility in determining whether they will require that the functions be performed as one activity by a single agency or individual, or whether they wish to separate those functions and have different entities involved.

7. Person-Centered Service Plan

Section 1915(i)(1)(G) of the Act requires that the State plan HCBS benefit be furnished under an individualized care plan based on the assessment. The terms ''care plan'' and ''service plan'' are used interchangeably in practice. We will adopt the term ''service plan'' in this regulation for two reasons. First, to be consistent with the terminology in use with other HCBS, including § 1915(c) HCBS waivers, we wish to avoid the misunderstanding that the plan is a different type of requirement in the State plan HCBS benefit than in other HCBS authorities. We note the reference to ''service plan'' for self-directed HCBS at 1915(i)(1)(G)(iii)(II)(bb). Second, some individuals and advocates have commented that ''care plan'' has a medical or dependent connotation, inconsistent with a person-centered approach. Since we see no technical difference between the two terms, we propose to adopt ''service plan''.

Underpinning all aspects of successful HCBS is the importance of a complete and inclusive person-centered planning process that addresses health and long-term services and support needs in a manner that reflects individual preferences. The person-centered approach is a process, directed by the individual with long-term support needs, and may also include a representative whom the individual has freely chosen.

To fully meet individual needs and ensure meaningful access to their surrounding community, systems that deliver HCBS must be based upon a strong foundation of person-centered planning and approaches to service delivery. Thus, we propose to require such a process be used in the development of the individualized service plan for all individuals to be served by section 1915(i) benefit. This can be achieved when States affirmatively and creatively support individuals in the planning process. We would propose certain requirements for developing the service plan, but note that the degree to which the process achieves the goal of person-centeredness can only be known with appropriate quality monitoring by the State, which should include substantial feedback provided by individuals who received or are receiving services.

The person-centered service plan must identify the strengths, preferences, needs (clinical and support), and desired outcomes of the individual. The person-centered planning process is conducted in a manner that reflects what is important for the individual to meet identified clinical and support needs determined through a person-centered functional needs assessment process and what is important to the individual to ensure delivery of services in a manner that reflects personal preferences and choices.

In addition to being driven by the individual receiving services, the person-centered planning process would—

• Include people chosen by the individual;

• Provide necessary support to ensure that the individual has a meaningful role in directing the process to the maximum extent possible, and is enabled to make informed choices and decisions;

• Is timely and occurs at times and locations of convenience to the individual;

• Reflects cultural considerations of the individual;

• Include strategies for solving conflict or disagreement within the process, including clear conflict of interest guidelines for all planning participants;

• Offers choices to the individual regarding the services and supports they receive and from whom.

• Includes a method for the individual to request updates to the plan.

• Records the alternative home and community-based settings that were considered by the individual.

The plan resulting from this process should reflect that the setting in which the individual resides is chosen by the individual. The plan should reflect the individual's strengths and preferences, as well as clinical and support needs (as identified through an assessment of functional need). The plan should include individually identified goals, which may include goals and preferences related to relationships, community participation, employment, income and savings, health care and

wellness, education, and others (we note that not all goals will have comparable services covered under Medicaid). The plan should reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals, and who provides them. The plan should reflect risk factors and measures in place to minimize them, including individualized back-up plans. The plan must be signed by all individuals and providers responsible for its implementation, and should reflect the approach in place to ensure that it is implemented as intended. A copy of the plan must be provided to individuals and others involved in the plan.

Consistent with these person-centered principles and the requirements for community integration under the Americans with Disabilities Act, we are proposing that the service plan should be constructed in a manner that promotes service delivery and independent living in the most integrated setting possible. Therefore, we propose that the plan must not only address medical and support needs, but should also reflect other individual goals related to community living to the extent that services covered under the State Medicaid plan would be available to support such goals. Although these goals may include activities that may not themselves be funded through medical assistance, the coordination of Medicaid services with other activities in which the individual would be engaged as part of community living is an essential part of ensuring community integration. These activities might include employment, education, recreation or social activities, and/or other activities that occur regularly for individuals living in the community.

Subject to any additional needs-based criteria established for individual services, the State must make the services available to all eligible individuals who are assessed to need them. We conclude that the statute permits determining the level of services required by an individual only according to assessment of the individual's needs, not based on available funds. Just as significantly, individuals who qualify for HCBS may not be compelled to receive them. Individuals may also exercise their freedom to choose among qualified providers in the planning process.

The State Medicaid agency may delegate other agents to develop the service plan, but remains responsible for ensuring compliance with all requirements for each service plan developed. While the agency may delegate the authority for plan development and approval, the Medicaid agency is ultimately responsible for ensuring that the plans are completed according to the requirements of this regulation. This can be done through the establishment of appropriate controls, including monitoring and a quality improvement process.

Section 1915(i)(1)(G)(ii)(I)(aa) of the Act requires that the service plan is developed in consultation with the individual. The requirements for who is consulted in developing the service plan parallel those describing who may be consulted during the assessment process as determined by the State. As with the assessment, providers or others who may be responsible for providing services identified in the plan may be involved in the process. For example, providers may contribute to these processes by providing portions of an assessment and recommending a service plan, so long as the entity that retains final responsibility for the assessment or service plan meets all of the requirements of this final rule, including meeting the conflict of interest standards (See section II.B.10. for further discussion of conflict of interest).

Section 1915(i)(1)(G)(ii)(I)(bb) of the Act requires that the development of the service plan take into account the extent of family or other supports, which we refer to as ''natural supports,'' for the individual, and section 1915(i)(1)(G)(ii)(II) of the Act requires that such plan identify needed services. We interpret these provisions to indicate that to the extent available, natural supports should be explicitly included in the service plan. This means that individuals with equivalent needs for support but differing levels of family or other natural supports may be authorized for different levels of HCBS. In the context of person-centered planning and consultation with natural supports, we conclude that the statute requires that the service plan should neither duplicate, nor compel, natural supports.

Section 1915(i)(1)(G)(ii)(III) of the Act provides that plans of care will be reviewed at least annually and upon significant change in the individual's circumstances. We interpret this provision to indicate that diagnostic or functional changes are not required in order to adjust a service plan. Changes in external factors such as gain or loss of other supports may trigger a review. Additionally, an individual may request a review of the plan at any time. We would require revision of the service plan if the review indicates that revision is appropriate. By ''annually,'' we mean not less often than every 12 months. Finally, we would relate this requirement to the independent assessment, since the development or revision of the service plan is based on the assessment. Therefore, we would propose that the independent assessment (See section II.B.6.) is required at least annually, and when needed upon a change in circumstances, in order to comply with the requirement to review plans of care with that frequency.

8. Self-Direction

Section 1915(i)(1)(G)(iii)(I) and (II) provides that States may offer enrolled individuals the option to self-direct some or all of the State Plan HCBS that they require. Many States have incorporated elements of self-direction into section 1915(c) waiver programs as well as section 1115 demonstration programs. Self-directed State plan HCBS allow States another avenue by which they may afford individuals maximum choice and control over the delivery of services, while comporting with all other applicable provisions of Medicaid law. We have urged all States to afford waiver participants the opportunity to direct some or all of their waiver services, without regard to their support needs. With the release of an updated, revised section 1915(c) waiver application in 2008, we refined the criteria and guidance to States surrounding self-direction (also referred to as participant-direction), and established a process by which States are encouraged, to whatever degree feasible, to include self-direction as a component of their overall HCBS waiver programs. While section 1915(i) of the Act does not require that States follow the guidelines for section 1915(c) waivers in implementing self-direction in the HCBS State plan benefit, we anticipate that States will make use of their experience with section 1915(c) waivers to offer a similar pattern of self-directed opportunities with meaningful supports and effective protections. Individuals who choose to self-direct will be subject to the same requirements as other enrollees in the State plan HCBS benefit.

Section 1915(i)(1)(G)(iii)(II) of the Act defines self-direction, and requires that there be an assessment and service plan. We do not interpret these requirements to indicate assessments and plans in addition to those generally required in sections 1915(i)(1)(F) and (G) of the Act. Accordingly, we would propose that the requirements for a self-directed service plan under section 1915(i)(1)(G)(iii)(III) of the Act be incorporated as components of the assessment and

service plan required for all enrollees in the State plan HCBS benefit.

Section 1915(i)(1)(G)(iii)(III) of the Act contains specific requirements for the self-directed service plan, for which we describe proposed regulations in section III. The proposed regulations are consistent with our requirements for self-direction under section 1915(c) HCBS waivers. Section 1915(i)(1)(G)(iii)(III)(dd) of the Act requires that the service plan be developed with a person-centered process, which, as noted above, we would propose to require of all service plans for the State plan HCBS benefit.

Section 1915(i)(1)(G)(iii)(IV) of the Act describes certain aspects of a self-directed budget, which we have termed ''budget authority.'' Section 1915(i)(1)(G)(iii)(III)(bb) of the Act provides for self-directed selecting, managing, and/or dismissing of providers of the State plan HCBS, which we term ''employer authority.'' We interpret selecting to include the authority to hire a provider, as well as to direct an agency to hire a specific provider. Currently, section 1915(c) HCBS waivers include varying degrees of self-direction. The proposed rule explains both budget authority and employer authority in a manner consistent with section 1915(c) HCBS waiver policy.

Individuals require information and assistance to support them in successfully directing their services. Therefore, we would require States to design and provide functions in support of self-direction that are individualized according to the support needs of each enrollee. These functions should include, at a minimum, information and assistance consistent with sound principles and practice of self-direction, and financial management supports to serve as fiscal/employer agents or co-employers. The availability of an independent advocate to assist the individual with the access to and oversight of their waiver services, including self-direction, is also an important component of a strong self-directed system. We note that the adequacy of supports for successful self-direction will be important elements of the State's quality assurance strategy, which is required by section 1915(i)(1)(H) of the Act.

9. Quality Assurance

Section 1915(i)(1)(H)(i) of the Act requires the State to ensure that the State plan HCBS benefit meets Federal and State guidelines for quality assurance, which we interpret as assurances of quality improvement. Consistent with current trends in health care, the language of quality assurance has evolved to mean quality improvement, a systems approach designed to continuously improve services and support and prevent or minimize problems prior to occurrences. Guidelines for quality improvement have been made available through CMS policies governing section 1915(c) HCBS waivers available at *www.hcbswaivers.net* and published manuscripts available at *www.nationalqualityenterprise.com.*

Consistent with recent legislation with considerable focus on evidence-based quality and measurement, we would require States to have a quality improvement strategy, and to measure and maintain evidence of quality improvement including system performance, individual quality of care, and individual experience of care indicators approved and/or prescribed by the Secretary. These measures must take into account the relevant, targeted assurances, and include measures established through the DRA, CHIPRA, Affordable Care Act, and/or any other relevant health care indicators or quality measures developed by HHS, as applicable to the population(s) served by the section 1915(i) benefit. We would require States to make this information on their identified measures available to CMS upon request. In the event that a State elects to target the section 1915(i) benefit to specific populations, the State must submit evidence of quality improvement no later than 180 days before the end of each 5-year approval period. (See the discussion at I.B.19 of this proposed rule for more information regarding targeting and approval periods).

10. Conflict of Interest

Section 1915(i)(1)(H)(ii) of the Act provides that the State will establish conflict of interest standards for the independent evaluation and independent assessment. For reasons described above under independent assessment, we believe that the same independence is necessary for those involved with developing the person-centered service plan. In this discussion, we will refer to persons or entities responsible for the independent evaluation, independent assessment, and the service plan as ''agents'' to distinguish them from ''providers'' of home and community-based services.

Conflicts can arise from incentives for either over- or under-utilization of services; subtle problems such as interest in retaining the individual as a client rather than promoting independence; or issues that focus on the convenience of the agent or service provider rather than being person-centered. Many of these conflicts of interest may not be conscious decisions on the part of individuals or entities responsible for the provisions of service.

To mitigate any explicit or implicit conflicts of interest, the independent agent must not be influenced by variations in available funding, either locally or from the State. The service plan must offer each individual all of the HCBS that are covered by the State that the individual qualifies for, and that are demonstrated to be necessary through the evaluation and assessment process. The service plan must be based only on medical necessity (for example, needs-based criteria), not on available funding. When local entities directly expend funds or direct allocated resources for services, in accordance with section 1902(a)(2) of the Act, the State must have a mechanism to ensure that availability of local funds does not affect access to services, such as using State resources to compensate for variability in local funding.

In this proposed regulation, we would require States to define conflict of interest standards to include criteria that reflect State and Federal experience with the issue in administering HCBS waivers, and that reflect the principles of section 1877 of the Act. Section 1877 of the Act prohibits certain types of referrals for services when there is a financial relationship between the referring entity and the provider of services.

We are aware that in certain areas there may only be one provider available to serve as both the agent performing independent assessments and developing plans of care, and the provider of one or more of the HCBS. To address this potential problem we would propose to permit providers in some cases to serve as both agent and provider of services, but with guarantees of independence of function within the provider entity. In certain circumstances, we may require that States develop ''firewall'' policies, for example, separating staff that perform assessments and develop plans of care from those that provide any of the services in the plan; and meaningful and accessible procedures for individuals and representatives to appeal to the State. We would not permit States to circumvent these requirements by adopting State or local policies that suppress enrollment of any qualified and willing provider. We do not believe that under any circumstances determination of eligibility for the State plan HCBS benefit should be performed by parties with an interest in providers of HCBS.

We understand that the development of appropriate plans of care often requires the inclusion of individuals with expertise in the provision of long-term services and supports or the delivery of acute care medical services. As discussed previously, this rule is not intended to prevent providers from participating in these functions, but to ensure that an independent agent retains the final responsibility for the evaluation, assessment, and service plan functions.

11. Eligibility Redeterminations; Appeals

Section 1915(i)(1)(I) of the Act requires the State to conduct redeterminations of eligibility at least annually. We interpret ''annually'' to mean not less than every 12 months. The State must conduct redeterminations and appeals in the same manner as required under the State plan. States must grant fair hearings consistent with the requirements of part 431, subpart E.

12. Option for Presumptive Eligibility for Assessment

Section 1915(i)(1)(J) of the Act gives States the option of providing for a period of presumptive eligibility, not to exceed 60 days, for individuals the State has reason to believe may be eligible for the State plan HCBS benefit.

We interpret this provision as follows:

- ''Presumptive'' we interpret to indicate that FFP will be available for evaluation even when an individual is subsequently found not to be eligible for the State plan HCBS benefit.
- ''Eligibility'' does not connote eligibility for Medicaid generally, as this provision ''shall be limited to medical assistance for carrying out the independent evaluation and assessment'' under section 1915(i)(1)(E) of the Act. For clarity, we would refer to this limited option as ''presumptive payment''. Individuals not eligible for Medicaid may not receive State plan HCBS.
- ''Evaluation and assessment'' under section 1915(i)(1)(E) of the Act, is described as evaluation for eligibility for the benefit and assessment to determine necessary services. We believe the statutory phrase ''and if the individual is so eligible, the specific HCBS that the individual will receive'' is further describing the assessment under section 1915(i)(1)(E) of the Act for which presumptive payment is available, and that this phrase is not offering presumptive payment for the actual services. The phrase ''if the individual is so eligible'' indicates that payment is available once the individual is determined eligible, and not prior to that point.
- In section 1915(i)(1)(J) of the Act, we interpret the term ''medical assistance for carrying out the independent evaluation and assessment under subparagraph E'' to mean expenditures for both costs of evaluative services that are described in section 1905(a), such as physician or other practitioner services, as well as administrative costs to determine eligibility for the State plan HCBS benefit. We interpret section 1915(i)(1)(J) of the Act to offer the State an option for a period of presumptive payment, not to exceed 60 days, for individuals the State has reason to believe may be eligible for the State plan HCBS benefit. FFP would be available for both medical services and administrative costs incurred for evaluation and assessment activities. During the period of presumptive payment, the individual would not receive State plan HCBS, and would not be considered to be enrolled in Medicaid or eligible for the HCBS benefit for purposes of computing the number of individuals being served under the benefit.

We invite comments that offer other interpretations of this presumptive payment option and that comport with existing Federal requirements.

13. Individual's Representative

When an individual is not capable of giving consent, or requires assistance in making decisions regarding his or her care, the individual may be assisted or represented by another person. Section 1915(i)(2) of the Act defines the term ''individual's representative'' by listing certain examples, but also provides that ''* * * any other individual who is authorized to represent the individual'' may be included. We believe that ''authorized'' refers to State rules concerning guardians, legal representatives, power of attorney, or persons of other status recognized under State law or under the policies of the State Medicaid program.

States should ensure that the representatives conform to good practice concerning free choice of the individual, and assess for abuse or excessive control. States should also ensure that the person-centered planning process continues to be focused on the individual with HCBS support needs and his or her preferences and goals, and supports are provided so the individual can meaningfully participate and direct the process to the maximum extent possible. We are proposing to provide that the State may not refuse to recognize an authorized representative that the individual chooses, unless the State discovers and can document evidence that the representative is not acting in the best interest of the individual or cannot perform the required functions.

14. Nonapplication

As amended by the Affordable Care Act, section 1915(i)(3) of the Act allows States to be exempted from the requirements of two sections of the Medicaid statute: section 1902(a)(10)(B) of the Act, regarding comparability; and section 1902(a)(10)(C)(i)(III) of the Act, regarding income and resource rules for the medically needy in the community. The statute uses the terms ''nonapplication'' and ''may chose not to comply with'' rather than ''waive''. We would use this terminology to maintain clarity between HCBS waiver programs under section 1915(c) of the Act and State plan HCBS under section 1915(i) of the Act. However, it is important to reiterate that the choice not to apply these requirements applies only with regard to the provision of State plan HCBS.

Nonapplication of the requirement of comparability allows States to furnish the State plan HCBS benefit to specific targeted populations, similar to section 1915(c) waivers. Regardless of whether a State chooses to apply comparability requirements, it must define needs-based criteria to establish eligibility for the section 1915(i) benefit. If a State chooses not to apply comparability and to target the benefit, individuals must meet both the targeting criteria and the needs-based criteria in order to receive services through the section 1915(i) benefit. See the discussion in I.B.19 of this proposed rule for more detail regarding the option not to apply Medicaid comparability requirements and to target the benefit to a specific population or populations.

The nonapplication of the requirements of section 1902(a)(10)(C)(i)(III) of the Act enables States to provide medical assistance to medically needy individuals in the community by electing to treat the individuals as if they are living in an institution for purposes of determining income and resources. This would result in the State not deeming/counting income and resources from an ineligible spouse to an applicant or from a parent to a child with a disability. However, nonapplication of the income and resource rules applicable in the community applies only to the medically needy and only for the purposes of providing HCBS in accordance with the State plan amendment implementing section

1915(i) of the Act. Based on this language, we are interpreting the statute to mean that individuals made eligible on the basis of nonapplication of section 1902(a)(10)(C)(i)(III) of the Act may only be eligible for section 1915(i) services. In other words, for medically needy applicants, the State can elect not to deem income from an ineligible spouse, or from a parent to a child. If the State elects not to apply the requirements of section 1902(a)(10)(C)(i)(III) of the Act for the medically needy, it would determine Medicaid eligibility for section 1915(i) eligible medically needy individuals using institutional rules rather than community rules. Once the individual has been determined to be eligible as medically needy using institutional rules, and has been determined to meet the 150 percent of the FPL limit, the individual would only be eligible for State plan HCBS under section 1915(i) of the Act. The individual would not be eligible for any other Medicaid State plan services. However, individuals who are eligible for Medicaid as medically needy under income and resource rules applicable in the community, and whose income does not exceed the 150 percent of the FPL limit, would be eligible for State plan HCBS as well as all Medicaid State plan services.

15. No Effect on Waiver Authority

Section 1915(i)(4) of the Act emphasizes that State election to provide the State plan HCBS benefit does not in any way affect the State's ability to offer programs through a section 1915(b) or (c) waiver, or under section 1115 of the Act. We further note that States may consider including 1915(i) services as a part of capitation under section 1915(b) waivers or other authorities for managed care arrangements. A State could use joint authority of 1915(b) and 1915(i) to provide HCBS to individuals eligible for the 1915(i) benefit.

16. Continuation of Federal Financial Participation (FFP) for Institutional Level of Care for Individuals Receiving Services as of the Effective Date of the State Plan HCBS Amendment

If the State modifies institutional LOC requirements so that they will be more stringent than the needs-based criteria for the State plan HCBS benefit, section 1915(i)(5) of the Act permits States the option to continue receiving FFP for individuals who are receiving institutional services in NFs, ICFs/MR, and applicable hospitals or who are receiving services under a section 1915 waiver or through an 1115 HCBS demonstration project that is in effect at the time of the modification. We interpret the reference to section 1915 waivers to include waivers under sections 1915(c), 1915(d) or 1915(e) of the Act, which are the section 1915 waivers explicitly identified in section 1915(i)(6)(A) of the Act. Individuals receiving institutional care or HCBS under these authorities at the time that the institutional LOC is modified would not have to satisfy the more stringent criteria in order to continue receiving that care.

FFP under the unmodified criteria would continue to be available until such time as the individual is discharged from the institution, waiver program, or demonstration, or no longer requires this LOC. Moving between a waiver and an institution at the same LOC, or vice versa, by definition is not a change in LOC. Therefore, individuals who transition between waivers and institutions (for example, transitioning from an institution to waiver through the Money Follows the person program) would retain eligibility for institutional care and HCBS until they no longer meet the less stringent LOC requirements or until they lose eligibility for Medicaid or for institutional or waiver services due to a reason other than the application of the modified LOC criteria. An example of this would be if the individual aged out of a waiver, or if an increase in income or resources caused the individual to lose Medicaid eligibility.

In section 1915(i)(5) of the Act, the statute indicates that FFP remains available for individuals who meet the previous institutional criteria. We note that this does not create a requirement for States to continue to serve these individuals; rather, it creates an option for States to continue to receive FFP in order to provide care for individuals who would otherwise lose eligibility due to the implementation of the new criteria.

Due to the current requirements on maintaining eligibility standards, methodologies and procedures, we encourage States to consult with CMS before instituting any changes to LOC requirements.

17. State Option To Provide HCBS to Individuals Eligible for Services Under a Waiver

Section 2402(b) of the Affordable Care Act added section 1915(i)(6) to the Act, specifying that States may elect to provide HCBS to an individual who is eligible for an approved waiver under sections 1915(c), (d), (e), or 1115 of the Act. Section 1915(i)(6)(A) specifies that individuals who are eligible for a waiver may receive State plan HCBS under the authority of section 1915(i) if they satisfy the needs-based criteria under such section and if their income is less than 300 percent of the supplemental security income (SSI) Federal benefit rate (FBR), as established by section 1611(b)(1) of the Act.

We interpret this statute as creating an option for States to increase the income limit for the State plan HCBS benefit, but only for individuals who are eligible for HCBS through an approved waiver within the State. We interpret ''eligible'' to mean that the individual meets all of the criteria required for entrance into a HCBS waiver that is approved within the State, regardless of whether the individual is actually enrolled and receiving services through that waiver. As discussed below, if a State elects this option, the State must cover the new optional categorically needy eligibility group specified at section 1902(a)(10)(A)(ii)(XXII) of the Act, and individuals who are eligible for a waiver with income above 150 percent of the FPL, but below 300 percent of the SSI benefit rate, may receive State plan HCBS.

When establishing whether an individual's income is below 300 percent of SSI, under section 1915(i)(6)(B), the State should use the same rules that are applied for the special income level group specified at section 1902(a)(10)(A)(ii)(V) of the Act. Regardless of whether a State elects the option established by this section, the State could provide HCBS through both the section 1915(i) benefit, as well as through a HCBS waiver to any individual who meets the financial and needs-based criteria for both programs (that is, if an individual meets the waiver LOC criteria, and the needs-based criteria for the State plan HCBS benefit, and has income below 150 percent of the FPL, the individual could receive services under both authorities, provided that the services are not duplicative, whether or not the State elects to include the higher income level in their section 1915(i) benefit).

When a State elects to include this option, section 1915(i)(6)(C) of the Act allows services to differ in type, amount, duration, or scope from services provided to individuals who are eligible for the section 1915(i) benefit without also being eligible for a waiver. A State may choose to provide additional 1915(i) State plan HCBS to individuals who are eligible for HCBS under an approved waiver. If a State does so, it may also elect to establish additional needs-based criteria for those services. The establishment of additional criteria would be under the State authority to establish needs-based

criteria for any service in the 1915(i) benefit (see the discussion in I.B.2 of this proposed rule for more discussion).

Any additional service(s) provided through this subsection must be allowable under section 1915(c)(4)(B) and may not include room and board. A State may also include ''other'' services, as defined by the State and approved by the Secretary, within the package of section 1915(i) services that are limited to individuals who are eligible for a waiver. However, because individuals eligible for a waiver must also satisfy the needs-based criteria established for the section 1915(i) benefit to receive State plan HCBS, a State may not restrict access to benefits that are available to other individuals who receive the State Plan HCBS, except through a targeting criteria, or through the establishment of a needs-based criteria that applies uniformly to all individuals.

18. Establishment of Optional Eligibility Group To Provide Full Medicaid Benefits to Individuals Receiving State Plan HCBS

Section 2402(d) of the Affordable Care Act creates a new optional categorically needy eligibility group, specified at section 1902(a)(10)(A)(ii)(XXII) of the Act, for individuals ''who are eligible for HCBS under the needs-based criteria established under (1)(A) of 1915(i), or who are eligible for home and community-based services under paragraph (6) of such section, and who will receive home and community-based services pursuant to a State plan amendment under such subsection.''

Under this group States can elect to cover individuals who are not otherwise eligible for Medicaid. For example, an individual age 65 or older, who has chronic needs but not at an institutional level of care and has too much income and/or resources to qualify for Medical Assistance under a State's Medicaid plan, could be eligible for section 1915(i) services if he/she meets the needs-based criteria for the section 1915(i) benefit, has income up to 150 percent of the FPL and will receive section 1915(i) services. Under this group, States may also elect to cover individuals with income up to 300 percent of the SSI/FBR who would be eligible under an existing section 1915(c), (d), (e) waiver or section 1115 waiver and who will receive section 1915(i) services. These individuals do not have to be receiving services under an existing section 1915(c), (d), (e) waiver or section 1115 waiver; the individual only has to be eligible for the waiver. Individuals eligible for Medicaid under this group would be eligible for full Medicaid benefits. The State must also elect the option under section 1915(i)(6) of the Act if the State intends to cover individuals with income up to 300 percent of the SSI/FBR.

19. State Option To Offer HCBS to Specific, Targeted Populations

The Affordable Care Act added section 1915(i)(7) to the Act, which allows States to target the section 1915(i) benefit to specific populations. In addition, as of October 1, 2010, States may design section 1915(i) benefits without regard to the comparability requirements contained in section 1902(a)(10)(B) of the Act. As a result, the State may ''target'' services, that is, either provide the 1915(i) benefit only to individuals in certain Medicaid eligibility groups, or provide different services within the 1915(i) benefit to different groups. Due to the ability to define targeted populations, a State may now propose more than one set of section 1915(i) benefits, with each benefit package targeted toward a specific population. A State may also propose one set of section 1915(i) benefits that targets multiple populations, and may offer different services to each of the defined target groups within the benefit. Additionally, a State may propose a section 1915(i) benefit that does not choose nonapplication of comparability and instead uses only the needs-based criteria to establish eligibility for the benefit. States may find this to be a less administratively burdensome approach, as there is no renewal requirement or limit to the approval period if the State does not target the HCBS benefit (see below for a discussion on limits to the approval period).

We propose to require that a State that elects to target the benefit to specific groups of individuals must submit objective targeting criteria in the SPA implementing the HCBS benefit, subject to approval by CMS. These targeting criteria may define a target population or multiple target populations within parameters of diagnosis, disability, Medicaid eligibility groups, and/or age. Within these parameters, targeting criteria may be similar to those available through section 1915(c) waivers, as defined in § 441.301, but we note that based on experience, these target groups may not aptly capture the universe of individuals who could benefit from section 1915(i) of the Act. Therefore, a State may also establish broader criteria that encompass more than one of the three groups defined in § 441.301, or that target enrollees based on separate criteria. However, we note that the section 1915(i) benefit is described in the statute as ''HCBS for Elderly and Disabled Individuals.'' Therefore, we would expect any targeting criteria to apply to eligibility groups serving those individuals. We would also expect targeting criteria to align with the needs-based criteria established for the benefit.

For example, a State could target the benefit package to any children under the age of 21 with an intellectual disability, a developmental disability, autism, or a behavioral health condition. A State could also target the benefit using traditional section 1915(c) groups. An example of this would be to target the benefit to individuals age 65 and up. Further, this targeting option does not permit States to target the benefit in a manner that would not comply with section 1902(a)(23) of the Act regarding free choice of providers, or that forestalls the opportunity for individuals to receive services in the most integrated setting possible. Therefore, targeting criteria cannot have the impact of limiting the pool of qualified providers from which an individual would receive services, or have the impact of requiring an individual to receive services from the same entity from which they purchase their housing. For example, we would not allow States to establish targeting criteria that would restrict eligibility to only individuals who reside in provider-owned and/or operated settings.

If a State elects to target the benefit to a specific population or populations, it must still establish needs-based criteria that individuals must meet in order to be eligible for section 1915(i) services and the State may also establish needs-based criteria for individual services within the benefit. The needs-based criteria may include specific needs that are applicable to the targeting criteria, but may also include general needs that apply across all of the populations included in the benefit.

20. Five-Year Approval for Targeted Section 1915(i) HCBS Benefits and Renewal Requirements

Under sections 1915(i)(7)(B)(i) and (C) of the Act, if a State chooses to target State plan HCBS, the SPA approval will last for a 5-year period with the option for 5-year renewal periods. There is no statutory limit on the number of renewal periods available under this section. At the end of the initial 5-year period, and any subsequent renewals, CMS will review the State's approved SPA and evaluate State performance based upon the requirements contained within that SPA and the State plan HCBS quality outcomes.

We propose that a State must provide a written request for renewal at least 180 days prior to the end of the approval period. The request must be accompanied by a description of any proposed changes to the benefit, if applicable. Prior to renewal, CMS will request evidence of implementation of the State's quality improvement strategy in order to verify compliance with State plan HCBS requirements. Results of the quality monitoring process will be used to identify and make recommendations on areas of a State's section 1915(i) benefit that require modification prior to renewal. In accordance with section 1915(i)(7)(C) of the Act, we will approve renewals based upon adherence to Federal requirements, including adherence to the State's phase-in plan, as approved by CMS.

21. Phase-In of Services and Eligibility

Section 1915(i)(7)(B)(ii) allows States to phase-in the enrollment of individuals and/or the provision of services if the State elects to target the benefit to specific populations. The statute indicates that the State must enroll all eligible individuals and provide all of the services it has elected to include in the benefit by the end of the initial 5-year approval. Although the option to phase-in services and/or eligibility may seem contradictory with the requirements that the benefit be statewide and not limit enrollment, we interpret this section to provide States with the flexibility to prioritize enrollment to individuals with the highest need and/or to develop adequate infrastructure to ensure quality of care, and the health and safety of participants, prior to the provision of services. We do not interpret this option as providing States the authority to limit statewideness or to set a numerical limit on enrollment.

As an example, a State could elect to begin the provision of services to individuals with higher needs prior to the enrollment of all eligible individuals, based upon the assessment for eligibility to the benefit. In this instance, the needs-based criteria would allow States to identify individuals at greatest risk for health and safety, and to prioritize services to those individuals. Services would then be phased-in to individuals who qualify for the benefit but who have less assessed need.

States are permitted to modify the available services in a section 1915(i) benefit through a SPA at any time. Therefore, we do not believe that this option permits a State to include a service within the benefit without providing it to at least some enrolled individuals. However, at the option of a State, a phase-in plan might temporarily limit the provision of the entire benefit package, or of some specific services, based upon infrastructure considerations, such as the need to enroll an adequate number of qualified providers.

We propose that a State that elects to target the State plan HCBS benefit and to phase-in enrollment and/or services must submit a phase-in plan for approval by CMS that describes, at a minimum:

- The criteria used to phase-in enrollment or service delivery;
- The rationale for phasing-in services and/or eligibility; and
- Timelines and benchmarks to ensure that the benefit is available Statewide to all eligible individuals within the initial 5-year approval.

If a State elects and CMS approves a phase-in of services and/or eligibility in the section 1915(i) SPA, the statute indicates that the State must enroll all eligible individuals and provide all of the services it has elected to include in the benefit by the end of the initial 5-year approval. Therefore, if a State does not meet its phase-in plan by the end of the initial 5-year approval of the section 1915(i) benefit, the State will not be able to renew the benefit.

States are also prohibited from having a phase-in period longer than 5 years, and from receiving approval for a new section 1915(i) submission of a similar design with a phase-in period when a similar benefit with phase-in is discontinued before full implementation.

We are soliciting comments on alternative strategies and approaches for evaluating and approving the option to phase-in eligibility and enrollment.

C. Effective Date

The effective date on which States may provide HCBS through the State plan, as set forth by the DRA, is January 1, 2007. The effective date of the amendments to the section 1915(i) benefit, as established by the Affordable Care Act, is October 1, 2010.

D. The State Plan HCBS Benefit in the Context of the Medicaid Program as a Whole

The section 1915(i) State plan HCBS benefit is subject to provisions of the Medicaid program as a whole. Therefore, it is useful to note certain requirements of the Medicaid program that have an impact on the administration of the State plan HCBS benefit and that are not explicitly referenced in the regulation.

To be eligible for the State plan HCBS benefit, an individual must be included in an eligibility group that is contained in the State plan, including if the State elects, the new eligibility group defined at section 1902(a)(10)(A)(ii)(XXII) of the Act. Each individual must meet all financial and non-financial criteria set forth in the plan for the applicable eligibility group.

Children included in eligibility groups under the State plan may meet the needs-based criteria and qualify for benefits under the State plan HCBS benefit. States may also choose to target the benefit in a manner that either excludes children, or limits the benefit solely to children. HCBS benefits that are not otherwise available through 1905(a) State plan services under the Medicaid Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit may be furnished to Medicaid eligible children who meet the State plan HCBS needs-based eligibility criteria, and who meet the State's medical necessity criteria for the receipt of services. In addition to meeting EPSDT requirements through the provision of 1905(a) services, a State may also meet a particular child's needs under EPSDT through services that are also available through the 1915(i) benefit. However, all Medicaid-eligible children must have full access to services required under EPSDT, and the provision of 1915(i) State plan HCBS should in no way hinder their access to such services.

We further note that the mandate under EPSDT applies only to services authorized by section 1905(a) of the Act. Therefore, HCBS under section 1915(i) of the Act are not required under the EPSDT program. Children who are eligible for the State plan HCBS benefit are eligible to receive medically necessary State plan HCBS, but the State is not required to provide 1915(i) State plan HCBS as part of its EPSDT program. Clinic services (whether or not furnished in a facility) for individuals with chronic mental illness are listed in section 1915(c)(4)(B) of the Act and therefore may be covered in the State plan HCBS benefit. If a State chooses to offer these services, they will be subject to the clinic upper payment limit (UPL) at § 447.321. We also note that these services are defined differently than other clinic services offered under the State Plan in that they include services whether or not they are offered in a facility.

States may also elect to include 1915(i) benefits as part of a managed care contract. In the event that State plan HCBS are included in a managed care contract, they must meet all

applicable requirements contained in § 438, including actuarial soundness of rates, cost effectiveness of services, and CMS contract review and approval.

Additionally, since this benefit is established through a State plan amendment process, section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, enacted on February 17, 2009) requires the State to seek advice from Indian health programs and Urban Indian Organizations on the establishment of or modification to any State plan HCBS benefits.

FFP for the 1915(i) benefit is also subject to deferrals, withholding and disallowances in accordance with the requirements of subpart C of 42 CFR part 440. In the event that CMS determines a State to be out of compliance with the requirements of the HCBS benefit, standard Medicaid compliance actions will apply.

E. Other Background

1. Serving All Eligible Individuals While Targeting Limited Resources

As noted above, section 1915(i) of the Act applies the general Medicaid requirements regarding statewideness and, like other State plan options, does not allow States to limit enrollment. Nevertheless, the law offers significant discretion for defining the population served. Specifically, States may limit utilization of the State plan HCBS benefit through application of the following provisions of section 1915(i) of the Act:

- The requirement to set eligibility standards built on needs-based criteria. States choose the needs-based criteria used to establish the thresholds of program eligibility. States must set a lower threshold of need, but may also optionally define an upper threshold of need beyond which individuals may not be served under this provision.
- The option to target the benefit to specific populations. States may combine needs-based criteria with targeting criteria in order to create a very specific benefit that applies to defined groups of individuals.
- The option to establish needs-based criteria to determine eligibility for each State plan HCBS. These criteria may vary from service to service, and should assist States in identifying the individuals who could benefit from receipt of a particular State plan HCBS.
- The choice to offer a limited number of services under the State plan HCBS benefit. The scope of services that the State chooses to offer may include any, but need not include all, of the services permitted under section 1915(c)(4)(B) of the Act.
- The option to limit the amount or duration of each service, in accordance with all Medicaid rules and requirements.

Since all State plan HCBS must be provided under a written service plan, States have the opportunity to review an individual's service plan to ensure that HCBS continue to be responsive to the needs of the individual.

Additionally, as a reminder, general Medicaid requirements also apply to the State plan HCBS benefit. All Medicaid services are to be provided only to those who need them according to medical necessity and needs-based criteria, as defined by the State. Prior authorization is available to the State.

2. HCBS Provided in the Community, Not in Institutions

Section 1915(i) provides States the option to provide home and community-based services, but does not define ''home and community-based.'' Along with our overarching interest in making improvements to Medicaid HCBS, we seek to ensure that Medicaid is supporting needed strategies for States in their efforts to meet their obligations under the ADA and the Supreme Court decision in *Olmstead* v. *L.C.,* 527 U.S. 581 (1999). In the *Olmstead* decision, the Court affirmed a State's obligations to serve individuals in the most integrated setting appropriate to their needs. A State's obligations under the ADA and section 504 of the Rehabilitation Act are not defined by, or limited to, the scope of requirements of the Medicaid program. However, the Medicaid program can provide an opportunity to obtain partial Federal funding that supports compliance with the ADA, section 504 of the Rehabilitation Act, and *Olmstead* through the provision of Medicaid services to Medicaid-eligible individuals.

In the April 4, 2008 **Federal Register** (73 FR 18676), we proposed to define home and community settings for this new benefit. Then in the June 22, 2009 **Federal Register** (74 FR 29453), we published an advance notice of proposed rulemaking (ANPRM) that solicited comments on potential rulemaking for a number of areas within the section 1915(c) HCBS waiver program. Specifically, we requested public input on strategies to define home and community-based settings where waiver participants may receive services. Although the ANPRM is specific to section 1915(c) waivers, the services delivered and the settings they are available in are parallel to the section 1915(i) benefit. We recognize a need for a consistent definition of this term across Medicaid HCBS.

In response to the 1915(c) ANPRM, we received comments that supported the underlying goals to promote independence, community inclusion, and the goals of the *Olmstead* decision. However, many commenters also expressed concern about definitions of home and community-based settings that limited participant choice, and that excluded settings that may, in fact, promote independence and integration. Since that time, we have facilitated and participated in multiple stakeholder discussions related to this issue, and we also included proposed language for settings in which HCBS could be provided to elicit further comments on this issue in the section 1915(k) proposed rule published on February 25, 2011 and in the 1915(c) proposed rule published on April 15, 2011. We find the public comment process to be valuable in our attempt to develop the best policy on this issue for Medicaid beneficiaries. Therefore, with this rule, we again invite public comments on proposed language to establish the qualities for home and community-based settings under both sections 1915(i) State plan HCBS and the 1915(k) Community First Choice State plan option. It is our goal to align the final language pertaining to this topic across the sections 1915(k), 1915(i), and 1915(c) Medicaid HCBS authorities.

We have included proposed language for settings in which section 1915(i) services and supports could be provided to elicit additional comments on this issue. While it is not practical to create one singular definition that encompasses all settings that are home and community-based, with this rule we propose quality principles essential in determining whether a setting is community-based. We expect States electing to provide HCBS benefits under section 1915(i) to include a definition of home and community-based setting that incorporates these principles and will review all SPAs to determine whether they propose settings that are home or community-based. We will permit States with approved section 1915(i) SPAs a reasonable transition period, a minimum of one year, to come into compliance with the HCBS setting requirements as promulgated in our final rule.

Recognizing the imperative to provide clear guidance to States and in consideration of recent proposals from States that have clearly exceeded reasonable standards for HCBS, we are proposing to clarify now that home and community-based settings must exhibit

the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan, in order to be eligible sites for delivery of home and community-based services:

• The setting is integrated in, and facilitates the individual's full access to, the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, like individuals without disabilities;

• The setting is selected by the individual among all available alternatives and identified in the person-centered service plan;

• An individual's essential personal rights of privacy, dignity and respect, and freedom from coercion and restraint are protected;

• Individual initiative, autonomy, and independence in making major life choices, including but not limited to, daily activities, physical environment, and with whom to interact are optimized and not regimented; and

• Individual choice regarding services and supports, and who provides them, is facilitated.

In a provider-owned or controlled residential setting, the following additional conditions must be met. Any modifications of the conditions (for example to address the safety needs of an individual with dementia) must be supported by a specific assessed need and documented in the person-centered service plan:

++ The unit or room is a specific physical place that can be owned, rented, or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that the tenants have under the landlord/tenant laws of the State, county, city, or other designated entity. We are soliciting comments as to whether there are other protections, not addressed by landlord tenant law, that should be included;

++ Each individual has privacy in their sleeping or living unit:

—Units have lockable entrance doors, with appropriate staff having keys to doors;

—Individuals share units only at the individual's choice; and

—Individuals have the freedom to furnish and decorate their sleeping or living units;

++ Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time;

++ Individuals are able to have visitors of their choosing at any time; and

++ The setting is physically accessible to the individual.

In addition to the aforementioned criteria there are two criteria that we have not included in the proposed regulation, but wish to solicit comment regarding whether they should be added. The first is related to the proposed requirement that in a provider-owned or controlled residential setting, any modification of the conditions must be supported by specific assessed needs and documented in the person centered service plan. This requirement is meant to address two issues:

• Individuals receiving HCBS must not have their independence or freedoms abridged by providers for convenience, or well-meaning but unnecessarily restrictive methods for providing person-centered services and supports; and

• Individuals with cognitive disabilities and other impairments may require modifications of the aforementioned conditions for their safety and welfare.

This provision is meant to establish that service planning is the process in which these decisions are made, rather than ad hoc on a daily basis. While the proposed text establishes the requirement that any modification to the conditions are supported by a specific assessed need and documented in the person-centered service plan, we are also considering including language to explicitly set forth these activities. We are considering requiring the following points to be identified: identify a specific and individualized assessed safety need; document less intrusive methods that have been tried but did not work; include a clear description of the condition that is directly proportionate to the specific assessed safety need; include regular collection and review of data to measure the ongoing effectiveness of the modification; and establishing time limits for periodic reviews to determine if the modification can be lifted. We solicit comment on these points and any other potential requirements regarding modifications of the conditions set forth in this proposed rule. We also wish to solicit comment on a second criterion that would include a requirement that receipt of any particular service or support cannot be a condition for living in the unit. In discussing this specific criterion, we discovered that it could be read one of two ways. One interpretation is that this language does not require an individual residing in a provider owned or operated setting to receive HCBS from the setting provider. Rather the individual could choose another qualified individual to provide HCBS. The other interpretation is that this language would prevent the owner of the setting from evicting an individual because the individual refused to accept a particular service. This interpretation could have an effect on residential settings, such as housing programs to address homelessness. Some of these settings include a structure in which individuals are required to participate in treatment (substance use, for example) as a condition of residing there. We acknowledge the complexities that arise, when trying to support an individual's right to choose while recognizing that there are programs and services that have been developed as a result of identified service needs. As indicated earlier, we are specifically soliciting comments on whether these two criteria should be included as regulatory requirements.

We note that home and community-based settings do not include nursing facilities, institutions for mental diseases, intermediate care facilities for mentally retarded, hospitals, or any other locations that have the qualities of an institutional setting as determined by the Secretary. In considering whether a setting has the qualities of an institutional setting, we will exercise a rebuttable presumption that a setting is not a home and community-based setting, and will engage in heightened scrutiny, for any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or disability-specific housing complex. We expect to issue further guidance regarding such settings. Other characteristics that could cause CMS to consider a setting as ''institutional'' or having the qualities of an institution would include, but not be limited to, settings which are isolated from the larger community, do not allow individuals to choose whether or with whom they share a room, limit individuals' freedom of choice on daily living experiences such as meals, visitors, and activities, or limit individuals' opportunities to pursue community activities.

We have included these provisions to move toward a stronger articulation of the qualities that make a setting a home or truly integrated in the greater community for individuals living with

disabilities. We believe that these principles of home and community-based settings will support the use of the Medicaid program to maximize the opportunities for individuals to access the benefits of home and community living.

We specifically invite comments on whether there are settings in addition to those currently enumerated in statute, that are, by their nature, location or administration inherently non-community based, and therefore, should be expressly excluded from HCBS. We also invite comments on the community-based qualities we have proposed in this rule to ascertain whether additional or different characteristics should be included.

In considering comments received pertaining to this provision of the rule, we will also include consideration of all comments received pertaining to the aligned home and community-based setting requirements being proposed in this rule for the section 1915(k) Community First Choice State Plan Option. In recognizing the need for a consistent definition of this term across Medicaid HCBS, it is our goal to align the final language pertaining to this topic across the regulations for sections 1915(i), 1915(k), and 1915(c) Medicaid HCBS authorities.

We note that this proposal in no way preempts broad Medicaid requirements, such as an individual's right to obtain services from any willing and qualified provider of a service.

We further note that States are not prohibited from funding institutional care under Medicaid. The exclusion of these settings from HCBS waivers and from the State plan HCBS benefit does not limit the availability of institutional and facility-based care for those individuals who require long-term services and supports, and who freely choose to receive services in those settings. However, we believe that these types of services should not be funded through authorities that are intended to promote community-based alternatives to institutional care. Furthermore, we believe that the fundamental requirement that the needs-based criteria for section 1915(i) be less stringent than that for institutional care creates a mandate to ensure that services are provided in settings that are not institutional in nature.

While HCBS are not available while an individual resides in an institution, HCBS should be available to assist individuals to leave an institution. Recognizing that individuals leaving institutions require assistance to establish themselves in the community, we would allow States to include in a section 1915(i) benefit, as an ''other'' service, certain transition services to be offered to individuals to assist them in their return to the community. We propose that community transition services could be commenced prior to discharge and could be used to assist individuals during the period of transition from an institutional residence. Additionally, services could be provided to assist individuals transitioning to independent living in the community, as described in a letter to the State Medicaid Directors on May 9, 2002 (SMDL #02–008). We further recognize that, for short hospital stays, an individual may benefit from ongoing support through the HCBS State Plan for physical needs over and above such services available in a hospital, to ensure smooth transition from clinical setting to home, and to preserve a sense of continuity and normalcy (a notion particularly important for individuals with intellectual disabilities, cognitive disabilities associated with aging, and behavioral health support needs). Importantly, these services must be exclusively for the benefit of the individual, not the hospital, and must not substitute for services that the hospital is obligated to provide through its conditions of participation or through its obligations under the ADA.

3. Home and Community-Based Services Do Not Include Room and Board

Payments for room and board are expressly prohibited by section 1915(i)(1) of the Act. Except for respite care furnished in a setting approved by the State that is not the individual's residence, no service or combination of services may be used to furnish room and board through the State plan HCBS benefit.

When an individual must be absent from his or her residence in order to receive a service authorized by the individualized service plan, it may be impractical to obtain a meal outside the venue in which the service is provided. Therefore, in some instances and when it does not constitute a full nutritional regimen, the provision of food may be included as an incidental part of service delivery. When meals are furnished as an integral component of the service, we are proposing to permit the State to consider the cost of food in the rate it pays for the State plan HCBS, as the cost is then considered part of the service itself. We would not consider the meal to be an integral part of the State plan HCBS when two rates are charged to the public, one that includes a meal and one that does not include a meal.

4. Timing of Amendments

We seek to clarify expectations regarding timing of amendments when States propose modifications to the 1915(i) benefit. For the purposes of the 1915(i) benefit, we propose that amendments which result in a reduction of eligibility or services to 1915(i) participants must be submitted with a prospective, rather than retroactive, effective date.

F. Section 2601 of the Affordable Care Act: 5-Year Period for Demonstration Projects

This proposed rule includes changes to § 430.25 to implement section 2601 of the Affordable Care Act.

Section 2601 of the Affordable Care Act adds a new paragraph (2) to section 1915(h) to permit the Secretary, at her discretion, to approve a waiver that provides medical assistance for individuals dually eligible for Medicare and Medicaid (''dual eligibles'') for an initial period of up to 5 years and renewed for up to 5 years, at the State's request. The statute defines a dual eligible as: ''An individual who is entitled to, or enrolled for, benefits under part A of title XVIII, or enrolled for benefits under part B of title XVIII, and is eligible for medical assistance under the State plan under this title or under a waiver of such plan.'' This new authority enhances existing tools available to improve and coordinate care and services for this particularly vulnerable group of beneficiaries. This change provides an important tool for States to design programs to better coordinate services for dual eligible individuals.

While section 2601 of the Affordable Care Act does not provide a new type of waiver, it does provide an important opportunity for States to simplify the operation of existing waivers that serve dually eligible individuals, especially important when States combine waiver authorities that have different approval periods.

A growing number of States provide care to dual eligible individuals in a managed care service system. To be successful, these systems often include community and institutional long-term services and supports, utilize or partner with Medicare managed care plans or fee-for-service providers to improve care continuity and individual outcomes, and minimize disincentives to community-based or preventive care.

The Medicaid tools available to establish such an arrangement vary, but many States seek to use a 1915(b) Managed Care waiver concurrently with a 1915(c) Home and Community-Based

Services waiver. Some States interested in offering home and community-based supports to dual eligibles in a managed care delivery system raised concerns with the 2-year approval period for the 1915(b) managed care waivers and the 3- and 5-year approval periods for the 1915(c) HCBS waiver program. These different approval periods present administrative challenges for States that pose hurdles to operational success.

Section 2601 of the Affordable Care Act provides a solution for these situations, and others where States may wish to minimize administrative and renewal requirements in order to better focus on program implementation and quality oversight. Section 2601 of the Affordable Care Act includes an opportunity for extended approval periods for sections 1915(b), 1915(c), 1915(d) and 1115 of the Act.

For a State to apply for the extended approval periods, the demonstration or waiver program must provide services for individuals who are dually-eligible for Medicare and Medicaid. The approval of such periods is at the Secretary's discretion, and determinations will be made regarding applications for 5-year waivers in a manner consistent with the interests of beneficiaries and the objectives of the Medicaid program.

We are proposing that if a demonstration or waiver program does not serve or excludes dually eligible individuals, the 5-year approval period will not be available, and existing approval period requirements will apply. In addition, we are proposing to that in order for coverage-related waivers to be approved for 5 years periods, they must meet all necessary programmatic, financial, and quality requirements.

The statute provides that the State's request for extension of the waiver for additional 5-year periods will be approved unless the Secretary determines that one or more conditions of the waiver have not been met, that the waiver would no longer be cost neutral (for 1915(c) waivers), cost-effective (for 1915(b) waivers) or budget neutral (for 1115 demonstrations), that it would not be efficient to extend the waiver, or that it would no longer be consistent with the purposes of the Medicaid program. We are proposing to require that quality oversight mechanisms must be in place and that the State must demonstrate compliance with applicable program requirements, as well as the terms and conditions of the waiver as specified by the Secretary.

G. Prohibition Against Reassignment of Provider Claims

1. Prohibition on Payment Reassignment

Section 1902(a)(32) of the Act provides generally that ''no payment under the plan for care and services provided to an individual shall be made to anyone other than such individual or the person or institution providing such care or service, under an assignment or power of attorney or otherwise.''

The legislative history for this provision indicates that a primary purpose of the provision was to curb perceived abuses that stemmed from ''factoring'' of accounts receivable by physicians and individual practitioners. Factoring is when an individual or an organization, such as a collection agency or service bureau, purchases accounts receivable from a practitioner for a percentage of their face value.

Section 1902(a)(32) of the Act contains several specific exceptions to the general principle of direct payment to individual practitioners. There are exceptions for payments for practitioner services where payment is made to the employer of the practitioner, and the practitioner is required as a condition of employment to turn over fees to the employer; payments for practitioner services furnished in a facility when there is a contractual arrangement under which the facility bills on behalf of the practitioner; reassignments to a governmental agency, through a court order, or to a billing agent; payments to a practitioner whose patients were temporarily served by another identified practitioner; or payments for a childhood vaccine administered before October 1, 1994.

Similar provisions were enacted in title XVIII of the Act governing the Medicare program, at sections 1815(c) and 1842(b)(6) of the Act. Medicare payment assignment regulations are codified at 42 CFR part 424, subpart F (Limitations on Assignment and Reassignment of Claims). Because CMS is not proposing to amend or revise the regulations governing assignment of Medicare payments in this notice, we do not further discuss the Medicare rules. However, we are specifically soliciting public comment on the issue of consistency with Medicare payment policies, as discussed below.

2. Current Medicaid Payment Assignment Regulations

Medicaid regulations at § 447.10 implement the requirements of section 1902(a)(32) of the Act by providing that State plans can allow payments to be made only to certain individuals or entities. Specifically, payment may only be made to the individual practitioner that provided the service or the recipient, if he or she is a non-cash recipient eligible to receive payment under § 447.25, or under one of the limited exemptions. In addition, the regulations specifically state that ''[P]ayment for any service furnished to a recipient by a provider may not be made to or through a factor, either directly or by power of attorney.''

3. Medicaid Payment Reassignment

The regulations at § 447.10 contain several enumerated exceptions to the general direct payment principle that implement and interpret the statutory exceptions. There is an exception for payment in accordance with a reassignment to a government agency, or by a court order. There is another exception for payment to a business agent, such as a billing service or accounting firm, that furnishes statements and receives payments in the name of the individual practitioner, if the business agent's compensation for this service is related to the cost of processing the billing, and not dependent on the collection of the payment.

There are also three exceptions for payments to individual practitioners that reflect statutory exceptions discussed above.

4. Individual Practitioner Workforce Stability and Development Concerns

Since the direct payment principle was originally enacted in 1972 and expanded in 1977, the definition of medical assistance under section 1905(a) of the Act has been changed to permit States to offer coverage of categories of practitioner services, such as personal care services, that may be viewed as unique to the Medicaid program. For these practitioners, the Medicaid program may be the primary, or only, source of payment. Some States have sought methods to improve and stabilize the workforce by offering health and welfare benefits to such practitioners, and by requiring that such practitioners pursue periodic training.

Several States have requested that we consider adopting additional exceptions to the direct payment principle to permit withholding from the payment due to the individual practitioner for amounts paid by the State directly to third parties for health and welfare benefits, training costs, and other benefits customary for employees. These amounts would not be retained by the State, but would be paid to third parties on behalf of the practitioner for the stated purpose.

While section 1902(a)(32) of the Act does not expressly provide for additional exceptions to the direct payment principle, we believe the circumstances at issue were not contemplated under section 1902(a)(32) of the Act and, therefore, that the direct payment principle should not apply. In light of the statutory silence in addressing this circumstance, we are proposing that the direct payment principle should not apply because we think its application would contravene the fundamental purpose of the provision. As noted above, the apparent purpose of the direct payment principle was to prohibit factoring arrangements. Therefore, we are proposing an additional exception to describe payments that we do not see as within the intended scope of the statutory direct payment requirement. Under this exception, a State could claim as a provider payment amounts that are not directly paid to the provider, but are withheld and paid on behalf of the provider, such as health and welfare benefit contributions, training costs, or other benefits customary for employees.

H. Definition of Home and Community-Based Settings for the 1915(k) Community First Choice State Plan Option

Section 1915(k)(1)(A)(ii) of the Act provides that home and community-based attendant services and supports must be provided in a home and community-based setting. The statute specifies that home and community-based settings do not include a nursing facility, institution for mental diseases, or an intermediate care facility for the mentally retarded. Through the application process of sections 1915(c) waivers, 1915(i) HCBS State plan amendments and section 1905(a) State plan amendments, we are aware of settings other than those specified in section 1915(k)(1)(A)(ii) of the Act that exhibit qualities of an institutional setting.

Over the past several years, we have sought input on how to define the characteristics of what makes a setting ''home and community-based.'' In the section 1915(i) proposed rule published on April 4, 2008 (73 FR 18676), we proposed to define home and community settings for this benefit. In the advanced notice of proposed rulemaking published on June 22, 2009 (74 FR 29453), we solicited comments on potential rulemaking for a number of areas within the section 1915(c) waiver program. Specifically, we sought public input on strategies to define home and community-based settings where waiver participants may receive services. Since that time, we have facilitated and participated in multiple stakeholder discussions related to this issue. In the proposed rule for section 1915(k) Community First Choice (CFC) State plan option published on February 25, 2011 (76 FR 10736), we included the proposed language for settings in which CFC services and supports could be provided to elicit additional comments on this issue. In an effort to maintain consistency with this policy we also proposed similar language in the section 1915(c) proposed rule that published on April 15, 2011. We received many thoughtful comments on the proposed setting provisions published in the CFC proposed rule published on February 25, 2011. The comments received indicated to us that the proposed setting provisions caused more confusion and disagreement than clarity. In consideration of these comments, we decided to revise the setting provision and publish as a new proposed rule to allow for additional public comment before finalizing. We find the public comment process to be valuable in our attempt to develop the best policy on this issue for Medicaid beneficiaries.

Our policy regarding appropriate settings for the delivery of HCBS, as evidenced by our review of section 1915(c) waiver requests, has included a general prohibition on allowing HCBS in settings that are located on or adjacent to the campus of a public institution. We included this prohibition in the CFC proposed rule published on February 25, 2011. In response to the proposed rule, many commenters indicated strong support for this policy being incorporated into the final regulation, along with the proposal that buildings that included the delivery of inpatient services would not constitute acceptable settings for delivery of HCBS. Another commenter indicated that CMS should go a step further and in addition to excluding settings that are co-located with current institutions, also exclude settings on the grounds of former institutions to be clear that reorganizing and reclassifying an institution would not meet the criteria of a community-based setting. Many commenters believe that it is not possible for such a setting to ever be home and community-based. Others stated that all the characteristics of the setting should be given weight, and that we should not establish requirements based solely on the setting locations or types (for example, size or the presence of institutional services offered within the same building), which would automatically disqualify a setting from being appropriate for delivery of HCBS.

In particular, we heard concerns that a general prohibition on setting locations or types could significantly restrict access to services in settings that promote aging in place for elderly individuals, disrupt effective treatment and support opportunities for individuals with significant brain injury, and potentially restrict access to services in rural areas. Commenters also expressed concerns that by focusing our policy on setting locations or physical characteristics, we were inappropriately implying that smaller or more scattered settings were automatically appropriate, regardless of the quality of care or degree to which individuals receiving services in those settings were actually able to participate in community life, be assured of health and safety, or able to control their own daily activities. Many commenters stated that listing the excluded settings created unintended consequences, and could exclude living arrangements for individuals receiving attendant services and supports that we did not intend to prohibit, as well as permit others that are not integrated and person-centered.

In response to public comment, we have developed proposed regulatory language to focus primarily on those qualities we deem essential in determining whether a setting of care is community-based. We believe the most effective and consistent way to assure that individuals with disabilities, regardless of age or type of disability, are offered home and community-based services in the most integrated setting appropriate to their needs and preferences, is to focus on the quality and characteristics of ''home'' and ''community'' that assure independence and integration from the individuals' perspective. We agree with the many commenters who suggested this type of approach is most consistent with a person-centered system for delivering care and services.

Some commenters stated that if an individual or his or her family ''chooses'' a residence, it is therefore a ''home and community-based'' setting. We disagree, as individuals can and do choose to receive services in institutional settings. In addition, this reasoning is especially suspect in situations where an individual may not be given the option of receiving services in a variety of settings outside of an institution (for example, in their own home or apartment or, depending on the service, in a competitive employment situation), but rather is offered services only in a provider-owned or operated congregate setting.

We received a range of responses as to whether disability-specific congregate

settings are appropriate settings for delivery of HCBS. Some individuals and organizations are articulate about their right to live with anyone of their choosing, including those with disabilities. Others maintain that the only way to end unwanted segregation and forced ''choices'' is to forbid all segregation by disability, and that integration by definition means interaction with non-disabled individuals. All agree that unwilling segregation is a violation of civil rights. The Department of Justice has initiated a number of actions finding that States are violating the ADA by failing to provide more integrated alternatives to individuals in congregate settings whose residents are primarily or exclusively individuals with disabilities. States' obligations under the ADA and Section 504 of the Rehabilitation Act are independent of, and are not limited by, their obligations under Medicaid, including the requirements of CFC, section 1915(c) of the Act, or section 1915(i) of the Act. States should carefully evaluate their strategies for offering services in community-based settings and consider whether individuals have meaningful options beyond a segregated option.

In addition, some commenters stated that community can be defined in many ways, and therefore that home and community-based care could include integration into a community of peers; that is, in a disability-specific congregate or campus setting that includes a rich array of supports and activities within the setting of care. We acknowledge the importance of peer relationships but we do not agree that a community of one's peers is the same as ''community based'' in terms of settings in which HCBS is delivered. An important purpose of home and community-based services is to assist individuals to be able to live fully integrated in the greater, non-disabled community.

To provide greater clarity, we are proposing language to establish that home and community-based settings must exhibit specific qualities to be eligible sites for delivery of home and community-based services. We have included these provisions to move toward a stronger articulation of the qualities that make a setting a home or truly integrated in the broader community for individuals living with disabilities. These are the qualities most often articulated by persons with disabilities as key determinants of independence and community integration. We believe that these principles of home and community-based settings will support the use of the Medicaid program to maximize the opportunities for individuals to access the benefits of home and community living. We expect States electing to provide benefits under section 1915(k) to include a definition of home and community-based setting that incorporates these principles and will review all SPAs to determine whether they propose settings that are home or community-based. We will permit States with approved section 1915(k) SPAs a reasonable transition period, a minimum of one year, to come into compliance with the HCBS setting requirements as promulgated in our final rule. Under the regulation, settings must exhibit the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan, in order to be eligible sites for delivery of home and community-based services:

- The setting is integrated in, and facilitates the individual's full access to, the greater community including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, like individuals without disabilities;
- The setting is selected by the individual among all available alternatives and is identified in the person-centered service plan;
- An individual's essential personal rights of privacy, dignity and respect, and freedom from coercion and restraint are protected;
- Individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact are optimized and not regimented; and
- Individual choice regarding services and supports, and who provides them, is facilitated.

In a provider-owned or controlled residential setting, the following additional conditions must be met. Any modification of the conditions, for example to address the safety needs of an individual with dementia, must be supported by specific assessed needs and documented in the person centered service plan:

- The unit or room is a specific physical place that can be owned, rented or occupied under another legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that the tenants have under the landlord tenant laws of the State, county, city, or other designated entity. We are soliciting comments as to whether there are other protections, not addressed by landlord tenant laws that should be included.
- Each individual has privacy in their sleeping or living unit:
  - Units have lockable entrance doors, with appropriate staff having keys to doors;
  - Individuals share units only at the individual's choice; and
  - Individuals have the freedom to furnish and decorate their sleeping or living units;
- Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time;
- Individuals are able to have visitors of their choosing at any time; and
- The *setting is physically accessible to the individual.*

In addition to the aforementioned criteria there are two criteria that we have not included in the proposed regulation, but wish to solicit comment regarding whether they should be added. The first is related to the proposed requirement that in a provider-owned or controlled residential setting, any modification of the conditions must be supported by specific assessed needs and documented in the person centered service plan. This requirement is meant to address two issues:

(1) Individuals receiving HCBS must not have their independence or freedoms abridged by providers for convenience, or well-meaning but unnecessarily restrictive methods for providing services and supports; and

(2) Individuals with cognitive disabilities and other impairments may require modifications of the aforementioned conditions for their safety and welfare.

This provision is meant to establish that service planning is the process in which these decisions are made, rather than ad hoc on a daily basis. While the proposed text establishes the requirement that any modification to the conditions are supported by a specific assessed need and documented in the person-centered service plan, we are also considering including language to explicitly set forth these activities. We are considering requiring the following points to be identified: Identify a specific and individualized assessed safety need; document less intrusive methods of meeting that have been tried but did not work; include a clear description of the condition that is directly proportionate to the specific assessed safety need; include regular collection and review of data to measure

the ongoing effectiveness of the modification; and establishing time limits for periodic reviews to determine if the modification can be lifted. We solicit comment on these points and any other potential requirements regarding modifications of the conditions set forth in this proposed rule. We also wish to solicit comment on a second criterion that would include a requirement that receipt of any particular service or support cannot be a condition for living in the unit. In discussing this specific criterion, we discovered that it could be read one of two ways. One interpretation is that this language does not require an individual residing in a provider owned or operated setting to receive HCBS from the setting provider. Rather the individual could choose another qualified individual to provide HCBS. The other interpretation is that this language would prevent the owner of the setting from evicting an individual because the individual refused to accept a particular service. This interpretation could have an effect on residential settings, such as housing programs to address homelessness. Some of these settings include a structure in which individuals are required to participate in treatment (substance use, for example) as a condition of residing there. We acknowledge the complexities that arise, when trying to support an individual's right to choose while recognizing that there are programs and services that have been developed as a result of identified service needs. As indicated earlier, we are specifically soliciting comments on whether these two criteria should be included as regulatory requirements.

Additionally, in an effort to be consistent with other authorities providing home and community-based services, we propose to exclude hospitals as a community setting for the provision of Community First Choice Option. We believe this exclusion aligns with section 1915(k)(1)(A)(ii) of the Act requiring that services are provided in a home and community-based setting and section 1915(k)(3)(B) of the Act requiring services are provided in the most integrated setting appropriate to the individual's needs. We would like to clarify that the hospital prohibition applies to hospitals certified for the provision of long-term care services. We recognize that individuals with disabilities utilize personal attendant services and supports for various activities of daily living and instrumental activities of daily living. As a result, we understand that individuals will likely have a continued need for assistance while experiencing a short-term stay in general acute hospital settings. Therefore, while services provided in a general acute care hospital are not CFC services, individuals who have an assessed need for assistance with IADLs may continue to receive such services while an inpatient in an acute hospital setting. We would like to invite comment on this approach.

Lastly, we are proposing to include the list of the three prohibited institutional settings specified in statute, as settings in which CFC services and supports may not be provided, along with a general prohibition on any other locations that have qualities of an institutional setting, as determined by the Secretary.

In considering whether a setting has the qualities of an institutional setting for implementation of CFC, we will exercise a rebuttable presumption, as we will for the 1915(i) State plan HCBS benefit, that a setting is not a home and community-based setting, and will engage in heightened scrutiny, for any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or disability-specific housing complex. We expect to issue further guidance regarding such settings. Other characteristics that could cause us to consider a setting as ''institutional'' or having the qualities of an institution would include, but not be limited to, settings which are isolated from the broader community, do not allow individuals to choose whether or with whom they share a room, limit individuals' freedom of choice on daily living experiences such as meals, visitors, and activities, or limit individuals' opportunities to pursue community activities.

Specifically, as with the 1915(i) proposed rule, we would invite comments on the specific qualities we have proposed. In addition, we are soliciting comments as to whether there are settings in addition to those currently enumerated in statute, that are, by their nature, location or administration inherently non-community based, regardless of the nature of an individual's disability or age, and therefore, should be expressly excluded from HCBS. Issuing the revised setting provisions as a proposed notice will allow us to consider additional perspectives from the public on the modifications. In considering comments received pertaining to the setting provision of the section 1915(k) rule, we will also include full consideration of all comments received regarding the aligned home and community-based setting requirements being proposed in this rule and section 1915(i). In recognizing the need for a consistent definition of this term across Medicaid HCBS, it is our goal to align the final language pertaining to this topic across the regulations pertaining to sections 1915(i), 1915(k), and 1915(c) Medicaid HCBS authorities.

Along with our overarching interest in making improvements to Medicaid HCBS, we seek to ensure that Medicaid is supporting needed strategies for States in their efforts to meet their obligations under the ADA and the Supreme Court decision in *Olmstead* v. *L.C.,* 527 U.S. 581 (1999). In the *Olmstead* decision, the Court affirmed a State's obligations to serve individuals in the most integrated setting appropriate to their needs. A State's obligations under the ADA and section 504 of the Rehabilitation Act are not defined by, or limited to, the scope or requirements of the Medicaid program. However, the Medicaid program can provide an important opportunity to obtain Federal funding that supports compliance with the ADA, section 504 of the Rehabilitation Act, and *Olmstead* through the provision of Medicaid services to Medicaid-eligible individuals. Additionally, we expect States through the requirement at § 441.677(b) to have a comprehensive quality assurance system, to develop individual outcome measures that would support the State's compliance with providing CFC services in accordance with the individual's person-centered plan and in a setting that meets the home and community-based setting criteria set forth in this regulation.

III. Provisions of the Proposed Rule

To incorporate the policies and implement the statutory provisions described above, we are proposing the following revisions:

A. State Organization and General Administration (Part 431)

In § 431.54, we are proposing to add paragraphs (a)(3) and (h) to include State plan HCBS as exceptions to comparability and community income and resource rules.

B. Eligibility in the States, District of Columbia, the Northern Mariana Islands, and American Samoa (Part 435) and Eligibility in Guam, Puerto Rico and the Virgin Islands (Part 436)

In § 435.219 and § 436.219, we are proposing to add a provision to implement the optional categorical

eligibility group created by section 1902(a)(10)(A)(ii)(XXII) of the Act for individuals, ''who are eligible for home and community-based services under the needs-based criteria established under (1)(A) of 1915(i), or who are eligible for home and community-based services under paragraph (6) of such section, and who will receive home and community-based services pursuant to a State plan amendment under such subsection.'' By using the word ''or'' we interpret that the statute creates two distinct eligibility groups under section 1902(a)(10)(A)(ii)(XXII) of the Act with two sets of requirements, as follows:

(1) Those who are eligible for HCBS under the needs-based criteria established under section 1915(i)(1)(A) of the Act; or

(2) Those who are eligible for HCBS under paragraph (6) of such section, and who will receive HCBS pursuant to a State plan amendment under such subsection.

We believe that we have the following flexibility in defining eligibility for the first subset of this group of individuals:

- The first subset is made up of individuals who are not otherwise eligible for Medicaid. We believe that this interpretation is consistent with Congressional intent because this policy allows individuals who would not otherwise be eligible for Medicaid because they are not in a category (for example, certain adults prior to January 1, 2014) to become Medicaid eligible and receive section 1915(i) services. The early option established by section 1902(k)(2) of the Act covers individuals who are not otherwise categorically eligible for Medicaid. The new group defined in section 1902(a)(10)(A)(i)(VIII) of the Act, which goes into effect in 2014, also will cover individuals not eligible under the existing categorical groups listed in section 1902(a)(10) of the Act.
- Even though the description of the eligibility group in the statute at section 1902(a)(10)(A)(ii)(XXII) of the Act does not explicitly include an income cap we believe that a standard of 150 percent of the FPL, which is the same as the current income cap for individuals eligible under the State plan receiving section 1915(i) services, is reasonable. The needs-based criteria are described in section 1915(i)(1)(A) of the Act, which provides additional conditions for the provision of State plan HCBS under section 1915(i)(1) to individuals who are eligible under the State Medicaid plan and whose income does not exceed 150 percent of the FPL. In addition, the amendments to section 1915(i) of the Act in section 2402(b) of the Affordable Care Act which establish a new option to cover individuals eligible for HCBS under a waiver, gives States this option ''in addition to continuing to provide such services'' to individuals satisfying the needs-based criteria. Prior to the effective date of the new eligibility group under section 1902(a)(10)(A)(ii)(XXII) of the Act, States could only provide HCBS under section 1915(i) to those eligible under an existing State plan group whose income did not exceed 150 percent of the FPL and who met the needs-based criteria.
- Section 1902 of the Act requires States to use methods of determining income that are reasonable, consistent with the objectives of the Medicaid program, simple to administer, and in the best interests of the beneficiary. For purposes of determining income for this group, we believe the SSI program's rules (which are currently used in Medicaid for determining income eligibility for individuals aged 65 or older and people with disabilities) meet these criteria. Like the individuals covered under the SSI-related Medicaid eligibility category, many individuals eligible under this group will have disabilities or chronic illnesses. The SSI program provides for a number of income disregards specifically applicable to persons with disabilities that are not available under other program methodologies. States may also elect to use less restrictive income methodologies than are used under SSI. Any less restrictive methodology should apply to all members of the group.
- While the rules of the SSI program are an example of a methodology that we believe meets the requirements for determining income eligibility for this group, this does not preclude States from describing other methodologies in their SPAs that they believe also meet those requirements. We encourage States considering the use of other methodologies to discuss them with CMS before actually submitting a SPA.
- The statute does not refer to any resource test for this group and we are proposing that States may not apply a resource test in determining eligibility for this subset of the new group. We believe that not applying a resource test for this subset would be consistent with the absence of a resource test for the eligibility group described under section 1902(a)(10)(A)(i)(VIII) of the Act and the option for States to cover such individuals prior to January 1, 2014.
- The section 1915(i) statute does require that these individuals must receive section 1915(i) services in order to be eligible for Medicaid.
- Once eligible for Medicaid in this group, the individual will be eligible for all Medicaid services, not just section 1915(i) services.

The second subset of this group consists of individuals eligible for home and community-based services under an existing State waiver or demonstration. In determining eligibility for individuals with income that does not exceed 300 percent of the SSI/FBR, individuals must be eligible for an existing section 1915(c), (d), or (e) waiver or a waiver under section 1115, even though they do not have to receive services under these authorities. For individuals with income that does not exceed 300 percent of the SSI/FBR, we believe that there is little flexibility under the statue in determining eligibility for this subset, therefore—

- The individual must be eligible for a section 1915(c) waiver;
- The State must follow eligibility and post eligibility rules of an approved section 1915(c) waiver. More information regarding HCBS waiver eligibility and post eligibility rules is available in the HCBS waiver Technical Guide, online at *www.hcbswaivers.net;*
- Income and resource rules of the special income level group apply;
- Section 1902(r)(2) of the Act income disregards do not apply because income eligibility under the special income level group is determined using a gross income test that caps income at 300 percent of the SSI/FBR;
- Section 1902(r)(2) of the Act resource disregards apply;
- The individual must receive section 1915(i) services as a condition of Medicaid eligibility;
- If the State elects to cover individuals with income up to 300 percent of the SSI/FBR, it must elect the option under section 1915(i)(6) under the State plan; and
- The individual will be eligible for all Medicaid services, not just section 1915(i) services.

Additionally, when electing this new eligibility group States will have multiple options. States can cover—

(1) Individuals who meet the needs-based criteria established under section 1915(i)(1)(A) of the Act with income up to 150 percent of the FPL and individuals who meet the needs-based criteria established under 1915(i)(1)(A) eligible for HCBS under a waiver with income up to 300 percent of the SSI/FBR; or

(2) The subset of individuals who meet the needs-based criteria established under section 1915(i)(1)(A) of the Act with income up to 150 percent of the FPL; or

(3) The subset of individuals who meet the needs-based criteria established under section 1915(i)(1)(A)

of the Act eligible for HCBS under a waiver with income up to 300 percent of the SSI/FBR.

In order for States to elect any of the options listed above with respect to the new eligibility group, they must continue to cover individuals described in 1915(i)(1).

This is not the first time that an eligibility group has been treated in this manner; the aged or disabled poverty level group described at section 1902(m)(1) of the Act permits States to cover aged and disabled individuals, the aged only, or disabled only individuals.

We invite comment on the eligibility provisions of § 435.219 and § 436.219 of the regulation.

C. Services: General Provisions (Part 440)

In § 440.1, we are proposing to add a reference to a new statutory basis to read ''1915(i) HCBS furnished under a State plan to elderly and disabled individuals under the provisions of part 441, subpart L.''

In § 440.180, we are proposing to revise the heading ''Home or community-based services'' to read ''Home and community-based waiver services'' to standardize the term ''home and community-based services'' and clarify that this section concerns only HCBS provided through 1915(c) waivers.

In part 440 subpart A, we are proposing to add § 440.182, ''State plan home and community-based services'', which would define a new optional Medicaid service for which FFP is available to States, as specified in part 441, subpart K.

In § 440.182(a), we propose that the services authorized in section 1915(i) of the Act, and meeting the requirements outlined in proposed subpart K, be known as ''State plan home and community-based services.'' When referring to the specific service(s) offered under the State plan HCBS benefit listed in § 440.180(b), we use the term ''State plan HCBS.'' When referring to overall State activities under section 1915(i) of the Act as described in subpart K, we use the term ''benefit'', or ''State plan HCBS benefit''.

In § 440.182(b) and § 440.182(c)(1), we propose that the optional State plan HCBS benefit may consist of any or all of the HCBS listed in section 1915(c)(4) for waiver programs, as specified in regulation at § 440.180. Because section 1915(i) of the Act defines services by reference to section 1915(c) of the Act, we believe that the regulatory requirements should be parallel, except for the ''other'' services which the Secretary has the authority to approve for an HCBS waiver. In HCBS waivers, other services must be cost-effective and must be necessary to prevent institutionalization. However, the State plan HCBS does not require cost-neutrality and some individuals will be eligible for section 1915(i) of the Act without meeting an institutional LOC. Therefore, we list the permitted services for the State plan HCBS benefit in § 440.182 identically to the services specified in § 440.180 for HCBS waivers, except for ''other'' services. We require ''other'' services to be appropriate for individuals who meet the needs-based criteria that the State defines for the benefit. We further specify that the conditions set forth in § 440.180(b) for services to individuals with chronic mental illness, and in § 440.180(c) for expanded habilitation services, apply to State plan HCBS services.

In particular, due to concern over duplication of habilitation services and the State-defined ''other services,'' we propose to require at § 441.662(a)(7) and § 441.662(a)(8) (regarding requirements for independent assessment), explanations of the manner in which non-duplication of services will be documented in the assessment of each individual receiving habilitation services or Secretary approved other services. Additionally, since some individuals may be simultaneously receiving services through a HCBS waiver and the section 1915(i) benefit, we require in § 441.662(a)(9) documentation that the services provided through 1915(c) and 1915(i) authorities may not be duplicative for the same individual. This would also include coordination of assessments, service plan development, and case-management to ensure that individuals receiving services under both authorities are not subject to multiple assessments and service plans.

Section 1915(i) of the Act prohibits reimbursement for room and board. At § 440.182(c), we propose to state that, except for respite care furnished in a setting approved by the State that is not the individual's residence, no service or combination of services may be used to furnish room and board through the State plan HCBS benefit. When meals are furnished as an integral component of the service, we are proposing to permit the State to consider the cost of food in the rate it pays for the State plan HCBS, as the cost is then considered part of the service itself. We would not consider the meal to be an integral part of the State plan HCBS when two rates are charged to the public, one that includes a meal and one that does not include a meal.

Finally, we propose that a State may claim FFP for a portion of the rent and food expenses that may be reasonably attributed as a service cost to compensate an unrelated caregiver providing State plan HCBS, who is residing in the same household with the recipient. We propose, as is permitted in HCBS waivers under section 1915(c)(1) and § 441.310(a)(2)(ii), that FFP is available only for the reasonable additional rent and food costs of the caregiver residing in the recipient's home, not to support the cost of a caregiver's household in which the recipient resides. We would therefore provide that FFP not be available for caregiver rent and food costs when the residence is owned or leased by the caregiver.

D. Services: Requirements and Limits Applicable to Specific Services (Part 441)

In April 4, 2008, we issued a proposed rule in the **Federal Register** titled ''Medicaid Program; Home and Community-Based State Plan Services.'' In that proposed ruled, we specified that we would set forth our proposals in 42 CFR part 441 initially proposed in new subpart K titled ''State Plan Home and Community-Based Services for Elderly and Disabled Individuals,'' consisting of § 441.650 through § 441.677, which describes requirements for providing the State plan HCBS benefit. This construction parallels that for HCBS waivers, which are the subject of subpart G of part 441. Subsequently, we published a proposed rule (76 FR 10736) on February 25, 2011 in the **Federal Register** titled ''Medicaid Program; Community First Choice Option,'' which also proposed the addition of subpart K to part 441. Therefore, we are proposing to specify that the proposed provisions for the ''State Plan Home and Community-Based Services for Elderly and Disabled Individuals'' in subpart K under § 441.550 through § 441.577 be redesignated as subpart L (§ 441.650 through § 441.677).

In this new subpart, it is necessary in several paragraphs to indicate that certain provisions apply to an individual or an individual's representative. To reduce redundancy, we indicate in those paragraphs that ''individual'' means the eligible individual and, if applicable, the individual's representative, to the extent of the representative's authority recognized by the State. ''Individual and representative'' more accurately convey the person-centered process than ''individual or representative''. This provision clarifies that there is no

implication that individuals will or will not have representatives.

E. Basis and Purpose (§ 441.650)

We set forth in § 441.650 language to implement the provisions of section 1915(i) of the Act permitting States to offer HCBS to qualified elderly and disabled individuals under the State plan. Those services are listed in § 440.182, and are described by the State, including any limitations of the services. This optional benefit is known as the State plan HCBS benefit. This subpart describes what a State Medicaid plan must provide, and defines State responsibilities.

F. State Plan Requirements (§ 441.653)

In § 441.653, we propose that a State plan that includes HCBS for elderly and disabled individuals must meet the requirements of this subpart. We would require that the State plan amendment in which the State establishes the State plan HCBS benefit satisfy the requirements set forth in this proposed regulation.

G. Eligibility for Home and Community-Based Services Under Section 1915(i)(1) of the Act (§ 441.656)

We propose in § 441.656(a)(1) to require that if the State Medicaid agency elects to provide the 1915(i) HCBS benefit, it must provide services to categorically needy individuals who are eligible for Medicaid under an eligibility group that is covered under its State Medicaid plan and who have income that does not exceed 150 percent of the FPL. The State may also elect to provide the section 1915(i) HCBS benefit to medically needy individuals.

To implement the intent of the Congress that the benefit be ''home and community-based,'' we would require in § 441.656(a) that the individual reside in the home or community, not in an institution, according to quality principles for community-based settings prescribed by the Secretary. As discussed in section II.E.2. of this proposed rule, there are a variety of living arrangements that promote independence and community integration, as well as arrangements that do not.

We would require in § 441.656(b) that the individual must meet the needs-based eligibility criteria as set forth in § 441.659. We propose in § 441.656(c) that individuals are not eligible for the State plan HCBS benefit until they have met all eligibility requirements, including the need for at least one service provided under the State plan as part of the HCBS benefit at a frequency identified by the State. Finally, we require that, in the event that a State elects not to apply comparability requirements to the benefit, an individual must meet the State-defined and CMS approved targeting criteria in order to establish eligibility.

We propose in § 435.219(b) and § 436.219(b) that States may elect under section 1915(i)(6) of the Act the option to provide home and community-based State plan services to individuals eligible under a section 1915(c), (d), (e) or section 1115 waiver who have income up to 300 percent of the SSI/FBR.

We also propose in § 441.656(e)(1) that States may elect to follow institutional income and resource eligibility rules for the medically needy living in the community. Nonapplication of the requirements of section 1902(a)(10)(C)(i)(III) of the Act allows States to treat medically needy individuals as if they are living in an institution by not deeming income and resources from an ineligible family member. We use the term ''not to apply'' instead of ''waive'' since this is an election made by the State and does not require a waiver by the Secretary. We further propose that States may elect not to apply section 1902(a)(10)(B) of the Act, concerning comparability of services in Medicaid, which permits the State plan HCBS benefit to be targeted towards specific populations. In this section, we indicate that a State may elect to establish targeting criteria for the section 1915(i) benefit and for any specific services within that benefit, subject to CMS approval, based on factors such as age, diagnosis, and/or disability. These criteria provide States with the option to provide State plan HCBS services to specific populations, including specific Medicaid eligibility groups, but allows flexibility to combine multiple target groups within one benefit and to provide different services to each group. Targeting criteria cannot have the impact of limiting the pool of qualified providers from which an individual would receive services, or have the impact of requiring an individual to receive services from the same entity from which they purchase their housing.

H. Needs-Based Criteria and Evaluation (§ 441.659)

The statute uses a number of terms at times interchangeably. In general, in § 441.659 we adopt the wording used most frequently in the law, and specify a term for each requirement. For example, regarding the terms ''assessment'' and ''evaluation,'' we would adopt the language in section 1915(i)(1)(H)(ii) of the Act, which refers to the ''independent evaluation'' and the ''independent assessment.''

1. Needs-Based Eligibility Criteria

In § 441.659(a), we propose that States establish needs-based criteria for determining an individual's eligibility under the State plan for HCBS, and may establish needs-based criteria for each specific service. We do not define support needs, as we believe that States should have the flexibility to match eligibility criteria to the nature of the services they would provide under the HCBS benefit. By statute, the needs-based criteria would consist of needs for specified types of support, such as assistance with ADLs, IADLs, or other risk factors defined by the State. We propose to require that State-defined risk factors affecting eligibility may be included as needs-based eligibility criteria in the State plan amendment. While we do not propose requirements for State-defined risk factors, we believe that as needs-based criteria, risk factors should be related to support needs, such as lack of availability of family members or other unpaid caregivers willing and able to provide necessary care.

We distinguish support needs from other types of characteristics. We propose that a distinguishing characteristic of needs-based criteria is that they can only be ascertained for a given person through an individual evaluation. This differentiates a targeting criterion such as a diagnosis, which many individuals may identically share, from a support need, which will vary widely among those individuals with the same diagnosis.

We note that the regulation requires only that the needs-based criteria for the State plan HCBS benefit establish the lowest threshold of need to enroll in the benefit. There is an upper limit of need to be eligible for the HCBS benefit only if the State so specifies in the needs-based eligibility criteria. The more stringent institutional criteria required in § 441.559(b) of this section do not constitute an upper limit of need to be eligible for the State plan HCBS benefit. The institutional criteria are only a lowest threshold of need to receive institutional services. We also note that section 1915(i)(1) of the Act clarifies that State plan HCBS are not required to be direct alternatives to institutional care. The statute specifically provides that the State plan HCBS benefit does not need to meet the section 1915(c) requirement that, but for the services provided under the HCBS waiver, the individual would require institutional care.

2. More Stringent Institutional and Waiver Needs-Based Criteria

In § 441.659(b), we propose that the State plan HCBS benefit is available to a State only if individuals may demonstrate a lower level of need to obtain State plan HCBS than is required to obtain institutional or waiver services. States that have functional LOC criteria for institutions (that meet the requirements in § 441.659(a)(1)), may have no need to modify their existing institutional criteria so long as the needs-based eligibility criteria established for State plan HCBS are less stringent. States without need-based institutional LOC criteria must add need-based requirements to their LOC assessments in order to establish the State plan HCBS benefit.

We propose in § 441.659(b) to define by reference to statute and regulation the institutions for which section 1915(i) of the Act requires more stringent eligibility criteria. NF and ICF/MR are so cited. We interpret the reference in section 1915(i)(1)(B) of the Act to hospitals to mean facilities certified by Medicaid as hospitals that are providing long-term care services or services related to the HCBS to be provided under the benefit. The proposed regulation requires that States have or establish for such hospitals (if any), needs-based criteria for admission that are more stringent than those for eligibility in the State plan HCBS benefit. We further propose, when the State covers more than one service in the State plan HCBS benefit, to require that any needs-based criteria for individual HCBS may not have the effect of limiting who can benefit from the State plan HCBS in an unreasonable way, as determined by the Secretary.

In § 441.659(b), we further propose to require that the more stringent needs-based criteria for institutions and waivers be part of the State's LOC processes, to ensure that the criteria are uniformly utilized. We would require that these more-stringent needs-based criteria be submitted for comparison with the State plan amendment that establishes the State plan HCBS benefit. We note that needs-based criteria, as defined in § 441.659(a) require an evaluation to determine the individual's support needs. Therefore, the assessment process for institutional levels of care that include needs-based criteria must include an individual evaluation of support needs. We also propose to require that the State's more stringent institutional and waiver needs-based criteria be in effect by the effective date of the State plan HCBS benefit.[8]

Finally, in § 441.659(b)(2), we propose that if a State modifies its institutional level of criteria in order to satisfy the requirement that the levels of care be more stringent than the needs-based eligibility criteria for the State plan HCBS benefit, the States may continue to receive FFP when serving individuals who were eligible under the previous criteria. Exemption from the more stringent criteria is indefinite, but ends when the individual is discharged from the facility or waiver, the individual becomes ineligible for Medicaid due to factors unrelated to the LOC determination, or the individual no longer meets the criteria for the applicable LOC. We note that in long-term care facilities a transfer is not a discharge and would not cause the individual to lose this exemption. Similarly, if an individual transitions from an institution to a waiver it would not result in a separate LOC, and would not cause the individual to lose this exemption. States would determine the effect of any subsequent changes to general LOC requirements (unrelated to the more stringent criteria) upon individuals with this exemption. Additionally, nothing in this subsection would prevent the State from determining whether the person remains eligible for Medicaid based on other factors, such as income or residency.

3. Adjustment Authority

In § 441.659(c), we propose to permit States under certain conditions to adjust, without prior approval from the Secretary, the needs-based eligibility criteria and service criteria (if any) established under § 441.659(a), in the event that the State experiences enrollment in excess of the number projected to be served by the HCBS benefit. We propose a retroactive effective date, as approved by the Secretary, for the State plan amendment modifying the needs-based criteria under § 441.659(c)(1). We set forth the following conditions required by the statute.

The State must provide for at least 60 days notice to the Secretary, the public, and we would propose to require, each enrollee. Since the effect of adjusted criteria would be to reduce the scope of services, eligibility for services, or eligibility for the entire State plan HCBS benefit, the adjusted criteria established under this subsection would not apply to individuals already enrolled in the State plan HCBS. If the State also adjusts institutional levels of care, the adjusted institutional levels of care may not be less stringent than the institutional LOC prior to the effective date of the State plan HCBS benefit.

Additionally, in § 441.659(b), we indicate that any changes to the institutional LOC criteria under the State adjustment authority contained in § 441.659(c) are subject to the same requirements as an adjustment to the institutional LOC criteria under § 441.659(b).

In § 441.659(c), we further propose to explicitly require that the adjusted needs-based eligibility criteria for the State plan HCBS benefit must be less stringent than needs-based institutional LOC criteria in effect at the time of the adjustment.

We propose that the notice to the Secretary be submitted as a State plan amendment. In order to implement the adjustment authority without prior approval of the Secretary, the Secretary would approve a State plan amendment adjusting the needs-based HCBS benefit eligibility criteria with a retroactive effective date, as early as 60 days after the State notified each enrollee, the Secretary, and the public, (or whichever is later). Under the provision of section 1915(i)(1)(D)(ii) of the Act, the Secretary will evaluate the State's adjusted criteria for compliance with the provisions of this paragraph and subpart L. We also note that while the State may under this provision implement the adjusted criteria as early as 60 days after notification and before the State plan amendment is retroactively approved, the State is at risk for any actions it takes that are later disapproved.

Finally, we would require that the State notify affected individuals of their right to a fair hearing in accordance with 42 CFR part 431, subpart E.

4. Independent Evaluation and Determination of Eligibility

In § 441.659(d), we propose that eligibility for the State plan HCBS benefit be determined by an independent evaluation of each individual, applying the general eligibility requirements in § 441.656 of this subpart, and the needs-based criteria that the State has established under § 441.659(a). Independence of the review requires meeting the conflict of interest standards set forth in § 441.568, where provider qualifications for evaluators are specified.

The evaluation must assess an individual's support needs and strengths. We interpret this provision of

[8] Although not included in the regulation, we would caution states against raising the LOC due to the maintenance of eligibility requirements included in the Affordable Care Act.

the statute to indicate that the evaluation process draws conclusions about supports that the individual requires because of age or disability, and supports that the individual does not require because of abilities to perform those functions independently. The evaluation compares those conclusions with the needs-based eligibility criteria for the State plan HCBS benefit to determine eligibility for the benefit. Section 1915(i)(1)(D)(i) of the Act provides that the State may take into account the need for significant assistance to perform ADLs, indicating that the statute does not require that eligibility be dependent upon assistance for ADLs.

We note that appraisal of whether an individual has need for, and meets additional needs-based criteria (if any) for specific HCBS offered under the benefit, is part of the independent assessment and service plan development process. However, this assessment affects eligibility for the benefit in that we propose at § 441.656(a)(ii)(5) that individuals are considered enrolled in the State plan HCBS benefit only if they are assessed to require at least one home and community-based service offered under the State plan benefit in addition to meeting the eligibility and needs-based criteria for the benefit.

The evaluation process designed by the State would reflect the nature of the State plan HCBS benefit designed by the State. However, in order to meet the forgoing requirements, all independent evaluations require specific information about each individual's support needs, sufficient to draw the appropriate conclusions. In some cases this information may be well documented and current in the individual's existing records. In other cases, we would require that the evaluator obtain this information by whatever means are appropriate to secure a valid appraisal of the individual's current needs. This requirement could include professional assessment of certain functional abilities. State evaluation procedures that rely solely on review of medical records would not meet these requirements.

5. Periodic Redetermination

In § 441.659(e), we propose that individuals receiving the State plan HCBS benefit must be reevaluated at a frequency defined by the State, but not less than every 12 months, to determine whether the individuals continue to meet eligibility requirements. The independent reevaluations must meet the requirements for initial independent evaluations specified in § 441.659(d).

I. Independent Assessment (§ 441.662)

In § 441.662, we propose requirements for independent assessment of need of each individual who has been determined by the independent evaluation to be eligible for the State plan HCBS benefit. The purpose of the assessment is to obtain, in combination with the findings of the independent eligibility evaluation, all the information necessary to establish a service plan. The assessment is based on the needs of the individual, which we believe precludes assessment protocols that primarily determine diagnoses, or only assess function. Assessment protocols must not assign supports automatically by functional limitation. The independent assessment must determine the specific supports needed to address the individual's unique circumstances and needs, including other services available through Medicaid and other State and Federal programs.

The assessment also applies the State's needs-based criteria (if any) for each service. We propose that an individual be considered enrolled in the State plan HCBS benefit only if the assessment finds that the individual needs and meets the needs-based criteria (if any) for at least one State plan HCBS. This proposed requirement is to provide States with a mechanism to prevent the situation of an individual being eligible for the State plan HCBS benefit but not able to receive any of the services it offers; or for establishing Medicaid eligibility through the benefit without actually receiving State plan HCBS services. Such a circumstance could, among other problems, be of no utility to the individual, and may make it difficult for the State to meet an assessed need. Furthermore, the eligibility group defined in section 1902(a)(10)(a)(ii)(XXII) of the Act requires an individual to receive State plan HCBS in order to establish Medicaid eligibility through that category.

We propose to require in § 441.662(a)(1) that the assessment include a face-to-face meeting with the individual (''individual'' meaning in this context, if applicable, the individual and the individual's authorized representative). We further propose that a ''face-to-face'' meeting could be performed through telemedicine or other information technology medium, if the health care professional performing the assessment meets provider qualifications that includes additional training requirements for the operation of the information technology, the individual receives support during the assessment including the use of any necessary on-site staff, and the individual provides informed consent. In § 441.662(a)(1)(i), we propose to require that the assessment is performed by an agent that is independent and qualified as defined in § 441.668. The assessment is to be guided by best practice and research on effective strategies that result in improved health and quality of life outcomes. We further propose that the assessment includes consultation, as appropriate, with other responsible parties. The assessment must include an examination of the individual's relevant history, medical records, and care and support needs, including the findings from the independent eligibility evaluation.

If self-direction of services is offered by the State and elected by the individual, the independent assessment must include a self-direction appraisal as described in § 441.674.

For individuals receiving habilitation services, we propose to require documentation that no services are provided under Medicaid that would otherwise be available to the individual, specifically including but not limited to services available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973. We believe that these documentation requirements would provide a clear method for States to comply with Federal requirements, focus only on the individuals for whom these circumstances could apply, and would not add significantly to the burden of the assessment. We further propose that the assessment must ensure that services received through Secretary-approved ''other'' services are not duplicative of any other services provided through the Medicaid State-plan or through another State or Federal program. We note that extended State plan services would not be considered duplicative, since those services are not available to individuals through the State plan. We further note that payments must also be in accordance with section1903(c) of the Act. Finally, we require that the assessment must ensure that any individual simultaneously enrolled in State plan HCBS and receiving HCBS through a waiver does not receive duplicative services. We would include case management, assessment, and service plan development in the services that may not be duplicative. This does not necessarily mean that an individual cannot have more than one case manager, but instead is meant to ensure

that services are coordinated across multiple programs, and that individuals are not required to develop multiple service plans.

Finally, in § 441.662(b), we propose to require that the independent assessment of need is conducted at least every 12 months and as needed when the individual's needs and circumstances change significantly, in order to revise the service plan.

J. Service Plan (§ 441.665)

In § 441.665 we propose to require that based on the independent assessment specified in § 441.662, the State develops (or approves, if the plan is developed by others) a service plan through a person-centered planning process.

We propose that the service plan must be developed jointly with the individual. While we propose several specific requirements for the process of developing a service plan, we note that the intent of these requirements is to ensure a process with shared authority between the individual and the agency or agent. To achieve this intent, States must affirmatively and creatively work to establish such shared authority.

The assessment must include consultation with appropriate persons. While we include examples, we do not propose any required or excluded category of persons to consult. When the service plan is finalized between the parties, a written copy is provided to the individual.

Also, in § 441.665(a), we propose certain content to be required in the service plan. The person-centered service plan must identify the specific State plan HCBS to be provided to the individual, that take into account the individual's strengths, preferences, needs (clinical and support), and desired outcomes. We are proposing that the service plan should be constructed in a manner that promotes service delivery and independent living in the most integrated setting possible. Therefore, we propose that the plan must not only address medical and support needs, but should also reflect other individual goals related to community living to the extent that services covered under the State Medicaid plan would be available to support such goals. In the planning process, the degree of assistance with ADLs available to the individual outside of the State plan HCBS benefit may be taken into account in planning the scope and frequency of HCBS to be provided. Thus, the service plan provides for all needed services to the individual while preventing provision of duplicative or unnecessary services.

We propose a single service plan for both self-directed and non self-directed services. When individuals self-direct some or all of their HCBS, the service plan includes the information required in § 441.674.

We further propose to require that the service plan be reviewed and revised at least every 12 months, and as needed when the individual's circumstances or needs change significantly.

Finally, we propose that the individual must share the authority for developing and implementing the service plan. This shared authority increases the individual's self-efficacy and involvement in the activities and outcomes contained within the service plan.

K. Provider Qualifications (§ 441.668)

In § 441.668, we propose to require that the State provide assurance that necessary safeguards have been taken to protect the health and welfare of the enrollees in State plan HCBS by provision of adequate standards for all types of providers of HCBS. States must define qualifications for providers of HCBS services, and for those persons who conduct independent evaluation of eligibility for State plan HCBS, independent assessment of need, and are involved with developing the service plan.

We propose at § 441.668(b) and (c) to require minimum qualifications for individuals and agencies who conduct independent evaluation of eligibility for State plan HCBS, independent assessment of need, and are involved with developing the service plan. We will refer to these individuals and entities involved with determining access to care as ''agents'' to distinguish this role from providers of services. We believe that these qualifications are important safeguards for individuals enrolled in the State plan HCBS benefit and propose that they be required whether activities of the agents are provided as an administrative activity or whether some of the activities are provided as a Medicaid service. At a minimum, these qualifications include conflict of interest standards, and for providers of assessment and service plan development, these qualifications must include training in assessment of individuals whose physical or mental condition may trigger a need for HCBS and supports, and an ongoing knowledge of current best practices to improve health and quality of life outcomes.

The minimum conflict of interest standards we propose to require ensure that the agent is not a relative of the individual or responsible for the individual's finances or health-related decisions. The standards also require that the agent must not hold financial interest in any of the entities that provide care. Relatives and decision makers are required to be permitted in the assessment and planning process, as appropriate, but we do not see any necessity or value in family members being responsible for evaluation, assessment, or planning. Our experience with HCBS in waivers indicates that assessment and service plan development should not be performed by providers of the services prescribed. However, we recognize that in some circumstances there are acceptable reasons for a single provider of service that performs all of those functions. In this case, the Secretary would require the State Plan to include provisions assuring separation of functions within the provider entity.

L. Definition of Individual's Representative (§ 441.671)

In § 441.671, we propose to define the term ''individual's representative'' to encompass any party that is authorized to represent the individual for the purpose of making personal or health care decisions, either under State law or under the policies of the State Medicaid agency. We do not propose to regulate the relationship between an individual enrolled in the State plan HCBS benefit and his or her authorized representative, but note that States should have policies to assess for abuse or excessive control and ensure that representatives conform to applicable State requirements. We note that States must not refuse to allow a freely-chosen person to serve as a representative unless the State has tangible evidence that the representative is not acting in the best interest of the individual, or that the representative is incapable of performing the required functions.

M. Self-Directed Services (§ 441.674)

We propose in § 441.674 to permit States to offer an election for self-directing HCBS. We propose regulations containing the specific requirements for self-direction found in section 1915(i)(1)(G)(iii) of the Act. In § 441.674(a), we define ''self-direction.'' Provisions related to self-direction apply to an individual or an individual's representative. In § 441.674(b), we propose that when an individual chooses self-direction, the independent assessment and person-centered planning required under § 441.662 and § 441.665 would include examination of the support needs of the individual to self-direct the purchase of, or control the receipt of, such services.

The evaluation should not reject election to self-direct based solely on the individual's disability or a manifestation of his or her disability. We therefore propose to require that the evaluation for self-direction result in a determination of ability to self-direct both with and without specified supports.

These regulations are consistent with our policy for self-direction under section 1915(c) HCBS waivers. We propose to require in § 441.674(b) that the service plan indicate the HCBS to be self-directed and the methods by which the individual will plan, direct, or control the services; the role of family or others who will participate in the HCBS; and risk management techniques. Our experience with HCBS waivers indicates that contingency plans are an important protection for the individual, in the absence of an agency that would otherwise be responsible for absent workers or other common problems. Contingency plans are most effective when designed for the unique circumstances of each self-directing individual. We propose that the service plan describe the process for facilitating voluntary and involuntary transition from self-direction. When the service plan is finalized between the parties, a written copy is provided to the individual, as required in the proposed plan on care requirements at § 441.665(a).

In § 441.674(c) and (d), we define self-direction of services in terms of employer authority and budget authority, as we have with self-directed HCBS in Medicaid section 1915(c) waivers. In § 441.674(c), employer authority is defined as the ability to select, manage, or dismiss providers of the State plan HCBS. We propose that the service plan must specify the authority to be assumed by the individual and the individual's representative, any parties responsible for functions outside the assumed authority, and the financial management supports to be provided as required in § 441.674(e).

In § 441.674(d), we propose to define budget authority as an individualized budget which identifies the dollar value of the services and supports under the control and direction of the individual. We propose that the service plan must specify the method for calculating the dollar values in the budget, a process for adjusting the budget to reflect changes in assessment and service plan, a procedure to evaluate expenditures under the budget, and the financial management supports, as required in § 441.674(e), to be provided. We clarify here that while budget authority grants control of expenditures to the individual, it does not include performing the transactions or conveying cash to the individual or representative.

In § 441.674(e), we propose to define functions in support of self-direction that the State must offer, based on our experience with self-directed HCBS in section 1915(c) waivers and section 1115 demonstrations. These provisions are required in order to equip individuals for success in managing their services, and to comply with Federal, State, and local requirements, particularly the many tax, labor, and insurance issues that arise when the self-directing individual is the employer of record. Supports for self-direction should provide the technical expertise and business functions that will free individuals to exercise choice and control over their experience of the HCBS provided to them.

N. State Plan HCBS Administration: State Responsibilities and Quality Improvement (§ 441.677)

1. State Responsibilities

We would require in § 441.677(a)(1)(i) that the State annually provide CMS with the projected number of individuals to be enrolled in the benefit, and the actual number of unduplicated individuals enrolled in the State plan HCBS benefit in the previous year.

Section 1915(i) of the Act authorizes a State to elect not to apply comparability requirements, thus permitting States to target the entire 1915(i) benefit, specific services within the benefit, or both. We clarify in § 441.677(a)(1)(ii) that the State may not limit enrollee access to services in the benefit for any reason other than assessed need or targeting criteria. This includes the requirement that services be provided to all individuals who are assessed to meet the targeting criteria and needs-based criteria, regardless of income. This is an important distinction between the limits States place on the services to be offered when they design the benefit, as opposed to limiting access to the services that are in the benefit for particular enrolled individuals. As discussed in section II.E.1 of this proposed rule, States have a number of permitted methods to control utilization. We propose that once an individual is found eligible and enrolled in the benefit, access to offered services can only be limited by medical necessity. Medical necessity in the State plan HCBS benefit is determined by the needs-based criteria, as evaluated by the independent assessment and person centered service plan. By not limiting access, we mean that an enrollee must receive any or all of the HCBS offered by the benefit, in scope and frequency up to any limits on those services defined in the State plan, to the degree the enrollee is determined to need them. Enrollees should receive no more, and no fewer, HCBS than they are determined to require. We note that one function of the service plan as proposed at § 441.665(a)(3) is to prevent the provision of unnecessary, duplicative, or inappropriate care.

2. Administration

We propose in § 441.677(a)(2)(i) an option for presumptive payment. In accordance with section 1915(i) of the Act, the State may provide for a period of presumptive payment, not to exceed 60 days, for evaluation of eligibility for the State plan HCBS benefit and assessment of need for HCBS. This period of presumptive payment would be available for individuals who have been determined to be Medicaid eligible, and whom the State has reason to believe may be eligible for the State plan HCBS benefit. We propose that FFP would be available for evaluation and assessment as administration of the approved State plan prior to an individual's determination of eligibility for and receipt of other 1915(i) services. If the individual is found not eligible for the State plan HCBS benefit, the State may claim the evaluation and assessment as administration, even though the individual would not be considered to have participated in the benefit for purposes of determining the annual number of individuals served by the benefit. FFP would not be available during this presumptive period for receipt of State plan HCBS.

In § 441.677(a)(2)(ii), we indicate that a State may elect to phase-in the provision of services or the enrollment of individuals if the State also elects not to apply comparability requirements and to target the benefit to specific populations. However, there is no authority to limit the numerical enrollment in the benefit or to create waiting lists. Therefore, we propose that any phase-in of services may not be based on a numerical cap on enrollees. Instead, a State may choose to phase-in the benefit or the provision of specific services based on the assessed need of individuals, the availability of infrastructure to provide services, or both. Infrastructure is defined as the availability of qualified providers or of physical structures and information technology necessary to provide any service or set of services.

A State that elects to phase-in the benefit must submit a plan, subject to

CMS approval, that details the criteria used for phasing in the benefit. In the event that a State elects to phase-in the benefit based on needs, all individuals who meet the criteria described in the phase-in plan must receive services. If a State elects to phase-in services based upon infrastructure, the plan must describe the capacity limits, strategies to increase capacity, and must assure that services will be provided to all individuals who are able to acquire a willing and qualified provider. Any phase-in plan must provide assurance that the benefit, and all included services, will be available statewide to all eligible individuals within the first 5-year approval period.

In § 441.677(a)(2)(iii), we propose that a State plan amendment submitted to establish the State plan HCBS benefit must include a reimbursement methodology for each covered service. In some States, reimbursement methods for self-directed services may differ from the same service provided without self-direction. In such cases, the reimbursement methodology for the self-directed services must also be described.

In § 441.677(a)(2)(iv), we propose that the State Medicaid agency describe the line of authority for operating the State plan HCBS benefit. The State plan HCBS benefit requires several functions to be performed in addition to the service(s) provided, such as eligibility evaluation, assessment, and developing a service plan. To the extent that the State Medicaid agency delegates these functions to other entities, we propose that the agency describe the methods by which it will retain oversight and responsibility for those activities, and for the operation and quality improvement of the benefit as a whole.

In § 441.677(a)(2)(v), we include a provision regarding the effective dates of amendments with substantive changes. Substantive changes may include, but are not limited to changes in eligible populations, constriction of service amount, duration or scope, or other modifications as determined by the Secretary. We would add regulatory language reflective of our guidance that 1915(i) amendments with changes that CMS determines to be substantive may only take effect on or after the date when the amendment is approved by CMS, and must be accompanied by information on how the State has assured smooth transitions and minimal adverse impact on individuals impacted by the change.

In § 441.677(a)(2)(vi), we indicate that State plan amendments including targeting criteria are subject to a 5-year approval period and that successive approval periods are subject to CMS approval, contingent upon State adherence to Federal requirements. In order to renew State plan HCBS for an additional 5-year period, the State must provide a written request for renewal to CMS at least 180 days prior to the end of each approval period.

3. Quality Improvement Strategy

We propose in § 441.677(b) the guidelines for quality assurance required in the statute at section 1915(i)(1)(H)(i) of the Act. We propose to require a State, for quality assurance purposes, to maintain a quality improvement strategy for its State plan HCBS benefit. The State's quality improvement strategy should reflect the nature and scope of the benefit the State will provide.

We propose that the State plan HCBS benefit include a quality improvement strategy consisting of a continuous quality improvement process, and outcome measures for program performance, quality of care, and individual experience, as approved and prescribed by the Secretary, and applicable to the nature of the benefit.

In § 441.677(b), we propose to require States to have program performance measures, appropriate to the scope of the benefit, designed to evaluate the State's overall system for providing HCBS. ''Program performance'' measures can be described as process and infrastructure measures, such as whether plans of care are developed in a timely and appropriate manner, or whether all providers meet the required qualifications to provide services under the benefit. In § 441.677(b)(1), we also propose to require States to have quality of care measures as approved or prescribed by the Secretary. Quality of care measures may focus on program standards, systems performance, and individual outcomes.

P. Section 2601 of the Affordable Care Act: 5-Year Period for Demonstration Projects: Waiver Requirements (§ 430.25)

Section 2601 of the Affordable Care Act provides the opportunity for the Secretary to approve certain waivers for periods of up to 5 years. The proposed regulation includes an addition at § 430.25(h)(2)(i) and § 430.25(h)(2)(ii) to indicate the availability of extended approval periods for initial section 1915(c) waivers which are currently approved for 3-year periods (the renewals are already 5-year intervals), and for initial and renewal section 1915(b) waivers, which are currently approved for 2-year periods. In all cases, the extended approval period is only available for waivers that provide medical assistance to dual eligible individuals, and that meet all applicable statutory, regulatory, quality and programmatic requirements. The current § 430.25(h)(2)(ii) also includes reference to section 1916 of the Act, which remains unchanged by the Affordable Care Act. As such, we have created a new § 430.25(h)(2)(iii) to retain the original regulatory text specific to section 1916 of the Act.

Q. Prohibition Against Reassignment of Provider Claims (§ 447.10)

Under title XIX of the Act, State Medicaid programs generally can only pay for Medicaid-covered practitioner services through direct payments to the treating practitioners. States can develop payment rates that include considerations for costs related to health and welfare benefits, training, and other costs. Consistent with the statutory provision at section 1902(a)(32) of the Act, and reflected in current regulations at § 447.10, the entire rate must be paid to the individual practitioner who provided the service, unless certain statutory exceptions apply.

With respect to classes of practitioners for whom the State's Medicaid program is the only or primary payer, the ability of the State to ensure a stable and qualified workforce may be adversely affected by the inability to withhold funds and make payments on behalf of the individual practitioner for health and welfare benefit contributions, training costs, and other benefits customary for employees. Withholding funds for these purposes is an efficient and effective method for ensuring that the workforce has provision for basic needs and is adequately trained for their functions. Direct payment of funds to third parties on behalf of the practitioner may simplify program operations for the State and be viewed as advantageous by the practitioner. In addition, direct payment of funds to third parties on behalf of the practitioners may ensure that beneficiaries have greater access to such practitioners and higher quality services.

The statutory direct payment provision was intended to address the issue of factoring, and there is no indication that its purpose was to restrict State flexibility in investing in its workforce or quality improvement programs. In particular, we do not believe that the statutory direct payment provision addresses the unique circumstances that arise when the Medicaid program is the primary source of reimbursement for a class of practitioners.

We propose to interpret the scope of the direct payment provision to not include the circumstance when the Medicaid program operates as a primary payer for a class of practitioners, and assumes the ordinary responsibilities required in that circumstance to assure workforce stability and quality. This exception from the scope of the direct payment provision would be limited to situations in which payment is made under a State law that authorizes payments on behalf of an individual practitioner to a third party for health and welfare benefit costs, training costs, or other benefits customary for employees. The legislative history of section 1902(a)(32) of the Act indicates that such a situation is not within the scope of ''assignments'' or ''powers of attorney'' that were considered at the time, or even of the same nature. Instead, such payments are more of an ordinary arrangement to further workforce stability and quality.

The proposed change would permit each State the option to elect such payment arrangements to the extent that the State determines that they would further State objectives; however, States would not be required to elect the payment arrangements. States will need to review their individual circumstances and workforce needs to determine if the measures would help ensure a stable, high-performing workforce for the benefit of the entire Medicaid population seeking the services.

Within broad Federal Medicaid law and regulation, CMS has long sought to ensure maximum State flexibility to design State-specific payment methodologies that help ensure a strong, committed, and well-trained work force. Currently, certain categories of Medicaid covered services, for which Medicaid is a primary payer, such as home health and personal care services, suffer from especially high rates of turnover and low levels of participation. This proposed rule would provide to States additional tools to help foster a stable and high-performing workforce. Medicaid programs would be able, as authorized under State law, to deduct from the practitioner's reimbursement and remit to third parties amounts for health and welfare benefit contributions, training costs, and other benefits customary for employees.

We believe that permitting such payment arrangements would enhance the ability of the practitioners to perform their functions as health care professionals. The Medicaid program, at both the State and Federal levels, has a strong interest in ensuring the development and maintenance of a committed, well-trained workforce.

We propose to provide States this flexibility by enumerating an additional exception to the payment limitations for individual practitioners at § 447.10(g). Specifically, the proposed rule would add a new provision at § 447.10(g)(4) to define permissible payments in the case of individual practitioners for whom the Medicaid program is the primary source of revenue to include payment authorized by State law to be made to a third party on behalf of the individual practitioner for health and welfare benefit contributions, training costs, and other benefits customary for employees.

To the extent that State laws require practitioners to participate in such a payment arrangement, a State could elect in its Medicaid State plan that the payment arrangement would be automatic. If, however, State law does not require participation by individual practitioners in such payment arrangements, but authorizes voluntary participation, the State would only be allowed to deduct amounts from the payment rate and forward them to a third party with the express permission of each individual practitioner. In that instance, the individual practitioner would need to authorize the payment arrangement on a voluntary basis, prior to any deduction from the provider payment. In either case, the amounts remitted to a third party would be on behalf of the individual practitioner.

As proposed, a State would not be able to claim as a separate expenditure under its approved Medicaid State plan amounts that are withheld from payments to individual practitioners for these cost categories (health and welfare benefit contributions, training, and similar benefits customary for employees). Under the proposed rule, should a State wish to recognize such costs, they would need to be included as part of the rate paid for the service in order to eligible for Federal matching funds. No Federal matching funds would available for such amounts apart from the Federal match available for rate paid by the State for the medical assistance service. These costs could not be claimed by the Medicaid agency separately as an administrative expense. As a result, the proposed rule would have little to no impact on Federal Medicaid funding levels.

We are specifically soliciting public comments on the extent to which the proposed payment arrangements would benefit States and practitioners, as well as any adverse impacts it may have that have not been anticipated. Additionally, we are seeking comments on other exceptions to the general prohibition on assignment of practitioner claims that might similarly simplify and streamline States' operations of their Medicaid plans and payment processes. Finally, we are specifically requesting comments on the intersection between Medicaid and Medicare regulations governing assignment of payments and any potential contradictions therein.

R. Section 2401 of the Affordable Care Act: Community First Choice State Plan Option: Home and Community-Based Setting Requirements (§ 441.530)

Section 1915(k)(1)(A)(ii) of the Act provides that a home and community-based setting does not include a nursing facility, institution for mental diseases, or an intermediate care facility for the mentally retarded. We propose at § 441.530 to adopt this statutory language in our regulations. Additionally, to provide greater clarity, we are proposing language to establish that home and community-based settings must exhibit specific qualities to be eligible sites for delivery of home and community-based services.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following

sections of this document that contain information collection requirements:

A. ICRs Regarding Individuals Receiving State Plan Home and Community-Based Services (§ 435.219(b) and § 436.219(b))

To cover the categorically needy eligibility group, the State would be required to submit a SPA and may elect to cover individuals who meet certain requirements in § 435.219(a) or § 436.219(a). The burden associated with this requirement is the time and effort put forth by the State to complete, review, process and transmit/submit the pre-print which describes the eligibility criteria for the group. We estimate it would take each State 30 hours to meet this one-time requirement. We estimate that on an annual basis, 3 States will submit a SPA to meet these requirements; therefore, the total annual burden hours for this requirement is 90 hours. We believe that a State employee, with pay equivalent to GS–13 step one ($34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be $1,030; this equates to an annual cost of $3,091.

B. ICRs Regarding Eligibility for State Plan HCBS (§ 441.656)

If a State elects to target the benefit to specific populations, § 441.656(b)(2) requires submission of targeting criteria to CMS. The burden associated with this requirement is the time and effort put forth by the State to establish such criteria. We estimate it would take 1 State 10 hours to meet this one-time requirement. We estimate that on an annual basis, 3 States will submit a SPA to offer the State plan HCBS benefit that targets specific populations, and be affected by this requirement; therefore, the total annual burden hours for this requirement is 30 hours. We believe that a State employee, with pay equivalent to GS–13 step one ($34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be $343; this equates to an annual cost of $1,030.

C. ICRs Regarding Needs-Based Criteria and Evaluation (§ 441.659)

Section 441.659(a) requires a State to establish needs-based criteria for determining an individual's eligibility under the State plan for the HCBS benefit, and may establish needs-based criteria for each specific service. The burden associated with this requirement is the time and effort put forth by the State to establish such criteria. We estimate it would take 1 State 24 hours to meet this requirement. We estimate that on an annual basis, 3 States will submit a SPA to offer the State plan HCBS benefit, and be affected by this one-time requirement; therefore, the total annual burden hours for this requirement is 72 hours. We believe that a State employee, with pay equivalent to GS–13 step one ($34.34 per hour) would be responsible for this requirement. Thus, the cost for each responding State is anticipated to be $824; this equates to an annual cost of $2,472.

Section 441.659(b) reads that if a State defines needs-based criteria for individual State plan home and community-based services, the needs-based institutional eligibility criteria must be more stringent than the combined effect of needs-based State plan HCBS benefit eligibility criteria and individual service criteria. Section 441.659(b)(1)(ii) requires the State to submit the more stringent criteria to CMS for inspection with the State plan amendment that establishes the State Plan HCBS benefit.

The burden associated with this requirement is the time and effort for the State to define the more stringent criteria and submit it to CMS along with the State plan amendment that establishes the HCBS benefit. We anticipate 3 States would be affected by this requirement on an annual basis and it would require 1 hour to prepare and submit this information. The one-time burden associated with this requirement is 3 hours. We believe that a State employee, with pay equivalent to GS–13 step one ($34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be $34; this equates to an annual cost of $102. This would be a one time burden for each responding State.

Section 441.659(c) reads that a State may modify the needs-based criteria established under paragraph (a) of this section, without prior approval from the Secretary, if the number of individuals enrolled in the State plan HCBS benefit exceeds the projected number submitted annually to CMS.

Section 441.659(c)(1) requires the State to provide at least 60 days notice of the proposed modification to the Secretary, the public, and each individual enrolled in the State plan HCBS benefit. The State notice to the Secretary will be considered an amendment to the State plan.

Section 441.659(c)(2) requires the State notice to the Secretary be submitted as an amendment to the State plan.

The burden associated with the requirements found under § 441.659(c) is the time and effort put forth by the State to modify the needs-based criteria and provide notification of the proposed modification to the Secretary. We estimate it would take 1 State 24 hours to make the modifications and provide notification. This would be a one-time burden.

The total annual burden of these requirements (§ 441.659(c), § 441.659(c)(1), and § 441.659(c)(2)) would vary according to the number of States who choose to modify their needs-based criteria. We do not expect any States to make this modification in the next 3 years, thus there is no anticipated burden.

Section 441.659(d) states that eligibility for the State plan HCBS benefit is determined, for individuals who meet the requirements of § 441.656(a)(1) through (5), through an independent evaluation of each individual that meets the specified requirements. Section 441.659(d)(5) requires the evaluator to obtain information from existing records, and when documentation is not current and accurate, obtain any additional information necessary to draw a valid conclusion about the individual's support needs. Section 441.659(e) requires at least annual reevaluations.

The burden associated with this requirement is the time and effort put forth by the evaluator to obtain information to support their conclusion. We estimate it would take one evaluator 2 hours per participant to obtain information as necessary. The total annual burden of this requirement would vary according to the number of participants in each State who may require and be eligible for home and community-based services under the State plan. The individuals performing this assessment would vary based upon State benefit design, but will likely include individuals such as registered nurses, qualified mental retardation professionals, qualified mental health professionals, case managers, or other professional staff with experience providing services to individuals with disabilities or the elderly. While there is burden associated with this requirement, we believe the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities.

D. ICRs Regarding Independent Assessments (§ 441.662)

Section 441.662 requires the State to provide for an independent assessment of need in order to establish a service plan. At a minimum, the plan must meet the requirements as discussed under § 441.665.

While the burden associated with the requirements under § 441.662 is subject to the PRA, we believe the burden is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities.

E. ICRs Regarding State Plan HCBS Administration: State Responsibilities and Quality Improvement (§ 441.677)

Section 441.677(a)(1)(i) reads that a State will annually provide CMS with the projected number of individuals to be enrolled in the benefit, and the actual number of unduplicated individuals enrolled in State plan HCBS in the previous year.

The burden associated with this requirement is the time and effort put forth by the State to annually project the number of individuals who will enroll in State plan HCBS. We estimate it will take one State 2 hours to meet this requirement. The total annual burden of these requirements would vary according to the number of States offering the State plan HCBS benefit. The maximum total annual burden is 112 hours (56 States × 2 hours = 112 hours). We believe that a State employee, with pay equivalent to GS–13 step one ($34.34 per hour) would be responsible for this requirement. Thus, the anticipated for each State is anticipated to be $69; this equates to a maximum annual cost of $3,864 if all 56 States elect to provide this benefit. There are currently six States with approved State plan HCBS benefits. Thus, we anticipate based on current benefits that the total annual aggregated burden will be $414.

Section 441.677(a)(2)(iii) reads that the SPA to provide State plan HCBS must contain a description of the reimbursement methodology for each covered service.

The burden associated with this requirement is the time and effort put forth by the State to describe the reimbursement methodology for each State plan HCBS. We estimate that it will take one State an average of 2 hours to determine the reimbursement methodology for one covered HCBS. This would be a one-time burden. The total annual burden for this requirement would vary according to the number of services that the State chooses to include in the State plan HCBS benefit. We believe that a State employee, with pay equivalent to GS–13 step one ($34.34 per hour) would be responsible for this requirement. Thus, the cost to each State for each covered service is anticipated to be $69; this would vary based upon the number of services covered. This would be an annual burden for each responding State. Since we have estimated that 3 States will annually describe the reimbursement methodology, the total annual aggregated burden associated with this requirement is estimated to be $207.

Section 441.677(a)(2)(iv) reads that the SPA to provide State plan HCBS must contain a description of the State Medicaid agency line of authority for operating the State plan HCBS benefit, including distribution of functions to other entities.

The burden associated with this requirement is the time and effort put forth by the State to describe the State Medicaid agency line of authority. We estimate it will take one State 2 hours to meet this requirement. Since we have estimated that 3 States will annually request State plan HCBS, the total annual burden associated with this requirement is estimated to be 6 hours. This would be a one-time burden for each responding State. We believe that a State employee, with pay equivalent to GS–13 step one ($34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be $69.

Section 441.677(a)(2)(vi) limits the approval period for States that target the benefit to specific populations. If a State elects to target the benefit, this section requires a renewal application every 5 years in order to continue operation of the benefit. Actual time to meet this requirement will vary depending on the scope of the program and any changes the State includes. However, we estimate that it will take one State an average of 40 hours to meet this requirement. This includes reviewing the previous submission, making any necessary changes to the State plan document(s), and communicating with CMS regarding the renewal. This burden would occur once every five years and would be recurring. We estimate that, beginning in 2016, 3 States will annually request renewal and the total burden will be 120 hours. We believe that a State employee, with pay equivalent to GS–13 step one ($34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be $1,374; this equates to an annual cost of $4,122. This would be a burden for each State that targets its benefit once every 5 years; however, this burden will not take effect until 2016.

Section 441.677(b) requires States to develop and implement a quality improvement strategy that includes methods for ongoing measurement of program performance, quality of care, and mechanisms for remediation and improvement proportionate to the scope of services in the State plan HCBS benefit and the number of individuals to be served, and make this information available to CMS upon the frequency determined by the Secretary or upon request.

The burden associated with this requirement is the time and effort put forth by the State to develop and implement a quality improvement strategy, and to make this information available to CMS upon the frequency determined by the Secretary or upon request. We estimate it will take one State 45 hours for the development of the strategy, and for making information available to CMS. The total annual burden of these requirements would vary according to the number of States offering the State plan HCBS benefit. The maximum total annual burden is estimated to be 2,520 hours (56 States × 45 hours = 2,520 hours). We estimate that the burden associated with implementation of the quality improvement strategy will greatly vary, as the necessary time and effort to perform these activities is dependent upon the scope of the benefit and the number of persons receiving State plan HCBS. We believe that a State employee, with pay equivalent to GS–13 step one ($34.34 per hour) would be responsible for this requirement. Thus, the cost for each State is anticipated to be $1,545; this equates to a maximum annual cost of $86,537. Currently, there are six States with approved benefits, thus we anticipate an annual burden based on current States of $9,270.

TABLE 1—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
435.219(b) and 436.219(b)	0938–1148	3	3	30	90	34.34	1,030	0	1,030

TABLE 1—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS—Continued

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
441.656(b)(2)	0938–1148	3	3	10	30	34.34	1,030	0	1,030
441.659(a)	0938–1148	3	3	24	72	34.34	2,472	0	2,472
441.659(b)	0938–1148	3	3	1	3	34.34	103	0	103
441.677(a)(1)(i)	0938–1148	6	6	2	12	34.34	414	0	414
441.677(a)(2)(iii)	0938–1148	3	3	2	6	34.34	207	0	207
441.677(a)(2)(iv)	0938–1148	3	3	2	6	34.34	207	0	207
441.677(b)	0938–1148	6	6	45	270	34.34	9,270	0	9,270
Total					489		14,733	0	14,733

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you have comments on these information collection and record keeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–2249–P2. Fax: (202) 395–5806; or Email: *OIRA submission@omb.eop.gov.*

VI. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) and Executive 13563 on Improving Regulation and Regulatory Review (January 18, 2011). Executive Orders 12866 and 13563 direct 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). This proposed rule has been designated an ''economically significant'' rule under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

B. Statement of Need

The State plan HCBS benefit is authorized under section 1915(i) of the Act. Section 1915(i) was created by the Deficit Reduction Act of 2005 and was amended by the Affordable Care Act of 2010. The resulting statute provides States with authority to establish State plan HCBS benefits in their Medicaid program.

These regulations are necessary in order to include the State plan HCBS within the Code of Federal Regulations. Additionally, these regulations provide States with direction and clarity regarding the framework under which the programs can be established.

C. Overall Impacts

We estimate that, as a result of this proposed rule, the Medicaid cost impact for fiscal year (FY) 2012 would be $80 million for the Federal share and $60 million for the State share. The estimates are adjusted for a phase-in period during which States gradually elect to offer the State plan HCBS benefit.

D. Detailed Impacts

1. State Plan HCBS

State Medicaid programs will make use of the optional flexibility afforded by the State plan HCBS benefit to provide needed long-term care HCBS to eligible individuals the State has not had means to serve previously, or to provide services to these individuals more efficiently and effectively. The State plan HCBS benefit will afford States a new means to comply with requirements of the *Olmstead* decision, to serve individuals in the most integrated setting.

The cost of these services will be dependent upon the number of States electing to offer the benefit, the scope of the benefits States design, and the degree to which the benefits replace existing Medicaid services. States have more control over expenditures for this benefit than over other State plan services. For States that choose to offer these services, States may specify limits to the scope of HCBS, target the benefit to specific populations, and have the option to tighten needs-based criteria requirements if costs escalate too rapidly.

If States elect to include the new optional group, eligibility could be expanded because the group may include individuals who would not otherwise be eligible for Medicaid. However, costs of the State plan HCBS benefit may be offset by lowered potential Federal and State costs of more expensive institutional care. Additionally, the requirement for a written individualized service plan, and the provision of needed HCBS in accordance with the individualized service plan, may discourage inappropriate utilization of costly services such as emergency room care for routine procedures, which may be beneficial to Medicare and Medicaid when individuals are eligible for both programs. If a State targets this benefit, only individuals who meet the targeting criteria would receive 1915(i) services and be eligible for the group, thus limiting Medicaid expansion.

After considering these factors, we assumed that, if all States adopted this measure, program expenditures would increase by 1 percent of current HCBS expenditure projections. We further assumed that ultimately, States representing 50 percent of the eligible population would elect to offer this benefit, and that this ultimate level would be reached in FY 2014, with a phase-in period until then. Based on these assumptions, the Federal and State cost estimates are shown in Table 2.

TABLE 2—MEDICAID COST ESTIMATES RESULTING FROM CHANGES TO THE STATE PLAN

[HCBS Benefit (FYs 2012–2016, in $millions]

	FY12	FY13	FY14	FY15	FY16
Federal Share	$80	$120	$170	$190	$215
State Share	60	90	125	145	160

The effect on Medicaid beneficiaries who receive the State plan HCBS benefit will be substantial and beneficial in States where optional 1915(i) State plan HCBS are included, as it will provide eligible individuals with the opportunity to receive needed long-term care services and supports in their homes and communities.

The State plan HCBS benefit will afford business opportunities for providers of the HCBS. We do not anticipate any effects on other providers. Section 1915(i) of the Act delinks the HCBS from institutional LOC, and requires that eligibility criteria for the benefit include a threshold of need less than that for institutional LOC, so that it is unlikely that large numbers of participants in the State plan HCBS benefit will be discharged from the facilities of Medicaid institutional providers. There may be some redistribution of services among providers of existing non-institutional Medicaid services into State plan HCBS, but providers who meet qualifications for the State plan HCBS benefit have the option to enroll as providers of HCBS.

This rule has no direct effect on the Medicare program; however, an indirect and beneficial effect may occur if individuals eligible for both Medicare and Medicaid are enrolled in a State plan HCBS program.

E. Alternatives Considered

This proposed rule incorporates provisions of new section 1915(i) of the Act into Federal regulations, providing for Medicaid coverage of a new optional State plan benefit to furnish home and community-based State plan services. The statute provides States with an option under which to draw Federal matching funds; it does not impose any requirements or costs on existing State programs, on providers, or upon beneficiaries. States retain their existing authority to offer HCBS through the existing authority granted under section 1915(c) waivers and under section 1115 waivers. States can also continue to offer, and individuals can choose to receive, some but not all components of HCBS allowable under section 1915(i) through existing State plan services such as personal care or targeted case management services. Therefore, this rule is entirely optional for States. We solicit comment on the analysis within the ''Alternatives Considered'' section.

Alternatives to this proposed rule include:

(1) *Not Publishing a Rule:* Section 1915(i) of the Act was effective January 1, 2007. States may propose SPAs to establish the State plan HCBS benefit with or without this proposed rule. We considered whether this statute could be self-implementing and require no regulation. Section 1915(i) of the Act is complex; many States have contacted us for technical assistance in the absence of published guidance, and some have indicated they are waiting to submit a State plan amendment until there is a rule. We further considered whether a State Medicaid Director letter would provide sufficient guidance regarding CMS review criteria for approval of an SPA. We conclude that section 1915(i) of the Act establishes significant new features in the Medicaid program, and that it was important to provide States and the public the published invitation for comment provided by this proposed rule. Finally, State legislation and judicial decisions are not alternatives to a Federal rule in this case since section 1915(i) of the Act provides Federal benefits.

(2) *Modification of Existing Rules:* We considered modifying existing regulations at 42 CFR part 440.180, part 441 subpart G, Home and Community-Based Services: Waiver Requirements, which implement the section 1915(c) HCBS waivers, to include the authority to offer the State plan HCBS benefit. This would have the advantage of not duplicating certain requirements common to both types of HCBS. However, we believe that any such efficiency would be outweighed by the substantial discussion that would be required of the differences between the Secretary's discretion to approve waivers under section 1915(c) of the Act, and authority to offer HCBS under the State plan at section 1915(i) of the Act. While Congress clearly considered the experience to date with HCBS under waivers when constructing section 1915(i) of the Act, it did not choose to modify section 1915(c) of the Act, but chose instead to create a new authority at section 1915(i) of the Act.

F. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in the Table 3, we have prepared an accounting statement showing the classification of the transfers associated with the provisions of this proposed rule. This table provides our best estimate of the proposed increase in aggregate Medicaid outlays resulting from offering States the option to provide the State plan HCBS benefit established in section 1915(i) of the Act and proposed by CMS–2249–P (Medicaid program; Home and Community-Based State Plan Services).

TABLE 3—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS, FROM FYS 2012 TO 2016

[In $millions]

Category	TRANSFERS	
Annualized Monetized Transfers	3% Units Discount Rate $153.0	7% Units Discount Rate. $150.4.
From Whom To Whom?	Federal Government to Providers	

TABLE 3—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS, FROM FYS 2012 TO 2016—Continued

[In $millions]

Category	TRANSFERS	
Other Annualized Monetized Transfers	3% Units Discount Rate $114.5	7% Units Discount Rate. $112.5.
From Whom To Whom?	State Governments to Providers	

G. Conclusion

We anticipate that States will make widely varying use of the section 1915(i) State plan HCBS benefit to provide needed long-term care services for Medicaid beneficiaries. These services will be provided in the home or alternative living arrangements in the community, which is of benefit to the beneficiary and is less costly than institutional care. Requirements for independent evaluation and assessment, individualized care planning, and requirements for a quality improvement program will promote efficient and effective use of Medicaid expenditures for these services.

VII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), as modified by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121), requires agencies to determine whether proposed or final rules would have a significant economic impact on a substantial number of small entities and, if so, to prepare a Regulatory Flexibility Analysis and to identify in the notice of proposed rulemaking or final rulemaking any regulatory options that could mitigate the impact of the proposed regulation on small businesses. For purposes of the RFA, small entities include businesses that are small as determined by size standards issued by the Small Business Administration, nonprofit organizations, and small governmental jurisdictions). Individuals and States are not included in the definition of a small business entity.

For purposes of the RFA, we assume that approximately 75 percent of Medicaid providers are considered small businesses according to the Small Business Administration's size standards (with total revenues of $35 million or less in any one year), and 80 percent are nonprofit organizations. Medicaid providers are required, as a matter of course, to follow the guidelines and procedures as specified in State and Federal laws and regulations. Furthermore, this rule imposes no requirements or costs on providers or suppliers for their existing activities. The rule implements a new optional State plan benefit established in section 1915(i) of the Act. Small entities that meet provider qualifications and choose to provide HCBS under the State plan will have a business opportunity under this proposed rule. The Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule does not offer a change in the administration of the provisions related to small rural hospitals. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

VIII. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately $139 million. This proposed rule does not mandate any spending by State, local, or tribal governments, in the aggregate, or by the private sector, of $139 million.

IX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

List of Subjects

42 CFR Part 430

Administrative practice and procedure, Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs—health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income, Wages.

42 CFR Part 436

Aid to Families with Dependent Children, Grant programs—health, Guam, Medicaid Puerto Rico, Supplemental Security Income (SSI), Virgin Islands.

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 441

Aged, Family planning, Grant programs—health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

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

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

1. The authority citation for part 430 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart B—State Plans

2. Section 430.25 is amended by—

A. Revising paragraphs (h)(2)(i) and (ii).

B. Adding paragraph (h)(2)(iii).

The revisions and addition read as follows:

§ 430.25 Waivers of State plan requirements.

* * * * *

(h) * * *

(2) *Duration of waivers.* (i) *Home and community-based services under section 1915(c) of the Act.* The initial waiver is for a period of 3 years and may be renewed thereafter for periods of 5 years. For waivers that include individuals who are dually eligible for Medicare and Medicaid, 5-year initial approval periods may be granted at the discretion of the Secretary for waivers meeting all necessary programmatic, financial and quality requirements.

(ii) *Waivers under section 1915(b) of the Act.* The initial waiver is for a period of 2 years and may be renewed for additional periods of up to 2 years as determined by the Administrator. For waivers that include individuals who are dually eligible for Medicare and Medicaid, 5-year initial and renewal approval periods may be granted at the discretion of the Secretary for waivers meeting all necessary programmatic, financial and quality requirements.

(iii) *Waivers under section 1916 of the Act.* The initial waiver is for a period of 2 years and may be renewed for additional periods of up to 2 years as determined by the Administrator.

* * * * *

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

3. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart B—General Administrative Requirements

4. Section 431.54 is amended by adding paragraphs (a)(3) and (h) to read as follows:

§ 431.54 Exceptions to certain State plan requirements.

(a) * * *

(3) Section 1915(i) of the Act provides that a State may provide, as medical assistance, home and community-based services under an approved State plan amendment that meets certain requirements, without regard to the requirements of sections 1902(a)(10)(B) and 1902(a)(10)(C)(i)(III) of the Act, with respect to such services.

* * * * *

(h) *State plan home and community-based services.* The requirements of § 440.240 of this chapter related to comparability of services do not apply with respect to State plan home and community-based services defined in § 440.182 of this chapter.

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

5. The authority citation for part 435 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart C—Options for Coverage

6. Section 435.219 is added to subpart C to read as follows:

§ 435.219 Individuals receiving State plan home and community-based services.

If the agency provides home and community-based services to individuals described in section 1915(i)(1), the agency, under its State plan, may, in addition, provide Medicaid to any group or groups of individuals in the community who are described in one or both of the paragraphs under paragraphs (a) or (b) of this section.

(a) Individuals who—

(1) Are not otherwise eligible for Medicaid;

(2) Have income that does not exceed 150 percent of the Federal poverty line (FPL);

(3) Meet the needs-based criteria under § 441.659 of this chapter; and

(4) Will receive State plan home and community-based services as defined in § 440.182 of this chapter.

(b) Individuals who—

(1) Would be determined eligible by the agency under an existing waiver or demonstration project under sections 1915(c), 1915(d), 1915(e) or 1115 of the Act, but are not required to receive services under such waivers or demonstration projects;

(2) Have income that does not exceed 300 percent of the Supplemental Security Income Federal Benefit Rate (SSI/FBR); and

(3) Will receive State plan home and community-based services as defined in § 440.182 of this chapter.

(c) For purposes of determining eligibility under paragraph (a) of this section, the agency may not take into account an individual's resources and must use income standards that are reasonable, consistent with the objectives of the Medicaid program, simple to administer, and in the best interests of the beneficiary. Income methodologies may include use of existing income methodologies, such as the SSI program rules. However, subject to the Secretary's approval, the agency may use other income methodologies that meet the requirements of this paragraph (c).

PART 436—ELIGIBILITY IN GUAM, PUERTO RICO AND THE VIRGIN ISLANDS

7. The authority citation for part 436 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart C—Options for Coverage

8. Section 436.219 is added to subpart C to read as follows:

§ 436.219 Individuals receiving State plan home and community-based services.

If the agency provides home and community-based services to individuals described in section 1915(i)(1) of the Act, the agency, under its State plan, may, in addition, provide Medicaid to any group or groups of individuals in the community who are described in one or both of paragraphs (a) or (b) of this section.

(a) Individuals who—

(1) Are not otherwise eligible for Medicaid;

(2) Have income that does not exceed 150 percent of the Federal poverty line (FPL);

(3) Meet the needs-based criteria under § 441.659 of this chapter; and

(4) Will receive State plan home and community-based services as defined in § 440.182 of this chapter.

(b) Individuals who—

(1)Would be determined eligible by the agency under an existing waiver or demonstration project under sections 1915(c), 1915(d), 1915(e) or 1115 of the Act, but are not required to receive services under such waivers or demonstration projects;

(2) Have income that does not exceed 300 percent of the Supplemental Security Income Federal Benefit Rate (SSI/FBR); and

(3) Will receive State plan home and community-based services as defined in § 440.182 of this chapter.

(c) For purposes of determining eligibility under paragraph (a) of this section, the agency may not take into account an individual's resources and must use income standards that are reasonable, consistent with the objectives of the Medicaid program, simple to administer, and in the best

interests of the beneficiary. Income methodologies may include use of existing income methodologies, such as the rules of the OAA, AB, APTD or AABD programs. However, subject to the Secretary's approval, the agency may use other income methodologies that meet the requirements of this paragraph (c).

PART 440—SERVICES: GENERAL PROVISIONS

9. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart A—Definitions

10. Section 440.1 is amended by adding the new statutory basis in alphanumerical order to read as follows:

§ 440.1 Basis and purpose.

* * * * *

1915(i) Home and community-based services furnished under a State plan to elderly and disabled individuals.

11. Section 440.180 is amended by revising the heading to read as follows:

§ 440.180 Home and community-based waiver services.

* * * * *

12. Section 440.182 is added to subpart A to read as follows:

§ 440.182 State plan home and community-based services.

(a) *Definition.* State plan home and community-based services (HCBS) benefit means the services listed in paragraph (c) of this section when provided under the State's plan (rather than through an HCBS waiver program) for individuals described in paragraph (b) of this section.

(b) *State plan HCBS coverage.* State plan HCBS can be made available to individuals who—

(1) Are eligible under the State plan and have income, calculated using the otherwise applicable rules, including any less restrictive income disregards used by the State for that group under section 1902(r)(2) of the Act, that does not exceed 150 percent of the Federal Poverty Line (FPL); and

(2) In addition to the individuals described in paragraph (b)(1) of this section, to individuals based on the State's election of the eligibility groups described in § 435.219(b) or § 436.219(b) of this chapter.

(c) *Services.* The State plan HCBS benefit consists of one or more of the following services:

(1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Habilitation services, which include expanded habilitation services as specified in § 440.180(c) of this subpart.

(7) Respite care services.

(8) Subject to the conditions in § 440.180 of this subpart, for individuals with chronic mental illness:

(i) Day treatment or other partial hospitalization services;

(ii) Psychosocial rehabilitation services;

(iii) Clinic services (whether or not furnished in a facility).

(9) Other services requested by the agency and approved by the Secretary as consistent with the purpose of the benefit.

(d) *Exclusion.* FFP is not available for the cost of room and board in State plan HCBS. The following HCBS costs are not considered room or board for purposes of this exclusion:

(1) The cost of temporary food and shelter provided as an integral part of respite care services in a facility approved by the State.

(2) Meals provided as an integral component of a program of adult day health services or another service and consistent with standard procedures in the State for such a program.

(3) A portion of the rent and food costs that may be reasonably attributed to an unrelated caregiver providing State plan HCBS who is residing in the same household with the recipient, but not if the recipient is living in the home of the caregiver or in a residence that is owned or leased by the caregiver.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

13. The authority citation for part 441 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

14. Section 441.530 is added to read as follows:

§ 441.530 Home and Community-Based Setting.

(a) States must make available attendant services and supports in a home and community-based setting consistent with both paragraphs (a)(1) and (2) of this section.

(1) Home and community-based settings shall have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

(i) The setting is integrated in, and facilitates the individual's full access to, the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, in the same manner as individuals without disabilities.

(ii) The setting is selected by the individual from among all available alternatives and is identified in the person-centered service plan.

(iii) An individual's essential personal rights of privacy, dignity and respect, and freedom from coercion and restraint are protected.

(iv) Individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact are optimized and not regimented.

(v) Individual choice regarding services and supports, and who provides them, is facilitated.

(vi) In a provider-owned or controlled residential setting, the following additional conditions must be met. Any modification of the conditions, for example, to address the safety needs of an individual with dementia, must be supported by a specific assessed need and documented in the person-centered service plan:

(A) The unit or room is a specific physical place that can be owned, rented or occupied under another legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord tenant law of the State, county, city or other designated entity;

(B) Each individual has privacy in their sleeping or living unit:

(*1*) Units have lockable entrance doors, with appropriate staff having keys to doors;

(*2*) Individuals share units only at the individual's choice; and

(*3*) Individuals have the freedom to furnish and decorate their sleeping or living units.

(C) Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time;

(D) Individuals are able to have visitors of their choosing at any time; and

(E) The setting is physically accessible to the individual.

(2) Home and community-based settings do not include the following:

(i) A nursing facility;

(ii) An institution for mental diseases;

(iii) An intermediate care facility for the mentally retarded;

(iv) A hospital providing long-term care services; or

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. The Secretary will apply a rebuttable presumption that a setting is not a home and community-based setting, and engage in heightened scrutiny, for any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or disability-specific housing complex.

15. A new subpart L, consisting of §§ 441.650 through 441.677, is added to read as follows:

Subpart K—State Plan Home and Community-Based Services for Elderly and Disabled Individuals

Sec.

441.650 Basis and purpose.
441.653 State plan requirements.
441.656 State plan home and community-based services under the Act.
441.659 Needs-based criteria and evaluation.
441.662 Independent assessment.
441.665 Person-centered service plan.
441.668 Provider qualifications.
441.671 Definition of individual's representative.
441.674 Self-directed services.
441.677 State plan HCBS administration: State responsibilities and quality improvement.

Subpart L State Plan Home and Community-Based Services for the Elderly and Individuals With Disabilities

§ 441.650 Basis and purpose.

Section 1915(i) of the Act permits States to offer one or more home and community-based services (HCBS) under their State Medicaid plans to qualified individuals with disabilities or individuals who are elderly. Those services are listed in § 440.182 of this chapter, and are described by the State, including any limitations of the services. This optional benefit is known as the State plan HCBS benefit. This subpart describes what a State Medicaid plan must provide when the State elects to include the optional benefit, and defines State responsibilities.

§ 441.653 State plan requirements.

A State plan that provides 1915(i) State plan home and community-based services must meet the requirements of this subpart.

§ 441.656 State plan home and community-based services under the Act.

(a) Home and Community-Based Setting. Under section 1915(i)(1) of the Act, States must make State plan HCBS available in a home and community-based setting consistent with both paragraphs (a)(1) and (2) of this section.

(1) Home and community-based settings shall have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

(i) The setting is integrated in, and facilitates the individual's full access to, the greater community including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, in the same manner as individuals without disabilities.

(ii) The setting is selected by the individual from among all available alternatives and is identified in the person–centered service plan.

(iii) An individual's essential personal rights of privacy, dignity and respect, and freedom from coercion and restraint are protected.

(iv) Individual initiative, autonomy, and independence in making life choices, including but not limited to, daily activities, physical environment, and with whom to interact are optimized and not regimented.

(v) Individual choice regarding services and supports, and who provides them, is facilitated.

(vi) In a provider-owned or controlled residential setting, the following additional conditions must be met. Any modification of the conditions, for example, to address the safety needs of an individual with dementia, must be supported by a specific assessed need and documented in the person-centered service plan:

(A) The unit or room is a specific physical place that can be owned, rented, or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities and protections from eviction that tenants have under the landlord/tenant law of the State, county, city, or other designated entity;

(B) Each individual has privacy in their sleeping or living unit:

(*1*) Units have lockable entrance doors, with appropriate staff having keys to doors;

(*2*) Individuals share units only at the individual's choice; and

(*3*) Individuals have the freedom to furnish and decorate their sleeping or living units.

(C) Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time;

(D) Individuals are able to have visitors of their choosing at any time; and

(E) The *setting is physically accessible to the individual.*

(2) Home and community-based settings do not include the following:

(i) A nursing facility;

(ii) An institution for mental diseases;

(iii) An intermediate care facility for the mentally retarded;

(iv) A hospital; or

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. The Secretary will apply a rebuttable presumption that a setting is not a home and community-based setting, and engage in heightened scrutiny, for any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or in a building on the grounds of, or immediately adjacent to, a public institution, or disability-specific housing complex.

(b) *Needs-Based Eligibility Requirement.* Meet needs-based criteria for eligibility for the State plan HCBS benefit, as required in § 441.659(a).

(c) *Minimum State plan HCBS Requirement.* Be assessed to require at least one section 1915(i) home and community-based service at a frequency determined by the State, as required in § 441.662(a)(5).

(d) *Target Population.* Meet any applicable targeting criteria defined by the State under the authority of paragraph (b)(2) of this section.

(e) *Nonapplication.* The State may elect in the State plan amendment approved under this subpart not to apply the following requirements when determining eligibility:

(1) Section 1902(a)(10)(C)(i)(III) of the Act, pertaining to income and resource eligibility rules for the medically needy living in the community, but only for the purposes of providing State plan HCBS.

(2) Section 1902(a)(10)(B) of the Act, pertaining to comparability of Medicaid services, but only for the purposes of providing section 1915(i) State plan HCBS. In the event that a State elects not to apply comparability requirements:

(i) The State must describe the group(s) receiving State plan HCBS, subject to the Secretary's approval. Targeting criteria cannot have the

impact of limiting the pool of qualified providers from which an individual would receive services, or have the impact of requiring an individual to receive services from the same entity from which they purchase their housing. These groups must be defined on the basis of any combination of—

(A) Age;

(B) Diagnosis;

(C) Disability; or

(D) Medicaid Eligibility Group.

(ii)The State may elect in the State plan amendment to limit the availability of specific services defined under the authority of § 440.182(b) or to vary the amount, duration, or scope of those services, to one or more of the group(s) described in this paragraph.

§ 441.659 Needs-based criteria and evaluation.

(a) *Needs-based criteria.* The State must establish needs-based criteria for determining an individual's eligibility under the State plan for the HCBS benefit, and may establish needs-based criteria for each specific service. Needs-based criteria are factors used to determine an individual's requirements for support, and may include risk factors. The criteria are not characteristics that describe the individual or the individual's condition. A diagnosis is not a sufficient factor on which to base a determination of need. A criterion can be considered needs-based if it is a factor that can only be ascertained for a given person through an individualized evaluation of need.

(b) *More stringent institutional and waiver needs-based criteria.* The State plan HCBS benefit is available only if the State has in effect needs-based criteria (as defined in paragraph (a) of this section), for receipt of services in nursing facilities as defined in section 1919(a) of the Act, intermediate care facilities for the mentally retarded as defined in § 440.150 of this chapter, and hospitals as defined in § 440.10 of this chapter for which the State has established long-term level of care (LOC) criteria, or waivers offering HCBS, and these needs-based criteria are more stringent than the needs-based criteria for the State plan HCBS benefit. If the State defines needs-based criteria for individual State plan home and community-based services, it may not have the effect of limiting who can benefit from the State plan HCBS in an unreasonable way, as determined by the Secretary.

(1) These more stringent criteria must meet the following requirements:

(i) Be included in the LOC determination process for each institutional service and waiver.

(ii) Be submitted for inspection by CMS with the State plan amendment that establishes the State Plan HCBS benefit.

(iii) Be in effect on or before the effective date of the State plan HCBS benefit.

(2) In the event that the State modifies institutional LOC criteria to meet the requirements under paragraph (b) or (c)(7) of this section that such criteria be more stringent than the State plan HCBS needs-based eligibility criteria, States may continue to receive FFP for individuals receiving institutional services or waiver HCBS under the LOC criteria previously in effect.

(c) *Adjustment authority.* The State may modify the needs-based criteria established under paragraph (a) of this section, without prior approval from the Secretary, if the number of individuals enrolled in the State plan HCBS benefit exceeds the projected number submitted annually to CMS. The Secretary will approve a retroactive effective date for the State plan amendment modifying the criteria, as early as the day following the notification period required under paragraph (c)(1) of this section, if all of the following conditions are met:

(1) The State provides at least 60 days notice of the proposed modification to the Secretary, the public, and each individual enrolled in the State plan HCBS benefit.

(2) The State notice to the Secretary is submitted as an amendment to the State plan.

(3) The adjusted needs-based eligibility criteria for the State plan HCBS benefit are less stringent than needs-based institutional and waiver LOC criteria in effect after the adjustment.

(4) Individuals who were found eligible for the State plan HCBS benefit before modification of the needs-based criteria under this adjustment authority must remain eligible for the HCBS benefit until such time as:

(i) The individual no longer meets the needs-based criteria used for the initial determination of eligibility; or

(ii) The individual is no longer eligible for or enrolled in Medicaid or the HCBS benefit.

(5) Any changes in service due to the modification of needs-based criteria under this adjustment authority are treated as actions as defined in § 431.201 and are subject to the requirements of Part 431 Subpart E of this chapter.

(6) In the event that the State also needs to modify institutional LOC criteria to meet the requirements under paragraph (b) of this section that such criteria be more stringent than the State plan HCBS needs-based eligibility criteria, the State may adjust the modified institutional LOC criteria under this adjustment authority. The adjusted institutional LOC criteria must be at least as stringent as those in effect before they were modified to meet the requirements in paragraph (b) of this section.

(d) *Independent evaluation and determination of eligibility.* Eligibility for the State plan HCBS benefit must be determined through an independent evaluation of each individual according to the requirements of § 441.656(a)(1) through (5) of this subpart. The independent evaluation complies with the following requirements:

(1) Is performed by an agent that is independent and qualified as defined in § 441.668 of this subpart.

(2) Applies the needs-based eligibility criteria that the State has established under paragraph (a) of this section, and the general eligibility requirements under § 441.656(a)(1) through (3) and (b)(2) of this subpart.

(3) Includes consultation with the individual, and if applicable, the individual's authorized representative.

(4) Assesses the individual's support needs.

(5) Uses only current and accurate information from existing records, and obtains any additional information necessary to draw valid conclusions about the individual's support needs.

(6) Evaluations finding that an individual is not eligible for the State plan HCBS benefit are treated as actions defined in § 431.201 of this chapter and are subject to the requirements of part 431 subpart E of this chapter.

(e) *Periodic redetermination.* Independent reevaluations of each individual receiving the State plan HCBS benefit must be performed at least every 12 months, to determine whether the individual continues to meet eligibility requirements. Redeterminations must meet the requirements of paragraph (d) of this section.

§ 441.662 Independent assessment.

(a) *Requirements.* For each individual determined to be eligible for the State plan HCBS benefit, the State must provide for an independent assessment of needs, which may include the results of a standardized functional needs assessment, in order to establish a service plan. In applying the requirements of section 1915(i)(1)(F) of the Act, the State must:

(1) Perform a face-to-face assessment of the individual by an agent that is independent and qualified as defined in § 441.668 of this subpart and with a

person-centered process guided by best practice and research on effective strategies that result in improved health and quality of life outcomes.

(i) For the purposes of this section, a face-to-face assessment may include assessments performed by telemedicine, or other information technology medium, if the following conditions are met:

(A) The health care professional(s) performing the assessment meets the provider qualifications defined by the State, including any additional qualifications or training requirements for the operation of required information technology.

(B) The individual receives appropriate support during the assessment, including the use of any necessary on-site support-staff.

(C) The individual provides informed consent for this type of assessment.

(ii) [Reserved]

(2) Conduct the assessment in consultation with the individual, and if applicable, the individual's authorized representative, and include the opportunity for the individual to identify other persons to be consulted, such as, but not limited to, the individual's spouse, family, guardian, and treating and consulting health and support professionals responsible for the individual's care.

(3) Examine the individual's relevant history including the findings from the independent evaluation of eligibility, medical records, an objective evaluation of functional ability, and any other records or information needed to develop the service plan as required in § 441.665 of this subpart.

(4) Include in the assessment the individual's physical and behavioral health care and support needs, strengths and preferences, available service and housing options, and when unpaid caregivers will be relied upon to implement the service plan, a caregiver assessment.

(5) Apply the State's needs-based criteria for each service (if any) that the individual may require. Individuals are considered enrolled in the State plan HCBS benefit only if they meet the eligibility and needs-based criteria for the benefit, and are also assessed to require and receive at least one home and community-based service offered under the State plan for medical assistance.

(6) Include in the assessment, if the State offers individuals the option to self-direct a State plan home and community-based service or services, any information needed for the self-directed portion of the service plan, as required in § 441.674(b) of this subpart, including the ability of the individual (with and without supports) to exercise budget or employer authority.

(7) Include in the assessment, for individuals receiving habilitation services, documentation that no Medicaid services are provided which would otherwise be available to the individual, specifically including but not limited to services available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973, or the Individuals with Disabilities Education Improvement Act of 2004.

(8) Include in the assessment and subsequent service plan, for individuals receiving Secretary approved services under the authority of § 440.182 of this chapter, documentation that no State plan HCBS services are provided which would otherwise be available to the individual through other Medicaid services or other Federally funded programs.

(9) Include in the assessment and subsequent service plan, for individuals receiving HCBS through a waiver approved under § 441.300 of this subpart, documentation that HCBS provided through the State plan and waiver are not duplicative.

(10) Coordinate the assessment and subsequent service plan with any other assessment or service plan required for services through a waiver authorized under section 1115 or section 1915 of the Social Security Act.

(b) *Reassessments.* The independent assessment of need must be conducted at least every 12 months and as needed when the individual's support needs or circumstances change significantly, in order to revise the service plan.

§ 441.665 Person-centered service plan.

(a) *Person-centered planning process.* Based on the independent assessment required in § 441.662 of this subpart, the State must develop (or approve, if the plan is developed by others) a written service plan jointly with the individual (including, for purposes of this paragraph, the individual and the individual's authorized representative if applicable). The person-centered planning process is driven by the individual. The process:

(1) Includes people chosen by the individual.

(2) Provides necessary information and support to ensure that the individual directs the process to the maximum extent possible, and is enabled to make informed choices and decisions.

(3) Is timely and occurs at times and locations of convenience to the individual.

(4) Reflects cultural considerations of the individual.

(5) Includes strategies for solving conflict or disagreement within the process, including clear conflict-of-interest guidelines for all planning participants.

(6) Offers choices to the individual regarding the services and supports they receive and from whom.

(7) Includes a method for the individual to request updates to the plan.

(8) Records the alternative home and community-based settings that were considered by the individual.

(b) *The person-centered service plan.* The person-centered service plan must reflect the services and supports that are important for the individual to meet the needs identified through an assessment of functional need, as well as what is important to the individual with regard to preferences for the delivery of such services and supports. Commensurate with the level of need of the individual, and the scope of services and supports available under the State plan HCBS benefit, the plan must:

(1) Reflect that the setting in which the individual resides is chosen by the individual.

(2) Reflect the individual's strengths and preferences.

(3) Reflect clinical and support needs as identified through an assessment of functional need.

(4) Include individually identified goals and desired outcomes.

(5) Reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals, and the providers of those services and supports, including natural supports. Natural supports cannot supplant needed paid services unless the natural supports are unpaid supports that are provided voluntarily to the individual in lieu of State plan HCBS.

(6) Reflect risk factors and measures in place to minimize them, including Individualized backup plans.

(7) Be understandable to the individual receiving services and supports, and the individuals important in supporting him or her.

(8) Identify the individual and/or entity responsible for monitoring the plan.

(9) Be finalized and agreed to in writing by the individual and signed by all individuals and providers responsible for its implementation.

(10) Be distributed to the individual and other people involved in the plan.

(11) Include those services, the purchase or control of which the individual elects to self-direct, meeting the requirements of § 441.574(b) through (d) of this subpart.

(12) Prevent the provision of unnecessary or inappropriate care.

(13) Other requirements as determined by the Secretary.

(c) *Reviewing the person-centered service plan.* The person-centered service plan must be reviewed, and revised upon reassessment of functional need as required in § 441.662 of this subpart, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual.

§ 441.668 Provider qualifications.

(a) *Requirements.* The State must provide assurances that necessary safeguards have been taken to protect the health and welfare of enrollees in State plan HCBS, and must define in writing standards for providers (both agencies and individuals) of HCBS services and for agents conducting individualized independent evaluation, independent assessment, and service plan development.

(b) *Conflict of interest standards.* The State must define conflict of interest standards that ensure the independence of individual and agency agents who conduct (whether as a service or an administrative activity) the independent evaluation of eligibility for State plan HCBS, who are responsible for the independent assessment of need for HCBS, or who are responsible for the development of the service plan. The conflict of interest standards apply to all individuals and entities, public or private. At a minimum, these agents must not be any of the following:

(1) Related by blood or marriage to the individual, or to any paid caregiver of the individual.

(2) Financially responsible for the individual.

(3) Empowered to make financial or health-related decisions on behalf of the individual.

(4) Holding financial interest, as defined in § 411.354 of this chapter, in any entity that is paid to provide care for the individual.

(5) Providers of State plan HCBS for the individual, or those who have an interest in or are employed by a provider of State plan HCBS for the individual, except when the State demonstrates that the only willing and qualified agent to perform independent assessments and develop plans of care in a geographic area also provides HCBS, and the State devises conflict of interest protections including separation of agent and provider functions within provider entities, which are described in the State plan for medical assistance and approved by the Secretary, and individuals are provided with a clear and accessible alternative dispute resolution process.

(c) *Training.* Qualifications for agents performing independent assessments and plans of care must include training in assessment of individuals whose physical or mental conditions trigger a potential need for home and community-based services and supports, and current knowledge of best practices to improve health and quality of life outcomes.

§ 441.671 Definition of individual's representative.

In this subpart, the term *individual's representative* means, with respect to an individual being evaluated for, assessed regarding, or receiving State plan HCBS, the following:

(a) The individual's legal guardian or other person who is authorized under State law to represent the individual for the purpose of making decisions related to the person's care or well-being.

(b) Any other person who is authorized by policy of the State Medicaid Agency to represent the individual including but not limited to a parent, a family member, or an advocate for the individual.

(c) When the State authorizes representatives in accordance with paragraph (b) of this section, the State must have policies describing the process for authorization; the extent of decision-making authorized; and safeguards to ensure that the representative functions in the best interests of the participant. States may not refuse the authorized representative that the individual chooses, unless in the process of applying the requirements for authorization, the State discovers and can document evidence that the representative is not acting in the best interest of the individual or cannot perform the required functions.

§ 441.674 Self-directed services.

(a) *State option.* The State may choose to offer an election for self-directing HCBS. The term ''self-directed'' means, with respect to State plan HCBS listed in § 440.182 of this chapter, services that are planned and purchased under the direction and control of the individual, including the amount, duration, scope, provider, and location of the HCBS. For purposes of this paragraph, individual means the individual and, if applicable, the individual's representative as defined in § 441.671 of this subpart.

(b) *Service plan requirement.* Based on the independent assessment required in § 441.662 of this subpart, the State develops a service plan jointly with the individual as required in § 441.665 of this subpart. If the individual chooses to direct some or all HCBS, the service plan must meet the following additional requirements:

(1) Specify the State plan HCBS that the individual will be responsible for directing.

(2) Identify the methods by which the individual will plan, direct or control services, including whether the individual will exercise authority over the employment of service providers and/or authority over expenditures from the individualized budget.

(3) Include appropriate risk management techniques that explicitly recognize the roles and sharing of responsibilities in obtaining services in a self-directed manner and assure the appropriateness of this plan based upon the resources and support needs of the individual.

(4) Describe the process for facilitating voluntary and involuntary transition from self-direction including any circumstances under which transition out of self-direction is involuntary.

(c) *Employer authority.* If the service plan includes authority to select, manage, or dismiss providers of the State plan HCBS, the plan must meet the following requirements:

(1) Specify the authority to be assumed by the individual, any limits to the authority, and specify parties responsible for functions outside the authority to be assumed.

(2) Specify the financial management supports, as required in paragraph (e) of this section, to be provided.

(d) *Budget authority.* If the service plan includes an individualized budget (which identifies the dollar value of the services and supports under the control and direction of the individual), the plan must meet the following requirements:

(1) Describe the method for calculating the dollar values in the budget, based on reliable costs and service utilization.

(2) Define a process for making adjustments in dollar values to reflect changes in an individual's assessment and service plan.

(3) Provide a procedure to evaluate expenditures under the budget.

(4) Specify the financial management supports, as required in paragraph (e) of this section, to be provided.

(5) Not result in payment for medical assistance to the individual.

(e) *Functions in support of self-direction.* When the State elects to offer self-directed State plan HCBS, it must offer the following individualized supports to individuals receiving the services and their representatives:

(1) Information and assistance consistent with sound principles and practice of self-direction.

(2) Financial management supports to meet the following requirements:

(i) Manage Federal, State, and local employment tax, labor, worker's compensation, insurance, and other requirements that apply when the individual functions as the employer of service providers.

(ii) Function as employer of record when the individual elects to exercise supervisory responsibility without employment responsibility.

(iii) Make financial transactions on behalf of the individual when the individual has personal budget authority.

(iv) Maintain separate accounts for each individual's budget and provide periodic reports of expenditures against budget in a manner understandable to the individual.

§ 441.677 State plan HCBS administration: State responsibilities and quality improvement.

(a) *State plan HCBS administration.* (1) *State responsibilities.* The State must carry out the following responsibilities in administration of its State plan HCBS:

(i) *Number served.* The State will annually provide CMS with the projected number of individuals to be enrolled in the benefit and the actual number of unduplicated individuals enrolled in State plan HCBS in the previous year.

(ii) *Access to services.* The State must grant access to all State plan HCBS assessed to be needed in accordance with a service plan consistent with § 441.665 of this subpart, to individuals who have been determined to be eligible for the State plan HCBS benefit, subject to the following requirements:

(A) A State must determine that provided services meet medical necessity criteria;

(B) A State may limit access to services through targeting criteria established by § 441.656(b)(2) of this subpart; and

(C) A State may not limit access to services based upon the income of individuals, the cost of services, or the individual's location in the State.

(iii) *Appeals.* A State must provide individuals with the right to appeal terminations, suspensions, or reductions of Medicaid eligibility or covered services as described in part 431, subpart E.

(2) *Administration.* (i) *Option for presumptive payment.* (A) The State may provide for a period of presumptive payment, not to exceed 60 days, for Medicaid eligible individuals the State has reason to believe may be eligible for the State plan HCBS benefit. FFP is available for both services that meet the definition of medical assistance and necessary administrative expenditures for evaluation of eligibility for the State plan HCBS benefit under § 441.659(d) of this subpart and assessment of need for specific HCBS under § 441.662(a) of this subpart, prior to an individual's receipt of State plan HCBS services or determination of ineligibility for the benefit.

(B) If an individual the State has reason to believe may be eligible for the State plan HCBS benefit and is evaluated and assessed under the presumptive payment option and found not to be eligible for the benefit, FFP is available for services that meet the definition of medical assistance and necessary administrative expenditures. The individual so determined will not be considered to have enrolled in the State plan HCBS benefit for purposes of determining the annual number of participants in the benefit.

(ii) *Option for Phase-in of Services and Eligibility.* (A) In the event that a State elects to establish targeting criteria through § 441.656(b)(2) of this subpart, the State may limit the enrollment of individuals or the provision services to enrolled individuals based upon criteria described in a phase-in plan, subject to CMS approval. A State which elects to target the State plan HCBS benefit and to phase-in enrollment and/or services must submit a phase-in plan for approval by CMS that describes, at a minimum:

(*1*) The criteria used to limit enrollment or service delivery;

(*2*) The rationale for phasing-in services and/or eligibility; and

(*3*) Timelines and benchmarks to ensure that the benefit is available statewide to all eligible individuals within the initial 5-year approval.

(B) If a State elects to phase-in the enrollment of individuals based on highest need, the phase-in plan must use the needs-based criteria described in § 441.659(a) of this subpart to establish priority for enrollment. Such criteria must be based upon the assessed need of individuals, with higher-need individuals receiving services prior to individuals with lower assessed need.

(C) If a State elects to phase-in the provision of any services, the phase-in plan must include a description of the services that will not be available to all eligible individuals, the rationale for limiting the provision of services, and assurance that all individuals with access to a willing and qualified provider may receive services.

(D) The plan may not include a cap on the number of enrollees.

(E) The plan must include a timeline to assure that all eligible individuals receive all included services prior to the end of the first 5-year approval period, described in paragraph (a)(2)(vi) of this section.

(iii) *Reimbursement methodology.* The State plan amendment to provide State plan HCBS must contain a description of the reimbursement methodology for each covered service. To the extent that the reimbursement methodologies for any self-directed services differ from those descriptions, the method for setting reimbursement methodology for the self-directed services must also be described.

(iv) *Operation.* The State plan amendment to provide State plan HCBS must contain a description of the State Medicaid agency line of authority for operating the State plan HCBS benefit, including distribution of functions to other entities.

(v) *Modifications.* The agency may request that modifications to the benefit be made effective retroactive to the first day of a fiscal year quarter, or another date after the first day of a fiscal year quarter, in which the amendment is submitted, unless the amendment involves substantive change. Substantive changes may include, but are not limited to, the following:

(A) Revisions to services available under the benefit including elimination or reduction in services, and changes in the scope, amount and duration of the services.

(B) Changes in the qualifications of service providers, rate methodology, or the eligible population.

(*1*) *Request for* Amendments. A request for an amendment that involves a substantive change as determined by CMS—

(*i*) May only take effect on or after the date when the amendment is approved by CMS; and

(*ii*) Must be accompanied by information on how the State will ensure for transitions with minimal adverse impact on individuals impacted by the change.

(*2*) [Reserved]

(vi) *Periods of approval.* (A) If a State elects to establish targeting criteria through § 441.656(b)(2) of this subpart, the approval of the State Plan Amendment will be in effect for a period of 5 years from the effective date of the amendment. To renew State plan HCBS for an additional 5-year period, the State must provide a written request for renewal to CMS at least 180 days prior to the end of the approval period. CMS approval of a renewal request is

contingent upon State adherence to Federal requirements.

(B) If a State does not elect to establish targeting criteria through § 441.656(b)(2) of this subpart, the limitations on length of approval does not apply.

(b) *Quality improvement strategy: Program performance and quality of care.* States must develop and implement an HCBS quality improvement strategy that includes a continuous improvement process and measures of program performance and experience of care. The strategy must be proportionate to the scope of services in the State plan HCBS benefit and the number of individuals to be served. The State will make this information available to CMS at a frequency determined by the Secretary or upon request.

(1) *Quality Improvement Strategy.* The quality improvement strategy must include all of the following:

(i) Incorporate a continuous quality improvement process that includes monitoring, remediation, and quality improvement.

(ii) Be evidence-based, and include measures as determined by the Secretary.

(iii) Provide evidence of program performance and the establishment of sufficient infrastructure to effectively implement the program.

(iv) Measure individual outcomes associated with the receipt of HCBS, related to the implementation of goals included in the individual service plan.

(2) [Reserved]

PART 447—PAYMENTS FOR SERVICES

16. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

17. Section 447.10 is amended by adding paragraph (g)(4) to read as follows:

§ 447.10 Prohibition Against Reassignment of Provider Claims

(g) * * *

(4) In the case of a class of practitioners for which the Medicaid program is the primary source of revenue, payment may be made to a third party on behalf of the individual practitioner for benefits such as health insurance, skills training and other benefits customary for employees.

* * * * *

Authority

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: April 24, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 24, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–10385 Filed 4–26–12; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 77 Thursday,
No. 86 May 3, 2012

Part III

The President

Executive Order 13608—Prohibiting Certain Transactions With and Suspending Entry Into the United States of Foreign Sanctions Evaders With Respect to Iran and Syria

Federal Register
Vol. 77, No. 86
Thursday, May 3, 2012

Presidential Documents

Title 3—

The President

Executive Order 13608 of May 1, 2012

Prohibiting Certain Transactions With and Suspending Entry Into the United States of Foreign Sanctions Evaders With Respect to Iran and Syria

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*), section 212(f) of the Immigration and Nationality Act of 1952, as amended (8 U.S.C. 1182(f)), and section 301 of title 3, United States Code,

I, BARACK OBAMA, President of the United States of America, hereby find that efforts by foreign persons to engage in activities intended to evade U.S. economic and financial sanctions with respect to Iran and Syria undermine our efforts to address the national emergencies declared in Executive Order 12957 of March 15, 1995, as relied on for additional steps in subsequent Executive Orders, in Executive Order 13338 of May 11, 2004, as modified in scope and relied on for additional steps in subsequent Executive Orders, in Executive Order 12938 of November 14, 1994, as relied on for additional steps in subsequent Executive Orders, and in Executive Order 13224 of September 23, 2001, as relied on for additional steps in subsequent Executive Orders, and in order to take additional steps pursuant to these national emergencies, I hereby order:

Section 1. (a) The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to impose on a foreign person the measures described in subsection (b) of this section upon determining that the foreign person:

(i) has violated, attempted to violate, conspired to violate, or caused a violation of any license, order, regulation, or prohibition contained in, or issued pursuant to:

(A) any Executive Order relating to the national emergencies declared in Executive Order 12957 of March 15, 1995, or in Executive Order 13338 of May 11, 2004, as modified in scope in subsequent Executive Orders; or

(B) to the extent such conduct relates to property and interests in property of any person subject to United States sanctions concerning Iran or Syria, Executive Order 13382 of June 28, 2005, any Executive Order subsequent to Executive Order 13382 of June 28, 2005, that relates to the national emergency declared in Executive Order 12938 of November 14, 1994, or any Executive Order relating to the national emergency declared in Executive Order 13224 of September 23, 2001;

(ii) has facilitated deceptive transactions for or on behalf of any person subject to United States sanctions concerning Iran or Syria; or

(iii) is owned or controlled by, or is acting or purporting to act for or on behalf of, directly or indirectly, any person determined to meet the criteria set forth in subsection (a) of this section.

(b) With respect to any foreign person determined to meet the criteria set forth in subsection (a) of this section, the Secretary of the Treasury may prohibit all transactions or dealings, whether direct or indirect, involving such person, including any exporting, reexporting, importing, selling, purchasing, transporting, swapping, brokering, approving, financing, facilitating,

or guaranteeing, in or related to (i) any goods, services, or technology in or intended for the United States, or (ii) any goods, services, or technology provided by or to United States persons, wherever located.

(c) The prohibitions in subsection (b) of this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted prior to the date of this order.

Sec. 2. I hereby determine that the making of donations of the type of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)) by, to, or for the benefit of any person subject to the measures described in section 1 of this order would seriously impair my ability to deal with the national emergencies identified in the preamble to this order, and I hereby prohibit such donations as provided by section 1 of this order.

Sec. 3. The prohibitions in section 1 of this order include but are not limited to:

(a) the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person subject to the measures described in this order; and

(b) the receipt of any contribution or provision of funds, goods, or services from any such person.

Sec. 4. I hereby find that the unrestricted immigrant and nonimmigrant entry into the United States of aliens determined to meet one or more of the criteria in subsection 1(a) of this order would be detrimental to the interests of the United States, and I hereby suspend the entry into the United States, as immigrants or nonimmigrants, of such persons. Such persons shall be treated as persons covered by section 1 of Proclamation 8693 of July 24, 2011 (Suspension of Entry of Aliens Subject to United Nations Security Council Travel Bans and International Emergency Economic Powers Act Sanctions).

Sec. 5. (a) Any transaction by a United States person or within the United States that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this order is prohibited.

(b) Any conspiracy formed to violate any of the prohibitions set forth in this order is prohibited.

Sec. 6. Nothing in section 1 of this order shall prohibit transactions for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof.

Sec. 7. For the purposes of this order:

(a) the term ''person'' means an individual or entity;

(b) the term ''entity'' means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization;

(c) the term ''United States person'' means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States;

(d) the term ''deceptive transaction'' means any transaction where the identity of any person subject to United States sanctions concerning Iran or Syria is withheld or obscured from other participants in the transaction or any relevant regulatory authorities;

(e) the term ''person subject to United States sanctions concerning Iran or Syria'' means (i) any person, including the Government of Iran or the Government of Syria, with whom transactions are restricted pursuant to any Executive Order relating to the national emergencies declared in Executive Order 12957 of March 15, 1995, or in Executive Order 13338 of May 11, 2004, as modified in scope in subsequent Executive Orders, or (ii)

any person whose property and interests in property are blocked pursuant to IEEPA in connection with Iran's or Syria's proliferation of weapons of mass destruction or delivery systems for weapons of mass destruction, or Iran's or Syria's support for international terrorism;

(f) the term ''Government of Iran'' means the Government of Iran, any political subdivision, agency, or instrumentality thereof, including the Central Bank of Iran, and any person owned or controlled by, or acting for or on behalf of, the Government of Iran; and

(g) the term ''Government of Syria'' means the Government of the Syrian Arab Republic, its agencies, instrumentalities, and controlled entities.

Sec. 8. For those persons subject to the measures described in section 1 of this order who might have a constitutional presence in the United States, I find that because of the ability to transfer funds or other assets instantaneously, prior notice to such persons of measures to be taken pursuant to this order would render those measures ineffectual. I therefore determine that for these measures to be effective in addressing the national emergencies identified in the preamble to this order, there need be no prior notice of a listing or determination made pursuant to section 1 of this order.

Sec. 9. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA, as may be necessary to carry out the purposes of this order. The Secretary of the Treasury may redelegate any of these functions to other officers and agencies of the United States Government consistent with applicable law. All agencies of the United States Government are hereby directed to take all appropriate measures within their authority to carry out the provisions of this order.

Sec. 10. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 11. The measures taken pursuant to this order with respect to Iran are in response to actions of the Government of Iran occurring after the conclusion of the 1981 Algiers Accords, and are intended solely as a response to those later actions.

THE WHITE HOUSE,
May 1, 2012.

[FR Doc. 2012–10884
Filed 5–2–12; 11:15 am]
Billing code 3295–F2–P

Reader Aids

Federal Register

Vol. 77, No. 86

Thursday, May 3, 2012

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: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **www.ofr.gov.**

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.

Reminders. Effective January 1, 2009, the Reminders, including Rules Going Into Effect and Comments Due Next Week, no longer appear in the Reader Aids section of the Federal Register. This information can be found online at **http://www.regulations.gov.**

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, MAY

25577–25858 1
25859–26148 2
26149–26412 3

CFR PARTS AFFECTED DURING MAY

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.

3 CFR

Proclamations:
8805 25859
Executive Orders:
13607 25861
13608 26409

7 CFR

Proposed Rules:
3201 25632

10 CFR

11 26149
25 26149
Proposed Rules:
11 26213
25 26213

12 CFR

618 25577
1012 26154

14 CFR

39 ..... 26154, 26156, 26158
71 26160
Proposed Rules:
39 ..... 25642, 25644, 25647, 25930, 26216

15 CFR

Proposed Rules:
742 25932
774 25932

21 CFR

522 26161
558 26161
600 26162
610 26162
680 26162

22 CFR

123 25865
126 25865
Proposed Rules:
121 25944

24 CFR

Proposed Rules:
5 26218
200 26218
207 26218
232 26218

26 CFR

1 26175
602 26175

28 CFR

0 26181

29 CFR

104 25868

30 CFR

915 25868
936 25872
938 25874
1210 25877
1218 ..... 25877, 25881
Proposed Rules:
943 25949

33 CFR

110 25587
117 ..... 25590, 25591, 25592, 25889, 25890
165 ..... 25592, 25595, 25890, 25892
Proposed Rules:
100 25650
117 ..... 25653, 25655
334 ..... 25952, 26229

34 CFR

690 25893
Proposed Rules:
Ch. VI 25658

38 CFR

51 26183

39 CFR

111 26185
233 25596

40 CFR

52 25901
141 26072
142 26072
180 ..... 25903, 25904
Proposed Rules:
52 ..... 25660, 25953
147 26231
180 ..... 25661, 25954

42 CFR

Proposed Rules:
430 ..... 26232, 26362
431 ..... 26232, 26362
435 ..... 26232, 26362
436 ..... 26232, 26362
440 ..... 26232, 26362
441 ..... 26232, 26362
447 ..... 26232, 26362

47 CFR

54 25609

48 CFR

Proposed Rules:
2 26232
22 26232
52 26232

49 CFR

Ch. II 25610

1152.....25910

50 CFR

17.....25611, 26191
226.....25611
424.....25611
648 .....25623, 25630, 26104, 26129
660.....25915
679.....26212

Proposed Rules:

17 .....25664, 25668, 25792
600.....26238
635.....25669

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*.

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's Federal Digital System (FDsys) at *http://www.gpo.gov/fdsys*. Some laws may not yet be available.

H.R. 473/P.L. 112–103
Help to Access Land for the Education of Scouts (Apr. 2, 2012; 126 Stat. 284)

H.R. 886/P.L. 112–104
United States Marshals Service 225th Anniversary Commemorative Coin Act (Apr. 2, 2012; 126 Stat. 286)

Last List April 2, 2012

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.